

**Effects of Pictograms on Patients' Information Acquisition and
Preferences in Package Inserts of Over-The-Counter Drugs
– Investigation of young and elderly -**

January 2019

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(千葉大学審査学位論文)

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ABSTRACT

In recent years, as the over-the-counter (OTC) drug market has grown rapidly, consumers/patients have assumed much more responsibilities which the safe and effective use of drugs. For assuming these responsibilities, consumers/patients need to understand the drugs well definitely. Package inserts are the most complete sources of information on drugs, which contain authoritative information produced by the manufacturer and supported by legislation. However, to consumers/patient, it was difficult in searching the necessary information among of the amount of text descriptions. Furthermore, the information range means that many consumers/patients are uninterested in reading these package inserts or not.

The main goal of this dissertation is to improve the usability and accessibility of package inserts. To quantitatively compared package inserts with or without pictograms, and provided clearly the effects of pictograms incorporated in package inserts on patients' information acquisition and preferences.

Chapter 1 provides a general overview of the background of OTC drug package inserts, and proposes the impact of package inserts on patients' information acquisition. And then, it also reviewed the role of pictograms briefly which improved information acquisition, and formulated a new research hypothesis how to affect patients' information acquisition by pictograms in the nearest future.

Chapter 2 both an eye-tracking survey (attention) and questionnaire (comprehensibility) were conducted among university students. The study of quantitative comparative which three versions of the package insert (A, which used text only; B, which

used comprehensible pictograms in the “precautions for use” section; and C, which used incomprehensible pictograms in the “precautions for use” section) had been conducted for young consumers. The results showed, comprehensible pictograms could drive the young consumers effectually to get the required and proper information when they check the package inserts, and could also improve them to understand these information. Furthermore, compared to package inserts which used text only, the young consumers usually make a choice of the priority package inserts which pictograms.

And Chapter 3 discusses the effects of pictograms on elderly patients’ information acquisition (information recall and search) and preferences in the package inserts of OTC drugs. Specifically, three versions of the package insert (A, which used pictograms; B, which had wider spacing between paragraphs; and C, which had a larger font size) were created by unifying A4 paper sizes, then compared and researched them. It has been learned from the study, the presence of pictograms had a positive effect on information acquisition and preferences.

Chapter 4 summarized the practical implications of this study, and offered some suggestions on others research in the future.

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1. Introduction

1.1 About Package Inserts of OTC

1.1.1 Definition

The package insert (PI) also referred to as package leaflet, patient information leaflets (PIL) or consumer medicine information (CMI) contains authoritative drug information produced by the drug manufacturer and supported by legislation. The purpose of PIs is to help consumers/ patients to use their medicines safely and effectively (Sless & Shrensky, 2006).

In Japan, drugs are classified as prescription drugs and nonprescription drugs. Some drugs require permission from a doctor, that is, a prescription (Japan Self-Medication Industry). Others can be bought at a pharmacy without a prescription, these are over-the-counter (OTC) drugs (Japan Self-Medication Industry). The PIs for each type of drug varies in form and content. Since the PI of the prescription drug is an information leaflet provided to a specific patient, the inclusion of the content information is relatively simple. Instead, PI of OTC drugs is designed for a non-specific group of consumers and they generally contain a lot of information, therefore, it faces more challenges in the quality of the content and the information design.

1.1.2 Current Specification and Involved Content

In Japan, as specified in article 52 of the pharmaceutical affairs law, the package or package inserts of a drug product must include key information, such as “dosage and

administration” and “precautions for use”, which, in most cases, is explicitly provided in the package inserts of a product. In October 2011, order issued “about the entry guideline on the package insert of OTC drugs” by Pharmaceutical and Food Safety Bureau, Ministry of Health, Labor and Welfare was to specify the content and sequence of package inserts to enhance consumers’ understanding of relevant drugs by reading package inserts and using the products in a proper and safe manner (2011a).

About the entry guideline on the package insert of OTC drugs

Content and order of sections

1. Revision date
2. Be sure to look at the PI and keep it with the medicine
3. Sales name, medicinal efficacy and risk classification
4. The characteristics or properties of a drug
5. Precautions for use
6. Indications
7. Dosage and administration
8. Ingredients and amounts
9. Storage methods
10. Consumer consultation
11. Contact details and manufacturer information

A requirement of the "About points to be noted of the entry guideline on the package insert of OTC drugs" (Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, 2011b) is that the contents of PIs will be expressive enough that an ordinary consumer who reads it will understand it. Regarding the size of text, it requires to describe items such as precautions for use, dosage and administration, ingredients and amounts etc., using a minimum of 10-pt size font. Moreover, it also proposes that in order to accurately convey information to general users, the use of charts and illustrations is appropriate.

1.1.3 The Significance and Value of PIs

As described earlier in this article, OTC drugs are those not requiring a medical prescription and which are produced, distributed and sold to consumers for use on their own initiative. WHO Drug Information (2000) have mentioned that the "Responsible self-medication can be used to prevent and treat symptoms and ailments that do not need medical consultation or oversight" (p.1). This reduces pressure on medical services, and it reduces the time and effort of using medical institutions, especially when these are limited.

The package insert (PI) is written information supplied with OTC drugs to provide all the necessary information for the consumers/patients about the drug. By reading the PIs, one can better understand more details about a medicine's ingredients, relevant indications, directions for use and side effects (Japan Self-Medication Industry: What is a package insert?). Optum (2015) explains that "Written medicine information, such as

Consumer Medicine Information (CMI), plays an important role in educating patients about their medicines, improving knowledge, adherence and understanding, reducing the potential for harm and inadvertent misadventure". Some studies have suggested that PIs increases patient knowledge and understanding of their drugs which may lead to increased satisfaction (Gibbs, Waters, & George, 1989, 1990). Additionally, by reading the PI, patients can make an informed decision to use or stop using a medication (Morris, 1977), Consequently, reducing the misuse and the incidence of side effects.

In recent years, the government has been promoting self-medication (Prime Minister of Japan and His Cabinet, 2013), and it has also implemented a series of more feasible policies for OTC drug distribution, such as registered salespersons system (Ministry of Health, Labor and Welfare, 2009), permissions to sell drugs in the internet (Ministry of Health, Labor and Welfare, 2014), and allowing the sale of OTC drugs even in the absence of a pharmacist (Prime Minister of Japan and His Cabinet, 2016). These make it easier for consumers to get medicines. Meanwhile, by six of the first item of the act on securing quality, efficacy and safety of products including pharmaceuticals and medical devices (Role of the general public), the "general public must use pharmaceuticals, etc. In an appropriate manner, and make efforts to improve their own knowledge and understanding of the efficacy and safety thereof" (Act No. 145 of 1960).

Thus, it is clear that comprehending the details about Risks and Benefits of OTC drugs is becoming increasingly important for customers/patients. However, many side effects due to OTC drugs have been reported (Ministry of Health, Labor and Welfare,

2012), therefore, it is important to ensure customers/patients safe and effective use of OTC drugs.

1.2 Problem of Package Inserts on Patients' Information Acquisition

Despite PIs contains drugs information by legal grounds, according to some research, we found that PIs have not been used well. According to a survey by the Japan OTC Pharmaceutical Association, 95% of consumers answered that they read the PI before using the drugs (Japan Self-Medication Industry, 2009). However, some research suggests that not all the items get read. According to the survey on OTC drug use, consumers seldom read the “precautions for use” section carefully before using OTC drugs, which often leads to misuse and abuse of drugs, as well as delayed effective treatment (Saito, Takashi, Hashiguchi, Suenaga, & Mochizuki, 2007).

Moreover, Dozono (2014), based on a sample of 77 Japanese (male 27 and 50 female) aged 10 to 59, examined whether or not each item in the PI was read and its factors. Results showed that even first-time users of OTC drugs who read the "precautions for use" are less than 50%. The majority of the respondents indicated that they did not read it because they did not care about the information or reading it made them feel troubled. Furthermore, for non-first-time users, the reading rate for "precautions for use" is significantly lower than when it was used for the first time.

Hashiguchi et al. (2013) conducted a comprehension test on the “precautions for use” on package inserts. In their research, two different types of package inserts for H2-blocker were used. Each package insert had different layout and different font size and

were each given to different participant groups (group A and group B). Based on the results, they found that more than half of the participants in both groups failed to locate the information necessary during the test because of the dense text information.

As the “precautions for use” section provided with the OTC drugs is designed for a non-specific group of consumers, there is generally a lot of information. This amount of information not only makes it difficult for consumers to find the information they need, but often the information is not entirely useful for all consumers. Consequently, many consumers take no interest in reading these “meaningless” instructions. Some research indicates that content (e.g. large amounts of information) and design factors (e.g. small font) have an impact on readability and attractiveness, which affects consumer use of written information (Gibbs, Waters, & George, 1989, 1990). Conversely, patients' confidence may be undermined by over-simplified leaflets that they perceive as dull, patronizing, or lacking in authority (Coulter, 1998; Kenny et al., 1998; Koo, Kras, & Aslani, 2003). This indicates that there is an urgent task to provide information more effectively, that is, being able to maintain the same amount of information, while ensuring each item of information is clearly identifiable.

Kim and Ahn (2014) explain that “Imposing structure on package inserts may encourage people to consult them even when there is much information. In addition to structuring, increasing the visibility or salience of important information can enhance its accessibility”.

With the above background, in order to improve the visual attraction and the comprehension of OTC drug package inserts, we developed corresponding precautionary

pictograms before usage and implemented a comprehension test (Kurata et al., 2017). As a result, consideration was given to the degree of comprehension of the pictogram itself (Kurata et al., 2017), but when it is incorporated in the package insert, the effect on its attractiveness and psychology has not yet been studied. Therefore, in this study, pictograms were included in OTC-drug package inserts and we evaluated their influence on patients' information acquisition and preferences.

1.3 The Role of Pictograms in Improving Information Acquisition

1.3.1 Definitions and Background of Pictograms

Pictograms are a common method to easily impart important and easy-to-understand information to non-specific groups of consumers (Ministry of Land, Infrastructure, Transport and Tourism: Guidance symbol JIS Z8210). Examples of pictograms used for this purpose include automobile/traffic safety, building floor guides, sightseeing maps, and weather forecast maps. Regarding the effectiveness of pictograms in conveying drug information, many studies and researches have been done, and many papers, and even books, have been written in this field.

Montagne (2013) explain it this way:

A pictogram is constructed of two parts. The first part is a symbol or a graphic representation; the second part is the referent, or the meaning that is implied or elicited by the symbol or graphic.

The symbol's referent is what the image aims to represent (e.g., a real life object, action, place location, or concept) or the image's function (e.g., to warn about a harm or provide a direction) (pp. 610).

Houts, Doak, Doak, and Loscalzo (2006) have reviewed how pictures combined with text can facilitate attention, comprehension, recall, and adherence. In particular, they selected and reviewed studies that compare responses to just written text with responses to text plus pictures representing information in the text. Their review found that research in all four areas (attention, comprehension, recall, and intention/adherence) has shown that pictures can, in most instances, provide significant benefits, and patients with low literacy skills are especially likely to benefit. However, since results were not always consistent, one cannot predict with certainty how people will respond to pictures in health communications. The authors urge producers of health education materials to include systematic evaluation of the effects of pictures by comparing responses to materials with and without the pictures.

In line with Houts et al. (2006), Katz, Kripalani, and Weiss (2006) also concluded that incorporation of pictures into drug labels and patient information sheets has particular promise for helping individuals who have difficulty reading and interpreting textual instructions, namely patients with limited literacy skills or limited English proficiency. Moreover, they found that patients of all literacy levels actually prefer picture-based information. However, implementation of picture-based instructions has produced mixed results among the elderly and readers considered to have adequate literacy.

van Beusekom, Kerkhoven, Bos, Guchelaar, and van den Broek (2018) carried out a systematic search of databases. Their search included articles published from 1993 to 2018 on PubMed, CINAHL, Cochrane Library, Embase, PsycINFO, Academic Search Premier, and Web of Science. The authors found that almost 40% of the available studies intended to use their pictograms for patients with low (Health) Literacy, a quarter of the studies aimed to target ‘patients in general’, and about one in every ten of the articles developed pictograms for a specific age group.

The next section analyses what effects reviewing pictograms can have on people with normal literacy skills.

1.3.2 Related Studies

Young, Tordoff and Smith (2017) concludes that the “Optimal leaflet design increased the likelihood that patients would read and keep it for later use (Aslani, Hamrosi, & Feletto, 2010) and improved ability to locate information (Aslani, Hamrosi, & Feletto, 2010; Fuchs, Heyer, Langenhan, & Hippus, 2008; Fuchs, 2010; Maat & Lentz, 2010)”(pp.1187).

In this section, we highlight a selection of three aspects of pictograms that improve information acquisition.

1.3.2.1 Drawing attention to the materials or message

Through investigation, information users rarely, if ever, read a whole document through from beginning to end. They are reluctant to read more than they think they need,

so when people do use documents, they use them to look for what interests them and what they need, or think they need. For example, they usually pay more attention to the “Indications” and “Dosage and administration” sections, while ignoring the “Precautions for use” section (Choi et al., 2012).

Every piece of information in the “precautions for use section” is indeed important to a particular patient. Getting noticed and addressed are the first requirements of an effective warning (Wogalter, Conzola, & Smith-Jackson, 2002). One role of pictograms to information acquisition is to attract the attention of consumers/patients, stimulate them to address the information, and help them to easily distinguish which items are essential, which are important, which are advisable, and which are inconsequential. Noticeability, which is sometimes referred to as conspicuity, is often used to describe the extent to which the design of a warning will gain or attract attention against a field of competing visual stimuli (Wogalter et al., 2002).

Research has shown that the addition of pictograms to information that needs to be salient or conspicuous increases the likelihood of this information getting read. Kalsher, Wogalter and Racicot (1996) developed two alternative designs (tag and fold-out) to increase the available surface area on a fictitious prescription drug label. The alternative label designs, with and without pictorials depicting instructions and warnings, were compared to a standard control label. Eighty-four undergraduates and 58 older adults (mean age = 73 years) rated the labels on several preference dimensions, including: ease of reading the labels, likelihood of noticing the warnings, likelihood of reading the warnings, preference for each of the labels, and likelihood that they would recommend

each label for use by a friend or family member. Across all dimensions, both undergraduates and older adults preferred the alternative labels, especially the tag labels, and labels with pictorials.

Delp and Jones (1996) studied 234 patients coming to an emergency room with lacerations. After receiving treatment, but prior to discharge, patients were given printed instructions for caring for their wounds at home. Half were randomly given just text and the other half received the same text plus pictures that illustrated the information in the text. Subjects were interviewed by phone three days later and asked if they had read the instructions (attention). If they had, they were asked a series of questions about information in the handout (recall) and also about what they had done to care for their wounds (adherence). The result shows that patients receiving handouts with pictures were significantly more likely to read the handouts and, among those who read the handouts, patients receiving the illustrated versions were significantly more likely to remember what they read and to follow the instructions than those who read just text.

Eye tracking procedures were employed to study eye scan patterns of subjects searching for warning messages in product labels (Laughery & Young, 1991). Thirty-eight alcoholic beverage labels were constructed, 24 of which contained a warning. For each label, subjects indicated whether or not it contained a warning. Salience of the warning was manipulated by the presence or absence of four features which appeared individually or in combination. The features were a pictorial, an icon, a color and a border. Of particular interest was the ability to decompose the total time it took to find the warning in two components: “location time” and “decision time”. “Location time” refers

to the time it takes to find the area where the warning is, and “decision time” refers to the time it takes to determine if the given information is a warning and making an overt response. The results showed that the singular addition of only a pictorial actually decreased the decision time compared to the baseline warning. From this experiment we conclude that adding pictograms manipulates the saliency of a warning and makes it easier to catch a user’s attention.

1.3.2.2 Increasing recall of the message

In general, when it comes to any kind of medical written instructions, most people read them only once and then rely on their memories when taking health actions. Even if they do refer back to the original document, they must first remember the type of information available and where to find it. Therefore, improving patients’ recall of medical instructions can play an important role in helping them cope with illness.

Sojourner and Wogalter (1997, 1998) compared recall of medication information presented as just text, just pictures, and text with pictures where the text and pictures presented the same information. They found that free recall was higher for the text with pictures condition than for either of the other conditions. The text with pictures format was also rated more positively than the others. Their study (Sojourner,& Wogalter, 1998) also compared responses from a young group (mean age of 19) to an older group (mean age 68). While the older group had lower recall in general, the text with pictures condition had superior recall for both age groups.

Hill et al. (2016) evaluated the effect of standard vs pictograph-enhanced discharge instructions on patients' immediate and delayed recall of and satisfaction with their discharge instructions. Measures of immediate and delayed recall, and satisfaction with discharge instructions were compared between two randomized groups: pictograph-enhanced (n = 71) and standard (n = 73). The results showed that study participants who received pictograph-enhanced discharge instructions recalled 35% more of the instructions when leaving the hospital than those who received standard discharge instructions. Additionally, study participants who received pictograph-enhanced discharge instructions were more satisfied with the understandability of the instructions at one week post-discharge than those who received standard discharge instructions.

Although many studies have proven the superiority of pictograms in the recall of information, there are still some studies that doubt the effectiveness of pictograms.

Moll, Wright, Jeffrey, Gopode and Humberstone (1977) evaluated a sample of 50 patients with gout disease by means of a multiple-choice knowledge-testing questionnaire based on the Arthritis and Rheumatism Council's Gout: A Handbook for Patients. Patients were divided into two groups: (a) those tested with an illustrated booklet containing 89 cartoons, and (b) those tested with an unillustrated booklet with text exactly the same as in the illustrated booklet. No significant difference was observed in either the overall test scores between the two groups or between individual question scores. It was concluded that increasing the number of illustrations in the Arthritis and Rheumatism Council's Gout handbook did not significantly increase the value of this material as a communication aid. However, the researchers also discussed certain sources of error, including the possibility

of an 'interest factor' due to the inevitable interest patients have in reading about their own disease. Also, there is a possibility that technical factors related to page layout and picture/text imbalance might have been responsible for failing to show differences between the two groups.

Morrell, Park and Poon (1990) conducted a study to determine the effects of presenting prescription information in a mixed format (verbal instructions mixed with pictograms) compared to a verbal format (verbal instructions only) on comprehension and memory in young and old adults. Results indicated that younger adults' memory for prescription information was facilitated by the mixed format, but that the mixed format appeared to hamper older adults' memory for prescription information.

1.3.2.3 Improved ability to locate information.

PIs are intended for all patients/users, must be well designed and clearly worded, and must ensure that their design facilitates navigation and access of information (European commission, 2009). The main purpose of the PI is to provide consumers with instructions on how to use their medicine safely and effectively. Another important use is to further explain these instructions when necessary. For this reason, it has to be easy for users to find what they want or need.

In order to evaluate the attitude of patients towards package leaflets provided with symbols, Bernardini, Ambrogi, Perioli, Tiralti and Fardella (2000) planned a survey interviewing 1004 patients in pharmacies. they proposed five symbols for each heading (therapeutic indications, side effects, paediatric use, contraindications,

use in pregnancy). The results showed that The great majority of respondents (74.3%, non-respondents 6.3%) considered that the use of symbols and pictograms could help to find the necessary information. They made some suggestions that Since a great majority of people interviewed were in favors of the use of symbols for finding information more easily, it is necessary to assess whether symbols really help patients.

A study by Aker et al. (2013) evaluated two new PI formats against the current one. One of the new ones used icons, and the other one grouped information in bubble boxes but it had no icons. Both new formats scored higher in users' understanding of the information in the PI compared to the baseline format. However, consumers indicated that they preferred the format that used icons over the one other new format. They also indicated that the format with icons motivated them to read it and allowed them to find important information more easily.

1.4 Hypothesis for Effects of Pictograms on Patients' Information Acquisition in PIs

In the last section, previous research on pictograms was reviewed in three aspects of information acquisition: drawing attention to the materials or message, increasing recall of the message, and improving the ability to locate information. The use of pictograms has been positively associated with better information acquisition in a wide range of studies. Despite this, in certain instances and populations, pictograms may actually hinder the information acquisition. For example, a study found that older adults'

memory for labels that included graphics was poorer than for labels formatted in the more typical, text-only style (Morrell et al., 1990). And about the improved ability to locate information, the relationship between pictograms and text has received considerable research attention but the most studies used questionnaires and interviews to obtain data (Bernardini et al., 2000; Aker et al., 2013).

Studies have demonstrated the limits of human attention (Horowitz & Wolfe, 1998; Wolfe & Horowitz, 2004). It is unlikely that an individual will engage in a high cognitive-load activity such as intensive reading (Chandler & Sweller, 1996). Therefore, one tends to extract useful information from dense data by skimming and scanning instead of reading carefully (Steve Krug, 2005). Pictograms with better visibility and discrimination than text message are often used as warning signs. Therefore, the eye-catching effect of pictogram are widely recognized. But study also found that print-based text with pictures forces readers to split visual working memory resources between written words and pictures (Mayer, 2003; Mayer & Moreno, 2003).

In conclusion, more specific studies are needed to evaluate the impact and role of the utilization effects of pictograms in drugs information (PIs).

1.5 Research Objectives

Based on the analysis above, this study aims to use the experimental psychological method to probe the effects of pictograms incorporated in package inserts on information acquisition and preference of patients. The specific research objectives are to investigate if package inserts with pictograms are:

1. More effective in drawing attention to the useful information
2. More helpful to improve recall of useful information
3. More helpful to locating information quickly and accurately
4. Preferred by users

2. Study 1: Research on the young patients

This chapter is based on Piao, Koyama, Yamashita, Mochizuki, and Hibino (2018). The study 1 was approved by the Independent Ethics Committee of the Graduate School of Engineering, Chiba University, and informed consent was obtained from all participants (Permit number: 28-07).

2.1 Introduction

As pointed out in chapter I, consumers seldom carefully read the “precautions for use” section before using OTC drugs, which often leads to misuse and abuse of drugs, as well as delayed effective treatment (Saito et al., 2007). And Hashiguchi et al study (2013) found that over 50% of participants failed to locate the needed information because of the dense layout of the “precautions for use” section. As the “precautions for use” section provided with the OTC drugs is designed for a non-specific group of consumers, there is generally a lot of information. This amount of information not only makes it difficult for consumers to find the information they need, but often the information is not entirely useful for all consumers. Consequently, many consumers take no interest in reading these “meaningless” instructions.

As PIs are voluntarily read by consumers, it is important to understand whether or not one can read important items without missing them. As mentioned in chapter 1, most of the research results show that pictograms can draw attention to key information, and increase recall of the information. Therefore, in chapter 2, pictograms were included in OTC-drug PIs and we evaluated comparatively quantitatively their influence on consumer attention and degree of comprehension towards usage precautions.

2.2. METHOD

2.2.1 Participants

Forty-one college students (21 women and 20 men) from Chiba university participated in the study. They were from Graduate School of Engineering, Faculty of Engineering, Faculty of Education, Faculty of Letters, Faculty of Law, Politics and Economics, Graduate School of Science and Engineering. Before formally launching an investigation, We confirmed that all Participants never have worked in pharmaceutically related fields (Registered sales clerk, etc.).

2.2.2 Stimulus

In order to not only to prove the impact of the existence (insert) of the pictogram, but also to prove the impact of the (high and low) understanding of the pictogram itself, three package insert versions (A, B, C) were designed regarding a stomach medicine *H₂ Blocker* that is currently in the market. All of the content and sequences designed were the same. Each version consisted of two sides of front and back. The front page consisted of 1) the header, which consists of revision date, drug names, and risk classification, 2) The characteristics or properties of a drug, and 3) precautions for use. The back page consisted of 1) the indications, 2) dosage and administration, 3) ingredients and amount, 4) storage methods, and 5) contact details and manufacturer information.

Each of the three package inserts was unique. A contained text only, B contained comprehensible pictograms and text, and C contained incomprehensible pictograms and text. From the pictograms developed in the previous study (Kurata et al., 2017), the

pictograms that generated relatively high comprehension were selected and inserted into B, and the pictograms that generated relatively low comprehension were selected and inserted into C. For some items with only one pictogram in the previous study (Kurata et al., 2017), such as blood abnormality, sore throat, and so on, we have designed several new pictograms based on those pictograms. We verified both "comprehension (easy to understand)" and "visibility (easy to see)" of those pictograms (the before and the new one) using the paired comparison method. And then selected pictograms which relatively high evaluations inserted into B, while selected pictograms which relatively low evaluations inserted into C. The selected pictograms were shown in Appendix 1.

Recent research (Hashiguchi et al., 2013) has shown that differences in layout will have impact on understanding, So we unify design elements other than pictograms, such as dividing lines. Appendix2-1, 2-2 and 2-3 to demonstrate the design for each insert version.

The package insert used in this study received permission to use and to change the layout from the pharmaceutical company at the beginning of the research.

2.2.3 Place and Period of Research

This study was carried out at the Design Psychology Unit in Chiba University, from December 27th to February 8th 2017.

2.2.4 Experimental Design and Procedure

Each participants first read either one of the three types of package inserts for 2 minutes, following which they were separated into three groups (A, B, C) and compared.

At the time when they reading, we measured eye movement by eye tracker. With eye tracking the device knows where the user's focus is at any given point in time (Tobii Website) – that is, With this device, At the time when participants reading, can be measured that what information is received attention to what extent (Ohno, 2002; Choi et al., 2012).

After that, the participants filled out a questionnaire by Survey Monkey. The questionnaire included items on comprehension of the Drug information, Subjective evaluation on importance of each piece of information in “precautions for use”, and demographics. Appendix 3 to demonstrate the original version of Japanese.

Finally, participants completed a subjective evaluation of insert design by paired comparison method. Through these tests, three insert versions were quantitatively compared. Each of the above steps is described in further detail below.

2.2.4.1 Method and system for eye tracking

In the experiment, participants’ eye movements were recorded using a Tobii TX300 eye-tracking system running at 300 Hz, controlled by a Dell Precision M6800 and Tobii Studio 3.2.2. We installed a chin rest 65 cm away from the display and fixed the distance between the participant and the display. The package insert was displayed on a flat-screen monitor (with screen resolution of 1920 × 1080 pixels), and the set up allowed the participants to use a mouse to click on the page of package insert to pass from one to another (see Figure 2-1). The font size of the package inserts displayed on the screen was 10 point (visual angle: 0.309°), and the size of the pictograms was 20 mm × 20 mm (visual angle: 1.762°).

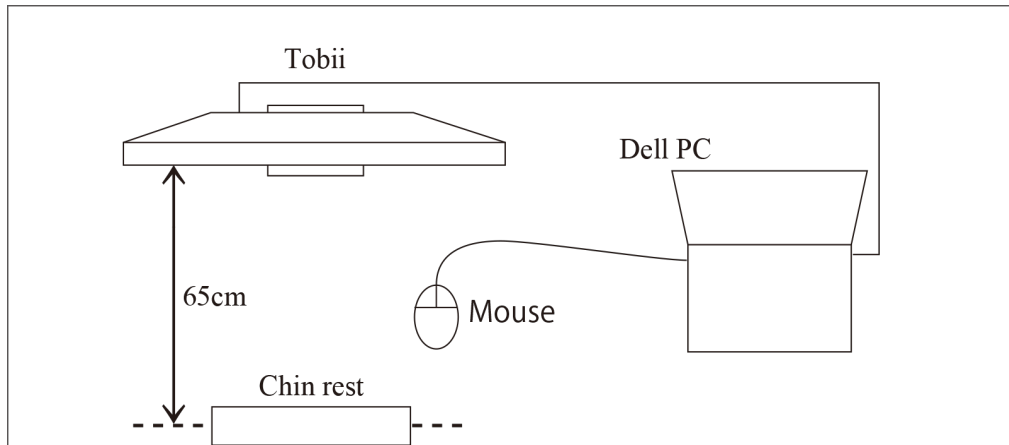


Figure 2-1. Experiment scenery of eye tracking

Reading Controls: Click on The cross icon in the center of the screen started the reading, the front page of the package insert shown first in the screen, and the back page of the package insert will be shown by click the “Front page”. Participant can read the information contents of the front page and the back page freely by clicking on each other (Front page and Back page) (see Figure 2-2). In addition, the package insert on screen will disappear automatically after 2 minutes. Based on the prepared experiments, the reading time are limited to two minutes as time required to understand the contents.

When participant was seated, firstly, introduces the contents and procedures of the experiment. After practicing about how use mouse reading insert on monitor, the following instruction was given:

“From now on, you will read the package insert of stomach medicine. way of reading the package insert are of course free, but please read it carefully as the aim of really to take this stomach medicine. The same as practice, you can freely view the front and back of the package insert by clicking the left mouse button. In addition, the package insert on screen will disappear automatically after 2 minutes.”

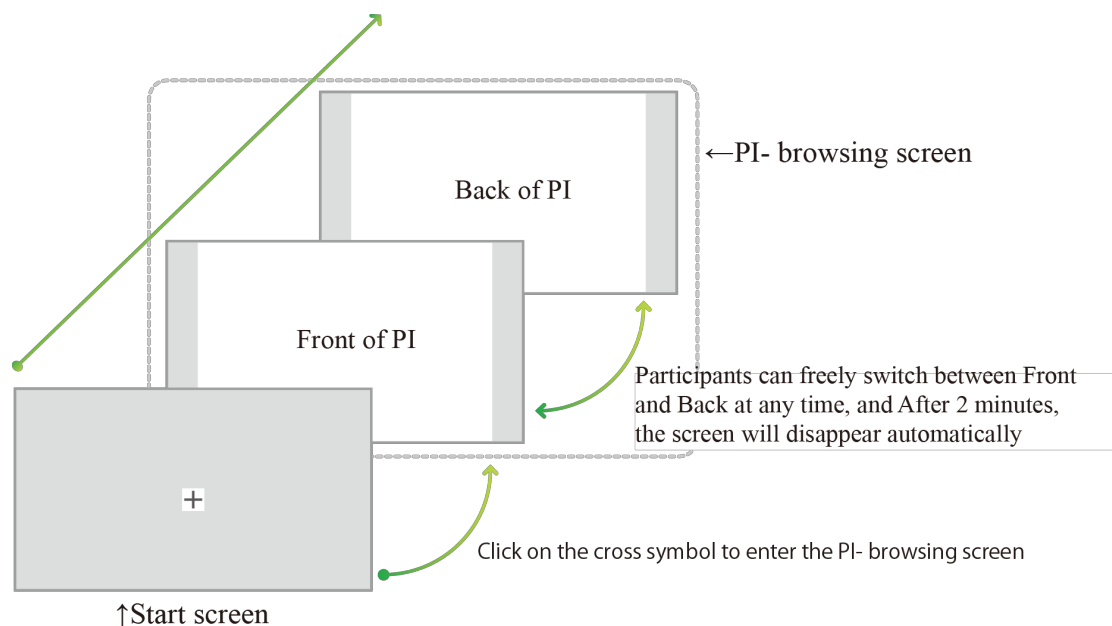


Figure 2-2. Experiment flow of eye tracking

We divided the “precautions for use” into five areas (see Appendix 4): 1) People who should not use, 2) Drugs not to be used in combination, 3) Warning about lactating women, 4) Consultation matter before use, 5) Consultation matter after use(Side effect), and the eye fixation time for these five areas was measured, during the time that participant is reading the package insert. Moreover, we also measured the eye fixation time for the area: 6) the header which consists of revision date, drug names, and classification, 7) indications, 8) dosage and administration, 9) ingredients and amount, 10) storage methods, and 11) contact details and manufacturer information.

2.2.4.2 Questionnaire survey

The questionnaire was composed of comprehension test of the drug information, evaluation of the 2 minutes that reading time, subjective evaluation on importance of each piece of information in “precautions for use”, and demographic survey.

1) Comprehension test of the drug information

The part consisted of four choice questions as shown table 2-1. There is one question with “dosage and administration”, one question with “when to discontinue use”, one question with “consultation matter before use”, and one question with “warning for specific people”.

2) About the time of reading insert information

After the comprehension test for the drugs information, participants were asked to evaluate 2 minutes of reading time. Specifically, raised this question: how did you feel the 2 minutes time that to read the necessary information? And there are 3 options: 1) Time was not enough, 2) Time was just enough and 3) Time was long.

3) Subjective evaluation on the importance of each piece of safety information

In order to understand the importance of each piece of safety information in the consumer's mind, it asked participants eight items by five-grade evaluation. They are: 1) People with allergies, 2) people with chronic disease, 3) Drugs not to be used in combination, 4) warning for children, 5) warning for elderly, 6) warning for Pregnant woman / lactating woman, 7) People with specific symptoms as High fever, cramping, abdominal pain, etc., and 8) Side effects. Specifically, the evaluation scale and its score are “not important” (1), “not very important” (2), “neither” (3), “important” (4), “very important” (5).

4) Demographics

In the last section of questionnaire survey, patients answered questions about Gender and age, frequency of purchase of OTC drugs, presence of allergies and chronic diseases, and so on (which are listed at the table 2-2).

Table 2-1 Contents of Comprehension test

No	Items & Contents
1	<p>Dosage and administration</p> <ul style="list-style-type: none"> ① 1 tablet once; twice daily ② 1 tablet at a time; up to 3 times a day ③ 2 tablets once; twice daily ④ 2 tablets once; up to 3 times a day
2	<p>When to discontinue use</p> <p>If you do not see symptomatic improvement even after taking this medicine for period <u> a </u>, you should stop taking it and consult a doctor or pharmacist. Please choose the period applicable to <u> a </u> from the following.</p> <p>1 day, 2 days, 3 days, 4 days, 5 days, 6 days, 7 days, 8 days, 9 days, 10 days, 11 days, 12 days, 13 days, 14 days.</p>
3	<p>About people who need consultation before taking</p> <p>According to the package insert, a person with specific symptoms needs to consult a doctor or pharmacist before taking this medicine. Which of the following is the symptom?</p> <ul style="list-style-type: none"> ① Nausea · vomiting, hemorrhoid bleeding, bleeding tendency, urination difficulty ② Diarrhea accompanied by symptoms such as constipation, loose stools, mouth sweat, vomiting ③ Sore throat, cough and high fever, unexplained weight loss, persistent abdominal pain ④ One who is in the mouth, stomachache, heartburn, leaning, nausea
4	<p>Use of specific user group</p> <p>The following options include three people who should not take and one who needs a consultation with a doctor or pharmacist before taking. Please select one person who needs consultation with your doctor or pharmacist before taking it from the following options.</p> <ul style="list-style-type: none"> ① Children under 15 years of age ② Elderly people over 65 years old ③ Pregnant women within 12 weeks due to birth ④ Breastfeeding person

2.2.4.3 Subjective evaluation of insert design by paired comparison method

The paired comparison method is one of relative evaluation methods for quantitatively evaluating a subjective sensation (Kimiyama, 2016). In the survey, Subjective Evaluation was performed on the design of four types (package inserts A, B and C + Original package inserts which became reference) of package inserts by Sheffe's ANOVA on Paired Comparison. And named the Original package insert as insert D. Since the influence of the dividing lines on subjective evaluation such as visibility has not been studied yet, the package insert D is also used as a comparison target in this survey.

Specifically, we showed participants two of the four versions of inserts and asked them to answer five questions, namely “which one propels me to read?”, “which one is easy to read?”, “which one is my favorite design?”, and “which one is suitable to be used as drug insert?”. Participants were then asked to complete an assessment table in seven phases, as shown in Appendix 5. The comparison order was not taken into consideration in this research. All groups ($4C_2=6$) Of sheffe's anova on paired comparison (Nakaya variation) Were compared (Ichihara & Kajitani, 2015).

2.3 RESULTS

2.3.1 Demographic Characteristics

Participants' demographic characteristics are presented in table 2-2. A and B each have 16 Participants are took part in read, and C have 9 Participants are took part in read. According to the results of the Chi-square test, there is no significant difference across the demographic characteristics between the three groups (Fisher's exact test, $p>.05$).

Table 2-2 Demographic characteristics of participants

	Group A, (N=16)	Group B, (N=16)	Group C, (N=9)
Age, y (mean \pm SD)	21.8 \pm 1.6	22.2 \pm 2.1	21.3 \pm 1.1
Gender			
Male	9	6	5
Female	7	10	4
Frequency of purchase			
At least once a month	1	3	1
At least once in 2-3 months	5	5	3
At least once in six months	3	3	2
At least once a year	3	0	2
Less than once a year	4	3	1
have never purchased	0	2	0
People with chronic illness	1	2	1
People with allergies	7	6	3

2.3.2 Duration of Eye Movement Fixation of Each Area on the PIs

Figure 2-3 shows the average duration of eye movement fixation of each area on the three inserts. One-way ANOVA was performed between 3 groups (A group, B group, C group) for duration of eye movement fixation of each area. It finds that the duration of eye movement fixation has significant main effect on area of “drugs not to be used in combination ($F[2, 20.744]=3.600, p=0.045$)”, “warning for lactating women ($F[2, 15.72]=9.657, p=.002$)” and “consultation matter before use ($F[2, 38]=3.928, p=.028$)”. Further based on variance analysis were compared the experiment results and found that, the average duration of eye movement fixation for "warning for lactating women " was significantly longer in group B and group C than in group A (Games-Howell, $p<.05$) .

Moreover, the average duration of eye movement fixation for “consultation matter before use” was only significantly longer in group B than in group A (Bonferroni, $p < .05$). However, there were no significant differences between each groups for “drugs not to be used in combination” area (Games-Howell, *N.S.*).

Next, the attention rate (Percentage of person who payed attention) for each group was calculated for the item of “warning for lactating women” with the lowest attention degree. Based on earlier finds, it is considered to payed attention if it remains on each area for longer than 0.2s (Findlay & Gilchrist, 2006). The calculated results show that the attention rate was 53% (8) in Group A, 32.6% (15) in Group B, and 31.1% in Group C (8). A Chi-squared test was performed, and the results revealed significant differences among them (Fisher’s exact test, $\chi^2(2) = 8.487$, $p = .015$). Therefore, multiple comparisons using the Ryan method were conducted, through which it was found that the attention rate of Group B was significantly higher than that of Group A ($p < .01$).

2.3.3 Results of Comprehension Test

The number and the percentage (correctness) of participants who answered correctly on each question are shown in table 2-3. In order to investigate whether there is a difference in the correctness, the correctness of each item underwent Chi-squared test. The results of this test find that a significant difference was noted in the correctness of item “consultation matter before use: People with sore throat and high fever ($\chi^2(2) = 6.175$, $p = .049$)”. Therefore, multiple comparisons using the Ryan method were

conducted, through which it was found that the correctness of Group B was significantly higher than that of Group A ($p < .05$).

2.3.4 Results of Evaluation for Reading Time

The results of evaluation for reading time of the 3 groups are shown in table 2-4. There are 10 people (62.5%) in group A and group B, and 4 (44.4%) in group C, that is, a total of 24 people (58.5%) answered 2 minutes of reading time is not enough to understand the necessary information.

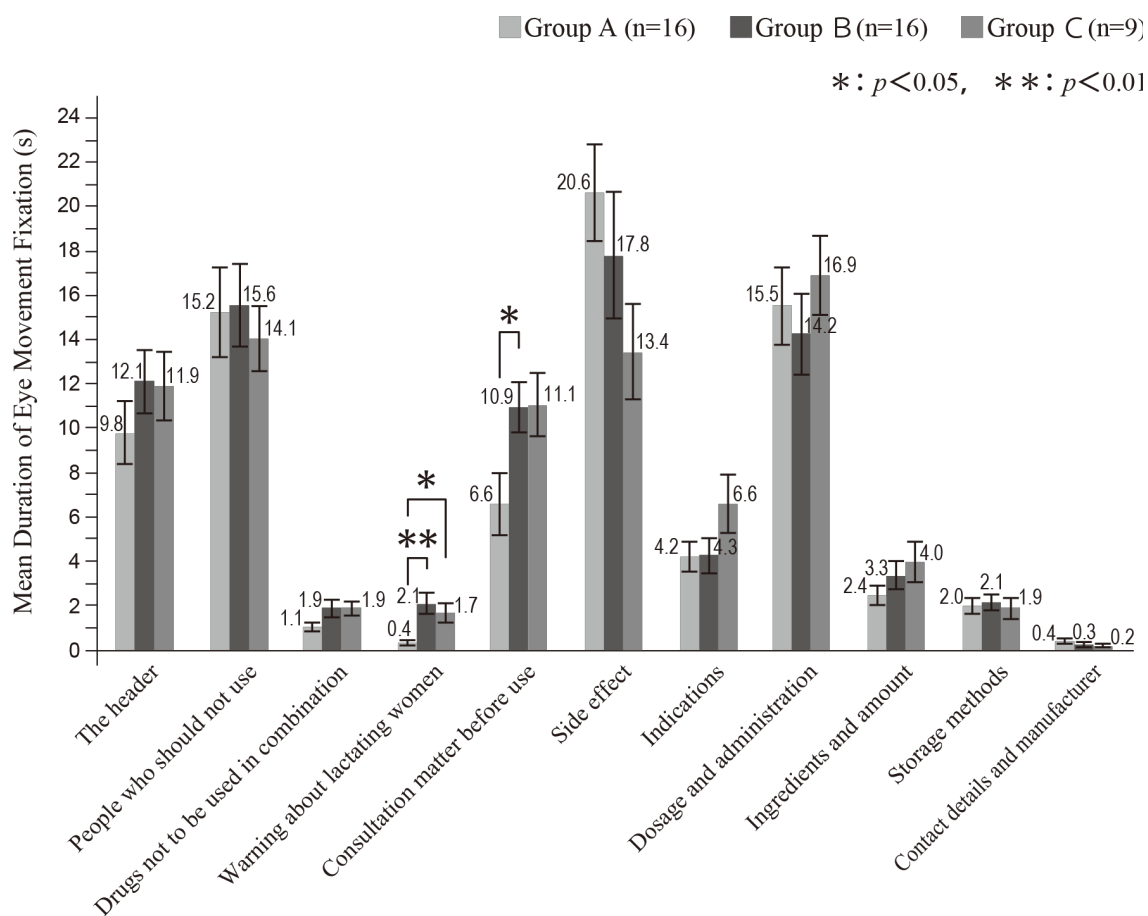


Figure 2-3. Mean duration of eye movement fixation for each area

Table 2-3 Results of comprehension test, *n*(%)

No	Items	Group A N=16	Group B N=16	Group C N=9
1	Dosage and administration	9(56.3)	11(68.8)	6(66.7)
2	When to discontinue use	4(25.0)	9(56.3)	4(44.4)
3	About people who need consultation before taking	* 4(25.0)	* 11(68.8)	4(44.4)
4	Use of specific user group	2(12.5)	5(31.3)	3(33.3)

There was a statistically significant difference between groups represented by the same symbol (* or †).

Table 2-4 Results of evaluation for reading time, *N*(%)

	Group A N=16	Group B N=16	Group C N=9	Total N=41
time was not enough	10 (62.5)	10 (62.5)	4 (44.4)	24 (58.5)
time was just enough	3 (18.75)	2 (12.5)	4 (44.4)	9 (22.0)
time was long	3 (18.75)	4 (25%)	1 (11.11)	8 (19.5)

2.3.5 Results of Subjective Evaluation on the Importance of Each Safety Information

The average score of the evaluation on the importance of each caution item of the 3 groups is as shown in figure 2-4. A one-way analysis of variance was performed among three groups on the score of each item. Results There were no main effects, but the average score of the two items of “People with specific symptoms as High fever, cramping, abdominal pain, etc.” and “ about side effects” is more than 4 score in all three groups.

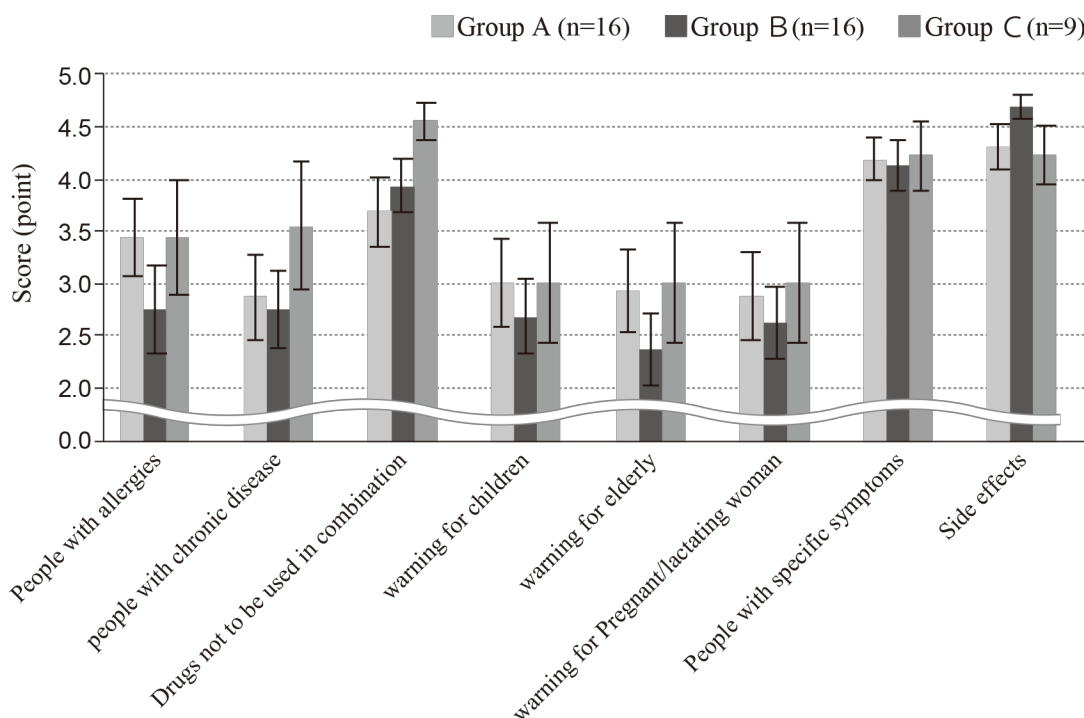


Figure 2-4. Results of subjective evaluation on the importance of each safety information

2.3.6 Results of insert design by paired comparison method

The scores of all participants were placed under a variance analysis by each evaluated item, and the results were expressed with a psychological scale, as see in Figure 2-5. According to the results, all items under evaluation, “Which one propels me to read? (A= -0.38, B=1.10, C=0.66, D=-1.38)”, “Which one is easy to read? (A= -0.07, B=0.92, C=0.46, D=-1.31)”, “Which one is my favorite design? (A= -0.27, B=1.04, C=0.38, D=-1.16)”, and “Which one is suitable to be used as drug insert? (A= -0.07, B=0.78, C=0.24, D=-0.95)” followed the order of B, C, A, and D in the psychological scale. A syn-position analysis showed that Group B and C , C and A, A and D were significantly different from one another at 1% for all items under evaluation.

** : $p < 0.01$

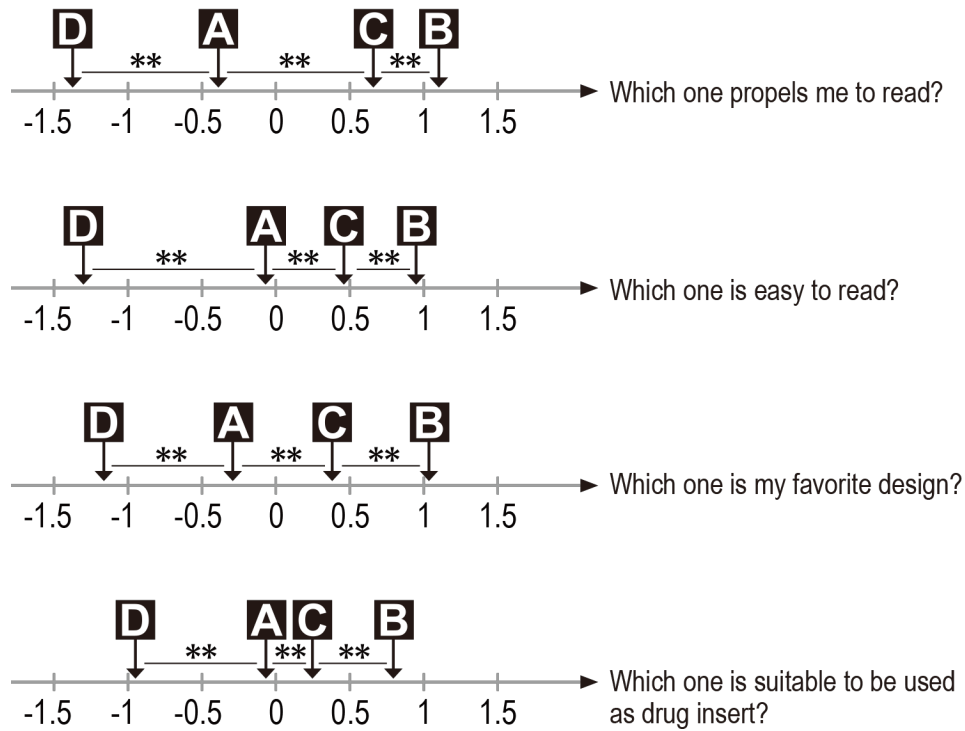


Figure 2-5. Results of insert design by paired comparison method

2.4 DISCUSSION

The results of the eye movement measurement experiment indicated that the attention rate for "warning for lactating women" was higher in Group B than in Group A. The "warning for lactating women" was listed at the end of "people who should not use" and was located in a place that was judged to be easily overlooked. Therefore, it was suggested that attention could be drawn to important information with the use of pictograms.

The results of the eye-tracking survey also indicated that the eye movement fixation duration on "Consultation matter before use" was significantly longer in Group B than in Group A. Furthermore, the correct answer rate for the question about "Consultation matter before use (People with specific symptoms)" described in this area was significantly higher in Group B than in Group A. Moreover, the results of the subjective evaluation of the importance of each piece of safety information showed that each of the three groups felt "Consultation matter before use (People with specific symptoms)" was important information. However, no difference was found between Groups C and A in the eye tracking experiment or in the comprehension test. These results suggested that incorporating easily understood pictograms improves not only the degree of attention to necessary information but also the understanding of important information.

In the correct answer rate for "Use of specific user groups (children, elderly people, pregnant women, lactating women)", no significant difference was found among the groups. Moreover, the correct rate of the three groups was found to be less than 35%. Based on the results of subjective evaluation of the importance of each piece safety

information, all 3 groups regarded that the information under "use of specific user groups" was insignificant (Score < 3). Therefore, it is highly probable that users do not remember information irrelevant to their own needs.

Through Scheffe's method of paired comparisons, this study found that the inserts with more easily understood pictograms were significantly more effective than the two other insets in the evaluations. In particular, the possibility to improve reading motivation by incorporating pictograms is suggested, which is considered to be significant. In addition, the evaluation of Package Insert A with partitions was significantly higher in any of the evaluation items than in Package Insert D. Even in inserts with only text, it is likely that differences in layout due to partitions will affect readability, legibility, etc.

Based on the results of this research, in order to make it easier for all users to recognise necessary safety information, such as "Usage precautions", pictograms should be used as an effective visual tool. Based on the results of this survey, when incorporating pictograms into package inserts, they must influence the degree of understanding of pictograms themselves on the degree of attention, readability, and motivation to read the pictograms themselves.

In this survey, teaching was given to university and graduate students in their twenties to assume "a state where they are actually using the medicines". A time limit of 2 minutes was the set, during which the differences in ease of remembering the content of the description were considered. About the 2 minutes of reading time more than half of those expressed it is not enough to understand the necessary information. Thus, it is

necessary to study this kind of problems in detail. For example, for reading without limiting the time, etc.

Regarding readability, the text displayed on the screen (visual angle: 0.309°) was bigger than the minimum readable character size for Japanese characters (Gothic Hiragana, Katakana, Arabic numerals: approximately equal to 2.168° p; Gothic Kanji: approximately equal to 2.787°) (Japan Industrial Standards Commission, JIS S 0032). However, there was no evaluation of the readability for the text displayed on the screen. To verify that the readability of the text did not influence the results, the readability of the character size should have been evaluated.

After instructing participants to read the package inserts, this study examined the degree of comprehension based on how easily the required information was memorised. However, this study must further investigate the discrimination (ease of finding) for necessary information as it necessary to comprehensively examine the influence of the incorporation of pictograms on the degree of comprehension.

Furthermore, the attitudes towards each item of "Precautions for use" differ depending on demographic characteristics. Therefore, in the future, research will target specific age groups, such as the elderly, children, pregnant women, or lactating women.

3. Study 2: Research on the elderly patients

This chapter is based on Piao, Yamashita, Mochizuki, and Hibino (2019). The present study was approved by the Independent Ethics Committee of the Graduate School of Engineering, Chiba University, and informed consent was obtained from all participants (Permit number: 29-03).

3.1 Introduction

With the proportion of the aging population increasing (Cabinet Office, 2017), it is probable that the elderly population will become the largest consumer group of OTC drugs. An individual is much more likely to be confronted with multiple health problems as he/she ages, which raises the odds of drug use in aging population in relation to other age groups. Moreover, considering the great variety of diseases, elderly individuals tend to use more drugs (which indicates a relatively high possibility of taking prescribed and OTC drugs at the same time). Furthermore, with the hypofunction of liver and kidneys, elderly individuals are exposed to a considerably higher risk of overdose or adverse drug interactions (The Japan Geriatrics Society, 2015). Therefore, in terms of safe and rational drug use, elderly individuals represent a more pressing demand for understandable drug information than young consumers. However, a low sensory capability (e.g., presbyopia) and weak cognitive ability (e.g., hypomnesia) are commonly seen in the aging population who cannot acquire and process information as efficiently as young people do (Qato DM et al., 2008; Akishita, 2016). It is found that

the inappropriate design of drug information can lead to improper drug use among the elderly, such as inaccurate frequency and dosage, ignorance of contraindications, and inappropriate consumption of both prescribed and OTC drugs (Wogalter, Magurno, Dietrich, & Scott, 1999; Gurwitz et al., 2003). Therefore, it is necessary to explore whether the design of drug information is favorable to the elderly in terms of information acquisition.

Poor readability is considered a major reason for older adults not using medicines information leaflets (Sadowski, 2011). Many studies have proven that font size plays an important role in drug information acquisition among the elderly (Wogalter & Vigilante, 2003; Murty & Sansgiry, 2007; Sato et al., 2010). Furthermore, We have discovered in the study of Chapter 2 that pictograms can draw consumers' attention and strengthen their memories for drug information. However, pictograms are not as accurate as text in terms of information delivery, in that not everyone can accurately understand pictograms (Kurata et al., 2017). To ensure the accurate delivery of drug information, pictograms must be used in combination with text. Without reduction or deletion of text, a larger paper (or a greater print size) is required to increase the font size and insert pictograms. However, some studies have suggested that using larger paper will reduce consumers' desires to read because it implies a higher cognitive load (Legge & Bigelow, 2011). Therefore, the paper size of the printed inserts of drug products must be taken into careful consideration during the design process. Before this study, a preliminary survey was conducted, and it was found that the elderly could accept the instructions of use being printed on a piece of paper no larger than A4, a

paper size defined by the ISO 216 standard. On this basis, despite most of the inserts of OTC drugs available in the market being printed on a paper smaller than A4, the authors of this paper decided to use A4 paper in the design proposed for this study.

Based on the analysis above, this study aims to probe the effect of pictograms incorporated in package inserts on information acquisition (effects on ability to recall and navigate the information) and preference of elderly consumers. Specifically, the study focuses on whether the package inserts with pictograms and on A4 paper are more favorable to the elderly, in terms of information acquisition in comparison with those with plain text on the same paper size. To this end, three designs of A4 package inserts were provided in this study: a. insert with pictograms; b. insert with greater spacing between paragraphs; and c. insert with larger font size. Subsequently, a comparative analysis was performed accordingly. Details of the three designs are provided in the next section.

3.2 METHOD

3.2.1 Participants

Sixty-six elderly individuals ($M=71.55$, $SD=1.48$) participated in this study. Participants were recruited from the Silver Talent Center of Chiba City. These participants should

- Never have worked in pharmaceutically related fields (Pharmacist, etc.)
- Have taken and been responsible for taking their own medication;
- If they used reading glasses, have had the glasses with them.

3.2.2 Stimulus

In the present study, three package insert versions (A, B, C) were designed regarding for a stomach medicine H2 blocker currently on the market. Each version consisted of two sides of A4 (210 x 297 millimeter) paper. All of the content and sequences designed were the same. The front page consisted of 1) the header, which consists of revision date, drug names, and classification, 2) drug characteristics, and 3) precautions for use. The back page consisted of 1) the indications, 2) dosage and administration, 3) ingredients and amount, 4) storage methods, and 5) contact details and manufacturer information. The three package insert versions were different from one other.

This study marked the three insert versions as Version A, Version B, and Version C, as shown in Table 3-1. In Insert A, all items adopted an 11-point size font, whereas contents 10-point size font. In addition, pictograms were inserted into 10 sub-items in the “precautions for use” section, which were separated by parting line in order to improve their legibility. Insert B used the same font sizes as Insert A, and the 10 subitems in “precautions for use” sections were also separated from one another using parting lines. However, lacking pictograms, the inter-paragraph spacing between those sub-items was wider. In Insert C, no pictograms or parting line were used to separate sub-items, but a larger font size were used. As a result, all items were in a 12-point font, while the contents were in 11-point font. Appendix6-1, 6-2 and 6-3 display the examples for each insert version.

Table 3-1 The difference in the design of the three inserts

	Font size	Pictograms	Spacing between paragraphs
A	11- & 10-point font	Inserted	With smaller spacing between paragraphs + dividing lines
B	11- & 10-point font	Not inserted	With larger spacing between paragraphs + dividing lines
C	12- & 11- point font	Not inserted	With smaller spacing between paragraphs and no dividing line

3.2.3 Experimental Design and Procedure

This study was carried out at the Design Psychology Unit in Chiba University, from January 10th to February 6th 2018.

Sixty-six elderly individuals were averagely distributed into three groups in order to evaluate three insert versions and were marked Group A, Group B, and Group C.

Participants were tested individually. Each participant was at first asked to read one insert, which was randomly selected from the three versions. Before participants read the inserts, the following instruction was given:

“Please read the inserts carefully and imagine that your stomach is uncomfortable, and that you really need to take this medicine”.

A stopwatch was used record the time from when they started reading to having self-reported finished reading.

The information recall test and information search test were conducted to investigate information acquisition. After these two tasks and a 5-minute break, participants completed a subjective evaluation of insert design. Through these tests, three insert versions were quantitatively compared. Each of the above steps is described in

further detail below.

Finally, participants answered a demographic questionnaire, as seen in Table 3-4.

3.2.3.1 Insert information recall test

This test aimed to examine the effects of insert design elements (pictograms, font size, and section space) on the information recall of elderly participants. After finishing the reading of the insert, participants were asked to complete a questionnaire about the medicine's contents. Based on Shaver and Wogalter (2003) we set three questions in the questionnaire, as shown in Table 3-2. Both Question 2 and Question 3 have multiple correct answers. Specifically, the answers to Question 2 are 1) If it is ineffective after taking this medicine for 3 days and 2) Do not take this medicine for more than 2 weeks. The answers to Question 3 are 1) Children younger than 15 years old cannot take this medicine, 2) Elderly individuals older than 80 years old cannot take this medicine, and 3) Individuals older than 65 years old should consult with pharmacists or doctors when using this medicine.

Table 3-2 Contents of insert information recalling test

No	Items	Contents
1	Dosage and administration 用法・用量について	What is the maximum amount you can take in one day (24-hour period)? 1日(24時間)に服用できる最大量は?
2	When to discontinue use 服用期限について	After how many days should you discontinue use? 服用始めてからいつ服用を止めるべきでしょうか?
3	Age limit 年齢制限について	Is there age limit for taking this medicine? If so, please write the age of limit clearly. この薬には、年齢制限がありますか? あると思う場合、具体的な制限年齢について覚えて いる範囲で教えてください。

3.2.3.2 Insert information search test

After the above insert information recall test, participants had to undergo the insert information search test. This test aimed to investigate whether the participants can locate the relevant information correctly and quickly. With this purpose, this study set nine questions based on Hashiguchi et al. (2013). Further details are shown in Table 3-3.

During the experiment, we used a 24-in LCD display to present questions (as seen Figure 3-1 a). Before the experiment, we first interpreted the experimental methods and steps for the participants. When the experiment began, the first question was displayed on the screen, and the experimenters would recount it orally. After making sure that the participants had understood the question, we provided a paper insert the same as what they had seen before and asked them to find and mark the answer on the insert as quickly and accurately as possible. The answer tended to be a specific word or phrase. The timer started when participants began information searching and ended when they confirmed and marked the answers. After this step, the experimenter collected the paper, and the next question would be displayed. These procedures were repeated until all questions were completed (as seen in Figure 3-1 b). In this experiment, questions were presented in a unified order for all participants, as seen in Table 3-3. Furthermore, to avoid the influence of marks, a new insert was given to the participant for every question.

Table 3-3 Items and content of the information search

No	Items	Contenta
1	People with allergies アレルギー症状のある人の服用	Mr. A had a rash previously, which was caused by H2 blocker drugs. Can Mr. A take this medicine? Aさんは、過去に H2 ブロッカー薬を飲んで、発疹(皮ふにブツブツ)ができたことがあります。Dさんはこの薬を飲んでもよいでしょうか?
2	People with asthma 喘息の病気の人の服用	Mr. M uses an inhaler for the treatment of asthma. Can Mr. M take this medicine? Mさんは、喘息の治療のために吸入薬を使っています。Mさんはこの薬を飲んでもよいでしょうか?
3	People with white blood cell disorders 白血球の病気の人の服用	The doctor said that Mr. C has few white blood cells. Can Mr. C take this medicine? Cさんは、医師から白血球が少ない病気といわれています。Cさんはこの薬を飲んで もよいでしょうか?
4	People over 65 years old 高齢者の服用(65 歳以上)	Mr. H is 66 years old. Can Mr. H take this medicine? Hさんは66歳です。Hさんはこの薬を飲んでもよいでしょうか?
5	People with sore throat and high fever のどの痛み・高熱のある場合の対処	Mr. B wants to take this medicine. B has had a sore throat and high fever since yesterday. What should Ms. B do? Bさんは、この薬を飲みたいと思っています。昨日からのどが痛く、高熱もあります。Bさんはどうするべきでしょうか?
6	Dealing with side effects 副作用発生時の対処	Mr. J had a convulsion after taking this medicine. What should Mr. J do? Jさんは、この薬を飲んだ後すぐに気がとおくなり、ひきつけ(けいれん)が起きました。Jさんはどうするべきでしょうか?
7	Dealing with overdose 用量を超えた場合の対処	Mr. K takes this medicine for 3 day (6 tablets) at a time. What should Mr. K do? Kさんは、この薬を一回に3日分(6錠)飲んでしまいました。Kさんはどうするべきでしょうか?
8	Dealing with deterioration of constipation symptom 便秘症状の悪化の対処	Mr. F, after taking this medicine, had symptoms of constipation. What should Mr. K do? Fさんはこの薬を飲んでから、便秘の症状が重くなってしまいました。Fさんはどうするべきでしょうか?
9	When taking this medicine for two weeks 2週間服用した場合	Mr. L has taken this medicine for two weeks. The symptoms are getting better than before but still remain. What should Mr. K do? Lさんは、2週間この薬を服用しました。以前より症状は良くなっていますが、まだ症状が残っています。Lさんはどうするべきでしょうか?
10	Drugs not to be used in combination 飲み合わせ禁止	When taking this medicine, what kind of medicine should not be used in combination? この薬を服用する際、絶対一緒に飲んではいけない薬はどんな薬でしょうか?

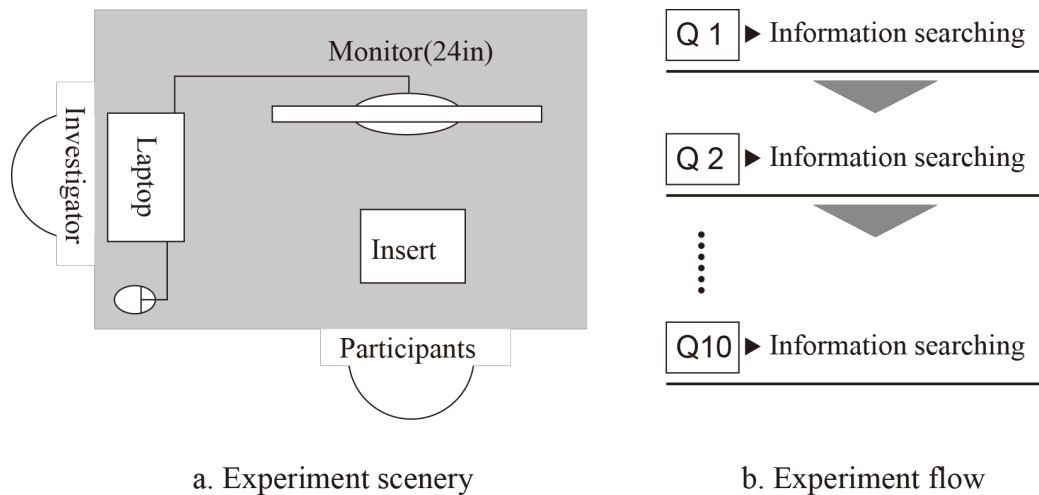


Figure 3-1. Experiment scenery and flow of insert information search test

3.2.3.3 Subjective evaluation for the design of package inserts

(1) Evaluation by rating scale method

In the subjective evaluation of the package insert designs, participants were first asked to evaluate the package insert they had read. Specifically, a five-grade evaluation was used to ask all participants about the font size and legibility of the layout. Five-grade evaluation was also used to ask participants of group A to evaluate the role of pictograms in package inserts (see table 3-7).

(2) Relative evaluation by the method of pair comparisons

After the evaluation of the scale method, Scheffe's method of paired comparisons (Kimiya, 2016) was used to compare participants' perceptions of three versions of the inserts. We showed participants two of the three versions of inserts and asked them to answer five questions, namely "Which one propels me to read?", "Which one is easy to read?", "Which one has the most eligible layout?", "Which one is my favorite design?", and "which one is suitable to be used as drug insert?". Participants were then asked to

complete an assessment table in seven phases, the same way as chapter 2. The comparison order was not taken into consideration in this research. All groups ($3C_2=3$) of Sheffe's ANOVA on paired comparison (Nakaya Variation) were compared.

3.3 RESULTS

3.3.1 Demographic Characteristics

Participants' demographic characteristics are presented in Table 3-4. According to the results of the Chi-square test, there is no significant difference across the demographic characteristics between the three groups (Fisher's exact test, $p>0.05$).

Table 3-4 Demographic characteristics of participants

	Group A, (N=22)	Group B, (N=22)	Group C, (N=22)
Age, y (mean \pm SD)	72.0 \pm 4.0	73.6 \pm 5.2	73.2 \pm 3.5
Gender, n(%)			
Male	11 (50.0)	11 (50.0)	10 (50.0)
Female	11 (50.0)	11 (50.0)	12 (50.0)
People with glasses, n(%)	16 (72.7)	18 (81.8)	17 (77.3)
People with chronic illness, n(%)	17 (77.3)	11(22.7)	13 (59.1)
People with allergies, n(%)	7 (31.8)	3 (13.6)	5 (22.7)
People experiencing side effects, n(%)	6 (27.3)	5 (22.7)	2 (9.1)
People currently taking OTC, n(%)	7 (31.8)	8 (36.4)	8 (36.4)
People currently taking prescription, n(%)	18 (81.8)	17 (77.3)	13 (77.3)
Purchase frequency of OTC /year, (mean \pm SD)	2.5 \pm 3.7	3.5 \pm 4.6	4.4 \pm 3.6
Number of hospital visits / year, (mean \pm SD)	6.5 \pm 4.1	6.4 \pm 3.9	6.7 \pm 4.5

3.3.2 Results of the Insert Information Reading Time

According to the time recorder, the average reading time of Group A was 280.0 seconds (SD = 69.8), Group B was 278.2 seconds (SD = 56.9), and Group C was 297.6 seconds (SD = 37.4). Using a one-way ANOVA procedure, the results were ($F [2, 39.17]=1.128, p=.334$). This result implies that there was no statistically significant difference in average reading time between the three groups.

3.3.3 Results of the Insert Information Recall Test

The number and the percentage (correctness) of participants who answered correctly on each question are shown in Table 3-5. Firstly, the total mean correctness was 53% in Group A, 32.6% in Group B, and 31.1% in Group C. A Chi-squared test was performed, and the results revealed significant differences among them ($\chi^2 (2)=16.433, p= .000$). Therefore, multiple comparisons using the Ryan method were conducted, through which it was found that the correctness of Group A was significantly higher than that of Group B and C ($p < .01$).

Likewise, the correctness of each item underwent Chi-squared test, and a significant difference was noted in the correctness of item dosage and administration ($\chi^2 (2)= 7.661, p= .023$) and when to discontinue use : 3 days ($\chi^2 (2)= 7.442, p= .028$). Further multiple comparisons based on the Ryan procedure were employed, and Group A performed significantly better than Group B or C in terms of correctness of item in dosage and administration and when to discontinue use : 3 days ($p < .05$).

By contrast, when the remaining four items, namely when to discontinue use: 2

weeks ($\chi^2 (2) = 0.340, p = 1.00$), age limit: under 15 years ($\chi^2 (2) = 1.948, p = .408$), age limit: over 80 years ($\chi^2 (2) = .511, p = .939$) and age limit: Older than 65 years old ($\chi^2 (2) = 6.252, p = .055$) were concerned, no significant difference was detected among the three groups in term of correctness.

Table 3-5 Results of recall tests

	Group A (N=22)	Group B (N=22)	Group C (N=22)
Dosage and administration	16(72.7) * †	8(36.4) *	8(36.4) †
When to discontinue use			
3 days	12(54.5) * †	4(18.2) *	5(22.7) †
2 weeks	4(18.2)	3(13.6)	3(18.2)
Age limit			
Younger than 15 years old	12(54.5)	8(36.4)	8(36.4)
Older than 80 years old	17(77.3)	16(72.7)	15(68.2)
Older than 65 years old	9(40.9)	4(18.2)	2(9.1)
Total	70(53.0) * †	43(32.6) *	41(31.1) †

There was a statistically significant difference between groups represented by the same symbol (* or †).

3.3.4 Results of the Insert Information Search Test

In the results analysis, we first calculated search time and then determined whether the participants successfully located the information.

Firstly, to search all information on the 10 items, Group A took 238.5s (SD= ± 77.0) on average, Group B 282.4s (SD= ± 133.7), and Group C 301.1s (SD= ±126.0). The one-way ANOVA program was employed to analyze the difference among the three groups in the total search, though no significant difference was found ($F[2, 63]= 1.718, p=.188$). Next, the same program was used in analyzing the difference in the time needed to search each item, and the time for searching Item “The use of the elders that older than 65 years old” was significantly different ($F[2, 37.483]= 3.544, p< .039$). Subsequent multiple analyses suggested that there was no significant difference in the search time across the three groups ($p> .05$).

By contrast, across the remaining nine items, namely people with allergies ($F[2, 37.274]= 1.929, p= .160$), people with asthma ($F[2, 63]= 2.628, p= .080$), people with white blood cell disorders ($F[2, 63]=1.326, p= .273$), people sore throat and high fever ($F[2, 63]= 1.854, p= .165$), dealing with side effects ($F[2, 63]=0.168, p= .846$), dealing with overdose ($F[2, 40.074]= 0.679, p> .05$), dealing with deterioration of constipation symptoms ($F[2, 36.893]= 2.674, p= .082$), when taking this medicine for two weeks ($F[2, 38.501]= 3.110, p= .056$), and drugs not to be used in combination ($F[2, 63]= 0.1, p= .990$), were concerned, no significant difference was detected among the three groups in term of correctness (see Figure 3-2).

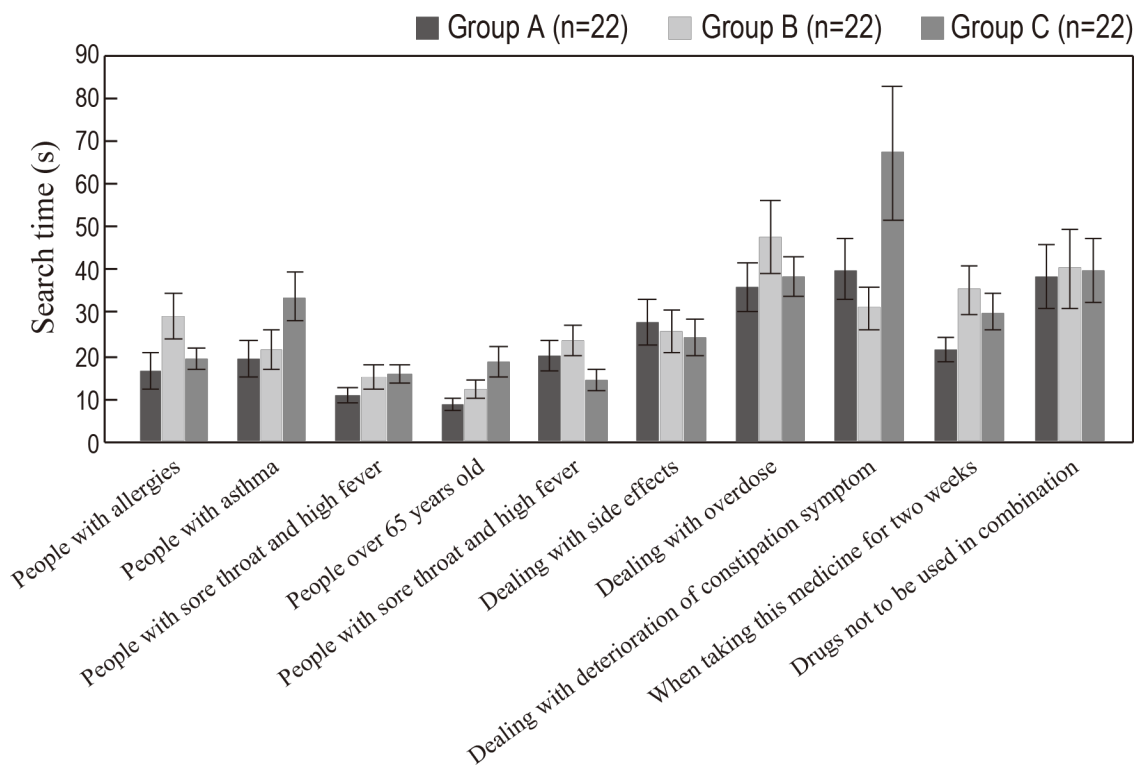


Figure 3-2. Average time for searching each item

After this step, the number of people who successfully found the information and their ratio (accurate positioning rate) for each item was determined and listed in Table 3-6. The total accurate positioning rate for all the items was 91.4% in Group A, 78.2% in Group B, and 71.7% in Group C. A Chi-squared test of these results revealed significant difference ($\chi^2 (2)=28.082, p= .000$). Further multiple comparisons using the Ryan procedure were conducted, which resulted that Group A had an accurate positioning rate significantly higher than that of Group B and C ($p<.01$). Likewise, the accurate positioning rate of each item underwent the Chi-squared test, and a significant difference was spotted in the accurate positioning rate of in people with allergies ($\chi^2 (2)= 14.074, p= .001$) and dealing with overdose ($\chi^2 (2)=6.338, p= .041$). Further multiple comparisons

based on the Ryan procedure were employed, and Group A performed significantly better than Group B or C in terms of correctness of people with allergies ($p < .01$), but only better than Group C in dealing with overdose ($p < .05$). By contrast, when the remaining eight items, were concerned, no significant difference was detected among the three groups in terms of correctness.

Table 3-6 Number of people that successfully found the information required (%)

	Group A (N=22)	Group B (N=22)	Group C (N=22)
1 People with allergies	19 (86.4) * †	8 (36.4) *	9 (40.9) †
2 People with asthma	20 (90.9)	18 (77.3)	15 (68.2)
3 People with white blood cell disorders	22 (100.0)	21 (95.5)	20 (90.9)
4 People over 65 years old	20 (90.9)	14 (63.6)	19 (86.4)
5 People with sore throat and high fever	17 (77.3)	15 (68.2)	17 (77.3)
6 Dealing with side effects	22 (100.0)	21 (95.5)	20 (90.9)
7 Dealing with overdose	22 (100.0) †	21 (95.5)	17 (77.3) †
8 Dealing with deterioration of constipation symptoms	19 (86.4)	17 (77.3)	12 (54.5)
9 When taking this medicine for two weeks	22 (100.0)	21 (95.5)	21 (95.5)
10 Drugs not to be used in combination	18 (81.8)	16 (72.7)	12 (54.5)
Total	201 (91.4) * †	172 (78.2) *	160 (71.7) †

There was a statistically significant difference between groups represented by the same symbol (* or †).

3.3.5 The Result of Subjective Evaluation for Design of Package Inserts

3.3.5.1 Results of evaluation by rating scale method

The results of the subjective evaluation of the package inserts are shown in tables 3-7. Most of the participants (95.5% of group A and 77.3% of both group B and group C) answered that the font size was just right. There was no statistical difference between the three groups regarding their evaluations of layout legibility. Regarding the role of pictograms, a total of 17 (77.3%) participants thought that pictograms were at least useful (3 of those 17 participants thought the pictograms were very useful). In addition, some of the participants gave explicit reasons for choosing each scale (see [Appendix 7](#)).

Table 3-7 Results of the evaluation PIs' design by rating scale method

	Group A (N=22)	Group B (N=22)	Group C N=22
About font size, n (%)			
Very small	0	0	0
Small	1 (4.5)	4 (18.2)	5 (22.7)
Just right	21 (95.5)	17 (77.3)	17 (77.3)
Large	0	1 (4.5)	0
Very large	0	0	0
Legibility of layout, n (%)			
Very Unclear	0	1 (4.5)	2 (9.1)
Unclear	5 (22.7)	7 (31.8)	4 (18.2)
Neither	6 (9.1)	5 (22.7)	6 (9.1)
Clear	10 (45.5)	9 (40.9)	10 (45.5)
Very clear	1(4.5)	0	0
The role of pictograms , n (%)			
Not useful	0		
Not very useful	2 (9.1)		
Neither	3 (13.6)		
Useful	14 (63.6)		
Very useful	3(13.6)		

3.3.5.2 Results of evaluation by the method of pair comparisons

The scores of all participants were placed under a variance analysis by each evaluated item, and the results were expressed with a psychological scale, as see in Figure 3-3. According to the results, all items under evaluation, “Which one propels me to read?”, “Which one is easy to read?”, “Which one has the most eligible layout?”, “Which one is my favorite design?”, and “Which one is suitable to be used as drug insert?” followed the order of A, B, and C in the psychological scale. A syn-position analysis showed that Group A and B were significantly different from one another at 1% for all items under evaluation. Furthermore, Groups B and C were found to be significantly different at 1% for “Which one has the most eligible layout?”, and 5% for “Which one is my favorite design?”.

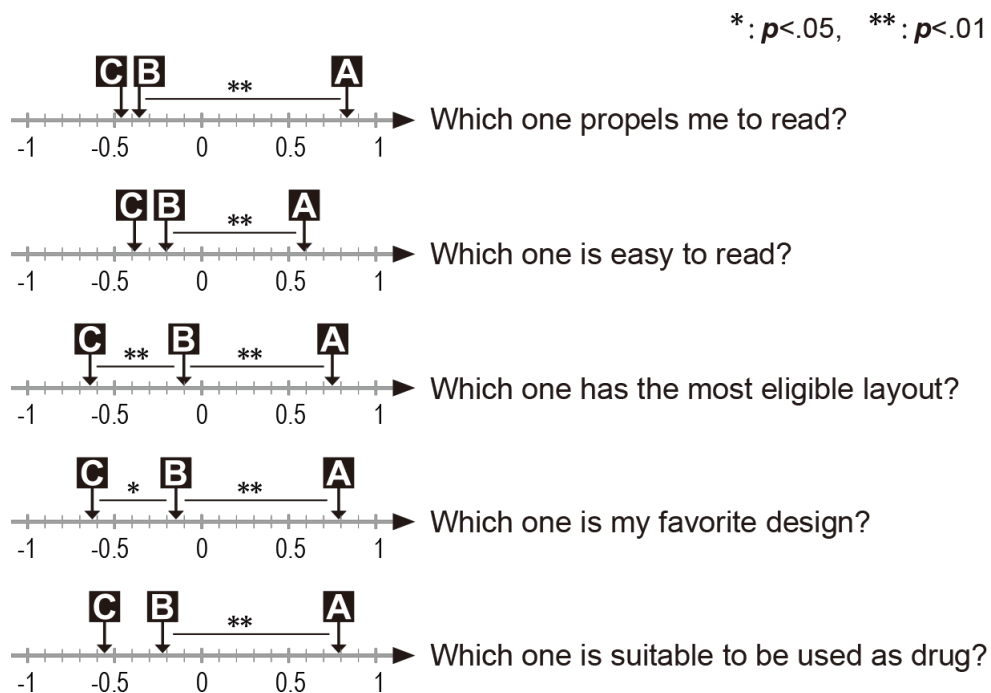


Figure 3-3. Results of scheffe's method of paired comparisons

3.4. DISCUSSION

In this study, by analyzing and comparing three inserts (A: insert with pictograms, B: insert with greater spacing between paragraphs, C: insert with larger font size), we demonstrated the superiority of pictograms incorporated in package inserts on information acquisition and preference of elderly consumers.

Firstly, by analyzing the results of the recall test, we found that the insertion of pictograms could significantly improve elderly individuals' memory of drug information. For the information about dosage and administration and when to discontinue use: 3 days, although the all three version of the inserts were recorded through pure text (without any pictograms), Group A was significantly superior to Group B and C in memorizing information. In cognitive psychology, people's ability to hold and manipulate limited amounts of information for a short period of time is called working memory (Baddeley, 1996; Cowan, 2008). Psychology study findings confirm a major role for working memory in the control of visual selective attention (Downing, 2000; de Fockert, Rees, Frith, & Lavie, 2001), and well-designed health materials can effectively minimize extraneous cognitive demands placed on individuals, making working memory resources more available to better process content-related information (Wilson & Wolf, 2009). Based on these theories, the results of our research indicate that the addition of pictograms into the insert reduced the reading and memorizing burden by raising the recognition of information, which allows people to focus more on the key information and memorize useful steps. When it came to answering item when to discontinue use: 2 weeks, all three groups had low correctness rate. There are two possible reasons behind

this result, one is that being recorded behind item when to discontinue use: 3 days, it is not fully read and understood by most people, and the other is that many people may assume that there is only one correct answer to this question.

For the question concerning “age limit”, the answer “older than 80 years old” was picked by nearly 70% of all three groups, but the answer of “younger than 15 years old” was rarely picked. This result may be explained by the fact that “younger than 15 years old” is beyond the age range cared about by most of the elderly. It is reported that a person usually strategically remembered items of high-value information (Castel, Murayama, Friedman, McGillivray, & Link, 2013). In this research, the participants are elderly people, therefore we can infer that the information relevant to elders is the high-value information to them, such as ‘older than 80 years old’. From the result mentioned earlier, it is apparent that those participants preferred to allocate their limited attention to information relevant to themselves.

In addition, for “older than 65 years old”, though being slightly higher than Group B and Group C, just a rate of 40.9% in Group A correctly got the information. The underlying cause for the total answer rate being below 50% may be that most people think that “people older than 65 years old should consult with pharmacists or doctors when using this medicine” did not imply age limitation. Because different from the information of “older than 80 years old” emphasizes itself by a red italic diagonal line, the information of “older than 65 years old” just uses the pictogram without any notice signal, thus the provoked impression is weaker (Stones, Knapp, & Malmgren, 2013). In addition, according to the study of Hashiguchi et al, if the description of "taking elderly people"

is described separately in two places the understanding of them will be hindered (Saito et al., 2007). Therefore, we suggest that putting the relevant information of age limit together, simultaneously using pictogram to clearly show the relation between those information. We consider it is effective to improve the acquisition.

In light of the information search test, we found that the total accurate positioning rate of Group A reached 91.4% which was significantly higher than that of Group B and C. This result proved that the addition of pictograms into the insert is conducive in the information search. It is especially evident in the first question item “allergies”, that Group A’s positioning rate was significantly higher than that of Group B and C. As for the word “allergies”, besides the position “precautions for use: People who can't take it ” recorded in correct answer, it was also recorded in “precautions for use: People who should consult with pharmacists or doctors when using this medicine”. Furthermore, “redness” and “rash” in the question were also recorded in the “side effects” column. This result may largely account for why most of the participants failed to determine the correct position of the information recording, for almost all of those failing participants left marks in these two places. Moreover, although no significant difference appeared in the accurate positioning rate of other raised items, Group A could still have displayed the inclination of having a higher accurate positioning rate than Group C in many items, such as dealing with overdose and dealing with deterioration of constipation symptoms. These results consistent with previous research that the addition of pictograms into the insert is conducive in the information search (Bernardini, Ambrogi, Periole, Tiralti,& Fardella, 2000).

Nevertheless, no prominent strengths were found from the addition of pictograms into insets in term of information search time, which was below our expectation. Two possible reasons for this are as follows: firstly, the pictograms we used were newly developed instead of being familiar to the general public; and secondly, the recognition and understanding of the pictograms remained low, and some of them failed to meet criteria in the understanding test (Kurata et al., 2017). Therefore, in order to further increase the effectiveness of the pictograms, it is important to develop highly recognizable and understandable pictograms.

Through Scheffe's method of paired comparisons, we found that the inserts with pictograms were significantly more effective than only text insets in the evaluations. This result shows that the insertion of pictograms makes it easier for consumers to read information and is likely to promote reading. In addition, through the evaluation of “layout” and “favorite”, the use of wider paragraph spacing and parting lines to separate the items in the design of the insert significantly improves preference. However, it is worthwhile to mention that the font size maybe need to reach a certain size, for example, greater than 10 point size.

4. Conclusions

4.1 Summary

In this research, the experimental psychological method has been used to investigate the effects of pictograms incorporated in package inserts on patients' information acquisition and preferences. One series of experiments was designed and performed with two groups of participants: a group of young people and a group of elderly.

For the survey of the young patients, three versions of the package insert were designed: A, which used text only; B, which used comprehensible pictograms in the "precautions for use" section; and C, which used incomprehensible pictograms in the "precautions for use" section. Using three versions of the same package insert helped to test the effects of not only the inserted pictograms but also the quality of the pictograms itself. The effects of all three versions of the package insert on patients' information acquisition were evaluated comparatively and quantitatively with an eye-tracking survey and comprehension test. The results of the eye-tracking survey indicated that use of comprehensible pictograms could draw attention to important information that could otherwise be easily overlooked in the "precautions for use" section. The results of the comprehension test also showed that including comprehensible pictograms improved the comprehension of information that was important for patients. Prior research has put forward that most Japanese young people ignore the "precautions for use" section (Kawase, Choi, Izumisawa, Hibino, & Koyama, 2016). This study found, however, that the package inserts with comprehensible pictograms helped the young patients to

comprehend useful information effectively. Furthermore, the subjective evaluation indicated that compared to the package inserts with text only, the young patients preferred the package inserts that contained pictograms.

In the survey of the elderly participants, three versions of the package insert were also used: A, which used pictograms; B, which had wider spacing between paragraphs; and C, which had a larger font size. The versions were created by unifying A4 paper sizes. The effects of the pictograms on the elderly patients' information acquisition were tested with an information recall test and an information search test. The tests revealed that the performance of patients' information recall and information search was significantly higher for the package insert A group than for the package insert B and C groups. In addition, the subjective evaluation indicated that most of the elderly participants felt that the 10-point font size, which was the smallest front used in this test, was just right. The subjective evaluation also indicated that the elderly patients preferred package inserts with pictograms. Many studies have also found that font size plays an important role in drug information acquisition among the elderly (Wogalter & Vigilante, 2003; Murty & Sansgiry, 2007; Sato et al., 2010). Therefore, as long as the font in the pictograms is of a certain size, namely above 10 point, pictograms could also improve elderly patients' performance of information acquisition.

Few people take the time and effort to read package inserts carefully. Even so, people prefer the documentation to be detailed. Package inserts thus have to balance completeness of contents and clarity of information. The two studies performed in the present research found that combining written information with pictograms raised

patients' interest in reading the information, increased recall of the important information, and improved patients' ability to locate information.

Wilson and Wolf (2009) concluded that well-designed health materials can effectively minimize the extraneous cognitive demands placed on individuals, making working memory resources more available to better process content-related information. In line with this theory, the results of the present research indicate that the addition of pictograms into the insert reduced the reading and memorizing burden by easing the recognition of information, thereby allowing participants to focus more on the key information and on the memorization of useful steps.

To synthesize the above analysis, this research concludes that using comprehensible pictograms in package inserts may be the most promising option to reduce cognitive load. The use of pictograms can help to improve the usability of drug leaflets by drawing patients' attention to important topics. In other words, the use of pictograms may benefit patients' information acquisition by decreasing the cognitive demands of reading.

4.2 Challenges for the future

The benefits of OTC medicines include convenience to consumers/patients, better self-management of minor problems, and a reduction in governmental medical costs (Aoyama I, Koyama S, & Haruo H, 2012). Thus, In recent years, the government has been promoting self-medication (Prime Minister of Japan and His Cabinet, 2013), and it has also implemented a series of more feasible policies for OTC drug distribution

(Ministry of Health, Labor and Welfare, 2009; Ministry of Health, Labor and Welfare, 2014; Prime Minister of Japan and His Cabinet, 2016).

Under such circumstances, Ensuring safely and effectively to use of medicines by all patients/customer has become an important issue. this research proved the performance of pictograms on patients' information acquisition by the experimental psychological method.

On the basis of this research, to further improve consumers' information acquisition from pictograms in the package inserts of OTC drugs, we must develop high-quality pictograms that are even easier to identify and understand. In addition, to promote their use, pictograms should be unified and standardized in the future as well.

In this study only considered adding pictograms to the "precautions for use" section. However, other existing researches have created seven kinds of pictograms regarding pharmacological effect, and the necessity for pictograms regarding pharmacological effects has been proven (Imanishi, Takamatsu, & Takayama, 2017). Therefore, pictograms for the other sections also need to be considered.

In addition, one study found that patients who feel frightened and anxious after reading through the package insert may be less willing to continue with therapy and may even stop their treatment (Koo, Krass, & Aslan, 2003). Hence, a balanced assessment of risks and benefits must be presented as well.

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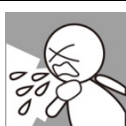


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Appendix 1

		わかりやすい ピクトグラム	わかりにくい ピクトグラム
1	高齢者（80歳以上）		
		一般利用者：92.5% 学生：96.5%	一般利用者：68.0% 学生：95.3%
2	小児（15歳未満）		
		一般利用者：98.0% 学生：84.7%	学生：27.9%
3	高齢者（65歳以上）		
		一般利用者：90.6% 学生：91.7%	一般利用者：68.5% 学生：65.4%
4	妊婦又は妊娠していると思われる人		
		一般利用者：96.2 % 学生：100%	一般利用者：8.0% 学生：67.0%
5	持続性の腹痛の症状		
		一般利用者：80.0% 学生：76.5%	学生：69.5%
6	授乳中の人		
		一般利用者：67.9% 学生：58.3%	一般利用者：35.8% 学生：91.5%
7	アレルギー		
		一般利用者：69.8% 学生：81.6%	学生：17.0%

8	他の胃腸薬		
		一般利用者：41.5% 学生：56.9%	学生：27.1%
9	原因不明の体重減少		
		一般利用者：26.0% 学生：26.4%	学生：15.1%
10	治療中，医薬品を投与中		
		一般利用者：28.0% 学生：16.7%	学生：3.4%
11	血液異常		
		新作，一対比較検証	一般利用者：0% 学生：24.4%
12	のどの痛み，咳		
		新作，一対比較検証	薬局：38.0% 学生：17.0%
13	高熱		
		新作，一対比較検証	新作，一対比較検証

**：2013年5月改訂
*：2012年10月改訂

第1類医薬品

日本薬局方 一般用
フアモチジン錠
ガスター10
H2プロトンポンプ阻害薬

使用前にこの説明文書を必ずお読み下さい。
また、必要な時に読めるよう大切に保管して下さい。

- ・3日間服用しても症状の改善がみられない場合は、服用を止めて、この文書を持って医師又は薬剤師に相談して下さい。
- ・2週間を超えて続けて服用しないで下さい。
(重篤な消化器疾患を見過ごすおそれがありますので、医師の診療を受けて下さい)

ガスター10の特徴

「ガスター10」は、胃の症状の原因となる胃酸の過剰な分泌をコントロールし、胃粘膜の修復を早める薬で、胃酸中和型の胃腸薬とは異なるタイプの胃腸薬です。

使用上の注意

- してはいけないこと** (守らないと現在の症状が悪化したり、副作用が起こりやすくなります)
1. 次の人は服用しないで下さい。

- (1) フアモチジン等のH2プロトンポンプ阻害薬によりアレルギー症状(例えば、発疹・発赤、かゆみ、のどまがた・口唇等のはれ)を起こしたことがある人
- (2) 医療機関で次の病気の治療や医薬品の投与を受けている人
血液の病気、腎臓・肝臓の病気、心臓の病気、胃・十二指腸の病気、ぜんそく・リウマチ等の免疫系の病気、ステロイド剤、抗生物質、抗がん剤、アゾール系抗真菌剤(白球減少、血小板減少等を起こすことがあります)
(腎臓・肝臓の病気を持っている場合には、薬の排泄が遅れて作用が強くなる場合があります)
(心筋梗塞・弁膜症・心筋症等の心臓の病気を持っている場合には、心電図異常を伴う脈のみだれがあらわれることがあります)
(胃・十二指腸の病気の治療を受けている人は、フアモチジンや類似の薬が処方されている可能性が高いので、重複服用に気を付ける必要があります)
(アゾール系抗真菌剤の吸収が低下して効果が減弱します)
- (3) 医師から赤血球数が少ない(貧血)、血小板数が少ない(血が止まりにくい)、血が出やすい、白血球数が少ない等の血液異常を指摘されたことがある人
(本剤が引き金となって再び血液異常を引き起こす可能性があります)
- (4) 小児(15歳未満)及び高齢者(80歳以上)
- (5) 妊婦又は妊娠していると思われる人

2. 本剤を服用している間は、次の医薬品を服用しないで下さい。
他の胃腸薬
3. 授乳中の人は本剤を服用しないか、本剤を服用する場合は授乳を避けて下さい。

相談すること

1. 次の人は服用前に医師又は薬剤師に相談して下さい。

- (1) 医師の治療を受けている人又は他の医薬品を服用している人
- (2) 薬などによりアレルギー症状を起こしたことがある人
- (3) 高齢者(65歳以上)
(一般に高齢者は、生理機能が低下していることがあります)

(4) 次の症状のある人

のどの痛み、咳及び高熱(これらの症状のある人は、重篤な感染症の疑いがあり、血球数減少等の血液異常が認められることがあります。服用前にこのような症状があるとき、本剤の服用によって症状が増悪し、また、本剤の副作用に気づくのが遅れることがあります)、原因不明の体重減少、持続性の腹痛(他の病気が原因であることがあります)

2. 服用後、次の症状があらわれた場合は副作用の可能性があるので、直ちに服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。

関係部位	症 状
皮膚	発疹・発赤、かゆみ、はれ
循環器	脈のみだれ
精神神経系	気がどくなる感じ、ひきつけ(けいれん)
その他	気がが悪くなったり、だるくなったり、発熱してのどが痛いなど体調異常があらわれる。

まれに下記の重篤な症状が起こることがあります。その場合は直ちに医師の診療を受けて下さい。

症状の名称	症 状
シヨック (アナフィラキシー) 皮膚粘膜眼症候群 (スティーブンス・ジョンソン症候群、 中毒性表皮壊死剥離症)	高熱、目の充血、目やに、唇のただれ、のどの痛み、皮膚の広範囲の発疹・発赤等が持続したり、急激に悪化する。 手足・肩・腰等の筋肉が痛み、手足がしびれる。力が入らない、こわばる。全身がだるい、赤褐色尿等があらわれる。
横紋筋融解症	手足・肩・腰等の筋肉が痛み、手足がしびれる。力が入らない、こわばる。全身がだるい、赤褐色尿等があらわれる。
肝機能障害	発熱、かゆみ、発疹、黄疸(皮膚や白目が黄色くなる)、褐色尿、全身のだるさ、食欲不振等があらわれる。
腎障害	発熱、発疹、尿量の減少、全身のむくみ、全身のだるさ、関節痛(節々が痛み)、下痢等があらわれる。
間質性肺炎*	階段を上ったり、少し無理をしたらすると息切れがする、息苦しくなる、空せき、発熱等がみられ、これらが急にあらわれたり、持続したりする。
血液障害	のどの痛み、発熱、全身のだるさ、顔やまがたのうらが白っぽくなる、出血しやすくなる(歯茎の出血、鼻血等)、胃あざができる(押ししても色が消えない)等があらわれる。

3. 誤って定められた用量を超えて服用してしまった場合は、直ちに服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。
4. 服用後、次の症状があらわれることがありますので、このような症状の持続又は増強がみられた場合には、服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。
便秘、軟便、下痢、口のかわき

**：2013年5月改訂
*：2012年10月改訂

第1類医薬品

日本薬局方 フアモチジン錠
一般用 **ガスター10**
H2ロツカー胃腸薬

使用前にこの説明文書を必ずお読み下さい。
また、必要な時に読めるよう大切に保管して下さい。

- ・3日服用しても症状の改善がみられない場合は、服用を止めて、この文書を持って医師又は薬剤師に相談して下さい。
- ・2週間を超えて続けて服用しないで下さい。
(重篤な消化器疾患を見逃さずおそれがありますので、医師の診察を受けて下さい)

ガスター10の特徴


「ガスター10」は、胃の症状の原因となる胃酸の過剰な分泌をコントロールし、胃粘膜の修復を早める薬で、胃酸中和型の胃腸薬とは異なるタイプの胃腸薬です。

⚠️ 使用上の注意


❌ **してはいけないこと** (守らないと現在の症状が悪化したり、副作用が起こりやすくなります)

1. 次の人は服用しないで下さい。

 フアモチジン等のH2ロツカー薬によりアレルギー一症状(例えば、発疹・発赤、かゆみ、のどまがた・口唇等のはれ)を起こしたことがある人

 医療機関で次の病気の治療や医薬品の投与を受けている人
血液の病気、腎臓・肝臓の病気、心臓の病気、胃・十二指腸の病気、ぜんそく・うつろアチ等の免疫系の病気、ステロイド剤、抗生物質、抗がん剤、アブソール系抗真菌剤
(白血球減少、血小板減少等を起こすことがあります)
(腎臓、肝臓の病気を持っている場合には、薬の排泄が遅れて作用が強くなる場合があります)

(心筋梗塞、弁膜症、心筋症等の心臓の病気を持っている場合には、心電図異常を伴う脈の乱れがあらわれることがあります)
(胃・十二指腸の病気の治療を受けている人は、フアモチジンや類似の薬が処方されている可能性が高いため、重複服用に気をつける必要があります)
(アブソール系抗真菌剤の吸収が低下して効果が減弱します)

 医師から赤血球数が少ない(貧血)、血小板数が少ない(血が止まりにくい)、血が出やすい(白血球数が少ない等の血液異常を指摘されたことがある人
(本剤が引き金となって再び血液異常を引き起こす可能性があります))

 **14**  **80**
小児(15歳未満)及び高齢者(80歳以上)

 妊婦又は妊娠していると思われる人

2. 本剤を服用している間は、次の医薬品を服用しないで下さい。

 他の胃腸薬

3. 授乳中の人は本剤を服用しないか、本剤を服用する場合は授乳を避けて下さい。

 授乳


🗨️ 相談すること

1. 次の人は服用前に医師又は薬剤師に相談して下さい。

医師の治療を受けている人又は他の医薬品を服用している人

薬などによりアレルギー一症状を起こしたことがある人

 **65**
高齢者(65歳以上)
(一般に高齢者は、生理機能が低下していることがあります)

 **非**
のどの痛み、咳及び高熱の症状のある人
(これらの症状のある人は、重篤な感染症の疑いがあり、白血球減少等の血液異常が認められることがあります。服用前にこのような症状があると、本剤の服用によって症状が増悪し、また、本剤の副作用に気づくのが遅れることがあります)
原因不明の体重減少、持続性の腹痛の症状のある人
(他の病気が原因であることがあります)

2. 服用後、次の症状があらわれた場合は副作用の可能性がありますので、直ちに服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。

関係部位	症状
皮膚	発疹・発赤、かゆみ、はれ
循環器	脈のみだれ
精神神経系	気がとおくなる感、ひきつけ(けいれん)
その他	気分が悪くなったり、だるくなったり、発熱してのどが痛いなど 体調異常があらわれる。

まれに下記の重篤な症状が起こることがあります。その場合は直ちに医師の診察を受けて下さい。

症状の名称	症状
ショック (アナフィラキシー)	服用後すぐに、皮膚のかゆみ、じんましん、声のかすれ、くしゃみ、のどのかゆみ、息苦しさ、動悸、意識の混濁等があらわれる。
皮膚粘膜眼症候群 (スティーブンス・ジョンソン症候群、中毒性表皮壊死剥離症)	高熱、目の充血、目やに、唇のただれ、のどの痛み、皮膚の広範囲の発疹・発赤等が持続したり、急激に悪化する。
横紋筋融解症	手足・肩・腰等の筋肉が痛み、手足がしびれる、力が入らない、こわばる、全身がだるい、赤褐色尿等があらわれる。
肝機能障害	発熱、かゆみ、発疹、黄疸(皮膚や白目が黄色くなる)、褐色尿、全身のだるさ、食欲不振等があらわれる。
腎障害	発熱、発疹、尿量の減少、全身のむくみ、全身のだるさ、関節痛(節々が痛む)、下痢等があらわれる。
間質性肺炎*	階段を上ったり、少し無理をしたらすると息切れがする、息苦しくなる、空せき、発熱等がみられ、これらが急にあらわれたり、持続したりする。
血液障害**	のどの痛み、発熱、全身のだるさ、顔やまがたのうらが白っぽくなる、出血しやすくなる(歯茎の出血、鼻血等)、青あざができる(押ししても色が消えない)等があらわれる。

3. 誤って定められた用量を超えて服用してしまつた場合は、直ちに服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。

4. 服用後、次の症状があらわれることがありますので、このような症状の持続又は増強がみられた場合には、服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。
便秘、軟便、下痢、口のかわき

**：2013年5月改訂
*：2012年10月改訂

第1類医薬品

日本薬局方 フラモチジン錠
一般用 **ガスター10**
H2ロツカー胃腸薬

使用前にこの説明文書を必ずお読み下さい。
また、必要な時に読めるよう大切に保管して下さい。


- ・3日服用しても症状の改善がみられない場合は、服用を止めて、この文書を持って医師又は薬剤師に相談して下さい。
- ・2週間を超えて続けて服用しないで下さい。
(重篤な消化器疾患を見逃さずおそれがありますので、医師の診察を受けて下さい)


ガスター10の特徴


「ガスター10」は、胃の症状の原因となる胃酸の過剰な分泌をコントロールし、胃粘膜の修復を早める薬で、胃酸中和型の胃腸薬とは異なるタイプの胃腸薬です。

⚠ 使用上の注意

- ❌ **してはいけないこと** (守らないと現在の症状が悪化したり、副作用が起こりやすくなります)
1. 次の人は服用しないで下さい。

 フラモチジン等のH2ロツカー薬によりアレルギー一症状(例えば、発疹・発赤、かゆみ、のどまがた・口唇等のはれ)を起こしたことがある人

 医療機関で次の病気の治療や医薬品の投与を受けている人
血液の病気、腎臓・肝臓の病気、心臓の病気、胃・十二指腸の病気、ぜんそく・うつゑ等の免疫系の病気、ステロイド剤、抗生物質、抗がん剤、アンプル系抗真菌剤(白血球減少、血小板減少等を起こすことがあります)
(腎臓・肝臓の病気を持っている場合には、薬の排泄が遅れて作用が強くなる場合があります)

 心筋梗塞、弁膜症、心筋症等の心臓の病気を持っている場合には、心電図異常を伴う脈のみだれがあらわれることがあります
(胃・十二指腸の病気の治療を受けている人は、フラモチジンや類似の薬が処方されている可能性が高いため、重複服用に気をつける必要があります)
(アンプル系抗真菌剤の吸収が低下して効果が減弱します)

 医師から赤血球数が少ない(貧血)、血小板数が少ない(血が止まりにくい、血が出やすい)、白血球数が少ない等の血液異常を指摘されたことがある人
(本剤が引き金となって再び血液異常を引き起こす可能性があります)

 **-15 80+** 小児(15歳未満)及び高齢者(80歳以上)
妊婦又は妊娠していると思われる人

 2. 本剤を服用している間は、次の医薬品を服用しないで下さい。



3. 授乳中の人は本剤を服用しないか、本剤を服用する場合は授乳を避けて下さい。




🗨️ 相談すること


1. 次の人は服用前に医師又は薬剤師に相談して下さい。

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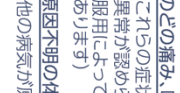
 薬などによりアレルギー一症状を起こしたことがある人

 **65+** 高齢者(65歳以上)
(一般に高齢者は、生理機能が低下していることがあります)

 **65+** 高齢者(65歳以上)
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のどの痛み、咳及び高熱の症状のある人
これらの症状のある人は、重篤な感染症の疑いがあり、白血球減少等の血液異常が認められることがあります。服用前にこのような症状があると、本剤の服用によって症状が増悪し、また、本剤の副作用に気づくのが遅れることがあります)

 原因不明の体重減少、持続性の腹痛の症状のある人
(他の病気が原因であることがあります)

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皮膚粘膜眼症候群 (スティーブンス・ジョンソン症候群、中毒性表皮壊死剥離症)	高熱、目の充血、目やに、唇のただれ、のどの痛み、皮膚の広範囲の発疹・発赤等が持続したり、急激に悪化する。
横紋筋融解症	手足・肩・腰等の筋肉が痛み、手足がしびれる、力が入らない、こわばる、全身がだるい、赤褐色尿等があらわれる。
肝機能障害	発熱、かゆみ、発疹、黄疸(皮膚や白目が黄色くなる)、褐色尿、全身のだるさ、食欲不振等があらわれる。
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間質性肺炎	階段を上ったり、少し無理をしたらすると息切れがする、息苦しくなる、空せき、発熱等がみられ、これらが急にあらわれたり、持続したりする。
血液障害	のどの痛み、発熱、全身のだるさ、顔やまがたのうらが白っぽくなる、出血しやすくなる(歯茎の出血、鼻血等)、青あざができる(押ししても色が消えない)等があらわれる。


3. 誤って定められた用量を超えて服用してしまった場合は、直ちに服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。

4. 服用後、次の症状があらわれることがありますので、このような症状の持続又は増強がみられた場合には、服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。
便秘、軟便、下痢、口のかわき


OTC医薬品添付文書のデザインに関する調査. 朴

ア. 添付文書の内容について


先ほどのアイカメラ実験で見た添付文書の内容についてうかがいます。正しいと思うものを1つ選んでください。

* 1. この薬の用法・用量は？ 

- 1回1錠；1日2回まで
- 1回1錠；1日3回まで
- 1回2錠；1日2回まで
- 1回2錠；1日3回まで

* 2. 以下の選択肢には、服用してはいけない3人と服用前に医師又は薬剤師に相談が必要な1人が含まれています。服用前に医師又は薬剤師に相談が必要な1人を以下の選択肢から選んで下さい。 

- 15歳未満の小児
- 65歳以上の高齢者
- 出産予定日12週以内の妊婦
- 授乳中の人

* 3. 添付文書によると、特定の症状がある人はこの薬を服用前に医師又は薬剤師に相談する必要があります。その症状は以下のどれですか？ 

- 吐き気・嘔吐、痔出血、出血傾向、排尿困難
- 便秘、軟便、口のかわき、吐きけ等の症状を伴う下痢
- のどの痛み、咳及び高熱、原因不明の体重減少、持続性の腹痛
- 口内のひといたたれ、胃痛、胸やけ、もたれ、むかつき

* 4. この薬を a 期間服用しても症状の改善が見られない場合は、服用を止めて、医師又は薬剤師に相談する必要があります。aに当てはまる期間を以下のドロップダウンから選んで下さい。
* 5. この薬を b 期間を超えて続けて服用してはいけません。bに当てはまる期間を以下のドロップダウンから選んで下さい。

OTC医薬品添付文書のデザインに関する調査.朴

イ. アイカメラ実験について

先ほどのアイカメラ実験の感想をうかがいます。

* 6. 先ほど2分間添付文書をご覧になりましたが、必要な情報を読むのに2分間という時間はどう感じましたか？ 

- 足りなかった
- ちょうどよかった
- 長かった

OTC医薬品添付文書のデザインに関する調査.朴

7. あなた自身について

あなた自身についてうかがいます。

* 7. 以下の使用上の注意の項目について自分にどの程度重要であると感じるかをお教えてください。 

	重要ではない	あまり重要ではない	どちらでもない	重要である	とても重要である
アレルギーの既往歴に関する注意情報	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
基礎疾患に関する注意情報 (持病を持っている人の服用に関する注意)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
併用薬に関する注意 (他の薬との飲み合わせに関する注意)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
小児への注意事項	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
高齢者への注意事項	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
妊婦・授乳婦への注意事項	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
特定の症状・状態のある人に関する注意 (高熱、けいれん、腹痛など)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
乱用に関する注意 (過量服用・長期連用しないこと)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
食品との相互作用に関する注意	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
副作用に関する注意	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
保管及び取扱い上の注意	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 8. あなたは今までに、おくすりの副作用を経験したことがありますか？



- はい
- いいえ

「はい」の方は差し支えない範囲で具体的に原因をお教えてください。

* 9. あなたはアレルギーをお持ちですか？



- はい
- いいえ

「はい」の方は差し支えない範囲で具体的に原因をお教えてください。

* 10. あなたは持病をお持ちですか？



- はい
- いいえ

「はい」の方は差し支えない範囲で具体的にお教えてください。

OTC医薬品添付文書のデザインに関する調査.朴


え. OTC医薬品の使用について

普段のOTC医薬品の使用状況についてうかがいます。

OTC医薬品とは、医師による処方箋を必要とせずに、薬局・ドラッグストアなどの販売所で消費者自らが購入できる医薬品のことです。

下記のものはOTC医薬品の例です。

かぜ薬・解熱鎮痛薬・胃腸薬・便秘薬・ビタミン剤・乗り物酔い薬・虫さされ薬・水虫薬・目薬・しっぶ薬・毛髪用剤・漢方薬など

* 11. 薬局・薬店、ドラッグストア、通信販売などでOTC医薬品をどのくらいの頻度で購入していますか？あてはまるものをお選びください。 

- 週に1回以上
- 月に1回以上
- 2・3ヶ月に1回以上
- 半年に1回以上
- 年に1回以上
- 年に1回未満
- 購入したことがない

OTC医薬品添付文書のデザインに関する調査.朴

7. あなた自身について

あなた自身についてうかがいます。

* 12. あなたの性別をお教えてください。



- 男性
- 女性

* 13. あなたの年齢をお答えください。（半角数字で）



年齢

**：2013年5月改訂
*：2012年10月改訂

使用前にこの説明文書を必ずお読み下さい。
また、必要な時に読めるよう大切に保管して下さい。

第1類医薬品

日本薬局方 フラモチジン錠
一般用 **ガスター10**
H2プロトンポンプ阻害薬

- ・3日間服用しても症状の改善がみられない場合は、服用を止めて、この文書を持って医師又は薬剤師に相談して下さい。
- ・2週間を超えて続けて服用しないで下さい。
(重篤な消化器疾患を見過ごすおそれがありますので、医師の診察を受けて下さい)

ガスター10の特徴

「ガスター10」は、胃の症状の原因となる胃酸の過剰分泌をコントロールし、胃粘膜の修復を早める薬で、胃酸中和型の胃腸薬とは異なるタイプの胃腸薬です。

⚠ 使用上の注意

- ❌ **してはいけないこと** (守らないと現在の症状が悪化したり、副作用が起こりやすくなります)
1. 次の人は服用しないで下さい。

- (1) フラモチジン等のH2プロトンポンプ阻害薬によりアレルギー症状(例えば、発疹・発赤、かゆみ、のどまがた・口唇等のはれ)を起こしたことがある人
- (2) 医療機関で次の病気の治療や医薬品の投与を受けている人
血液の病気、腎臓・肝臓の病気、心臓の病気、胃・十二指腸の病気、ぜんそく・リウマチ等の免疫系の病気、ステロイド剤、抗生物質、抗がん剤、アレルギー系抗真菌剤(白血球減少、血小板減少等を起こすことがあります)
(腎臓、肝臓の病気を持っている場合には、薬の排泄が遅れて作用が強くなる場合があります)
(心筋梗塞、弁膜症、心筋症等の心臓の病気を持っている場合には、心電図異常を伴う脈のみだれがあらわれることがあります)
(胃・十二指腸の病気の治療を受けている人は、フラモチジンや類似の薬が処方されている可能性が高いので、重複服用に気をつける必要があります)
(アレルギー系抗真菌剤の吸収が低下して効果が減弱します)
- (3) 医師から赤血球数が少ない(貧血)、血小板数が少ない(血が止まりにくい、血が出やすい)、白血球数が少ない等の血液異常を指摘されたことがある人
(本剤が引き金となって再び血液異常を引き起こす可能性があります)
- (4) 小児(15歳未満)及び高齢者(80歳以上)
- (5) 妊婦又は妊娠していると思われる人

2. 本剤を服用している間は、次の医薬品を服用しないで下さい。
他の胃腸薬

3. 授乳中の人は本剤を服用しないか、本剤を服用する場合は授乳を避けて下さい。

Ⓜ 相談すること

1. 次の人は服用前に医師又は薬剤師に相談して下さい。

- (1) 医師の治療を受けている人又は他の医薬品を服用している人
- (2) 薬などによりアレルギー症状を起こしたことがある人
- (3) 高齢者(65歳以上)
(一般に高齢者は、生理機能が低下することがあります)

(4) 次の症状のある人
のどの痛み、咳及び高熱(これらの症状のある人は、重篤な感染症の疑いがあり、血球数減少等の血液異常が認められることがあります。服用前にこのような症状があるとき、本剤の服用によって症状が増悪し、また、本剤の副作用に気づくのが遅れることがあります)、原因不明の体重減少、持続性の腹痛(他の病気が原因であることがあります)

2. 服用後、次の症状があらわれた場合は副作用の可能性があるので、直ちに服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。

関係部位	症 状
皮膚	発疹・発赤、かゆみ、はれ
循環器	脈のみだれ
精神神経系	気分が悪くなる感じ、ひきつけ(けいれん)
その他	気分が悪くなったり、だるくなったり、発熱してのどが痛いなど体調異常があらわれる。

またに下記の重篤な症状が起こることがあります。その場合は直ちに医師の診察を受けて下さい。

症状の名称	症 状
ショック (フラマシオンキープ)	服用後すぐに、皮膚のかゆみ、じんましん、声のかすれ、くしゃみ、のどのかゆみ、唇舌しびれ、動悸、意識の混濁等があらわれる。
皮膚粘膜眼症候群 (スティーブンス・ジョンソン症候群)、 中毒性表皮剥離症候群	高熱、目の充血、目やに、唇のただれ、のどの痛み、皮膚の広範囲の発疹・発赤等が持続したり、急激に悪化する。
横紋筋融解症	手足・肩・腰等の筋肉が痛む、手足がしびれる、力が入らない、こわばる、全身がだるい、赤褐色尿等があらわれる。
肝機能障害	発熱、かゆみ、発疹、黄疸(皮膚や白目が黄色くなる)、褐色尿、全身のだるさ、食欲不振等があらわれる。
腎障害	発熱、発疹、尿量の減少、全身のむくみ、全身のだるさ、関節痛(節々が痛む)、下痢等があらわれる。
** 間質性肺炎	階段を上ったり、少し無理をしたらすると息切れがする・息苦しくなる・せき、発熱等がみられ、これらが急にあらわれたり、持続したりする。
* 血液障害	のどの痛み、発熱、全身のだるさ、顔やまがたのうらが白っぽくなる、出血しやすい(歯茎の出血、鼻血等)、青あざができる(押しても色が消えない)等があらわれる。

3. 誤って定められた用量を超えて服用してしまった場合は、直ちに服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。

4. 服用後、次の症状があらわれることがありますので、このような症状の持続又は増強がみられた場合には、服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。
便秘、軟便、下痢、口のかゆき

③

②

①

⑥

④

⑤

Appendix 5

← 表示されている情報を読もうと思うのは →

非常にこちら	こちら	ややこちら	同程度	ややこちら	こちら	非常にこちら

← 表示されている情報が読みやすいのは →

非常にこちら	こちら	ややこちら	同程度	ややこちら	こちら	非常にこちら

← 添付文書のレイアウトが見やすいのは →

非常にこちら	こちら	ややこちら	同程度	ややこちら	こちら	非常にこちら

← 好ましいデザインであるのは →

非常にこちら	こちら	ややこちら	同程度	ややこちら	こちら	非常にこちら

← 医薬品の添付文書として適切であるのは →

非常にこちら	こちら	ややこちら	同程度	ややこちら	こちら	非常にこちら

使用前にこの説明文書を必ずお読み下さい。また、必要な時に読めるよう大切に保管して下さい。

第1類医薬品

日本薬局方 フアモチジン錠

一般用

H₂ブロッカー胃腸薬

ガスター10

- ・3日間服用しても症状の改善がみられない場合は、服用を止めて、この文書を持って医師又は薬剤師にご相談ください。
- ・2週間を超えて続けて服用しないでください。（重篤な消化器疾患を見通すおそれがありますので、医師の診療を受けてください。）

ガスター10の特徴

「ガスター10」は、胃の不快感の原因となる胃酸の過剰分泌をコントロールし、胃粘膜の修復を早める薬で、胃酸中和型の胃腸薬とは異なるタイプの胃腸薬です。

⚠️ 使用上の注意

- ❌ **してはいけないこと**（守らないと現在の症状が悪化したり、副作用が起こりやすくなります）
- ❌ **次の人は服用しないで下さい。**



フアモチジン等のH₂ブロッカー薬によりアレルギー症状（例えば、発赤・発赤、かゆみ、のど・まぶた・口唇等のはれ）を起こしたことがある人



医療機関で次の病気の治療や医薬品の投与を受けている人

- ① 血液の病気、（白血球減少、血小板減少等を起こすことがあります）
- ② 腎臓・肝臓の病気、（腎臓・肝臓の病気を持っている場合には、薬の排泄が遅れて作用が強くなる場合があります）
- ③ 心臓の病気、（心筋梗塞・弁膜症・心筋症等の心臓の病気を持っている場合）
- ④ 胃・十二指腸の病気、（心電図異常を伴う脈のみだれがあらわれることがあります）
- ⑤ ぜんそく・リウマチ等の免疫系の病気、（胃・十二指腸の病気の治療を受けている人は、フアモチジンや類似の薬が処方されている可能性があります）
- ⑥ ステロイド剤、
- ⑦ 抗生物質、
- ⑧ 抗がん剤、
- ⑨ プラズマ系抗真菌剤（プラズマ系抗真菌剤の吸収が低下して効果が減弱します）



医師から赤血球数が少ない（貧血）、血小板数が少ない（血が止まりにくい）、血が出やすい）、白血球数が少ない等の血液異常を指摘されたことがある人（本剤が引き金となって再び血液異常を引き起こす可能性があります）



● 小児（15歳未満）及び高齢者（80歳以上）
● 妊婦又は妊娠していると思われる人
● 授乳中の人（授乳中の人には本剤を服用しないで、本剤を服用する場合は授乳を避けて下さい）



他の胃腸薬

- ❌ **本剤を服用している間は、次の医薬品を服用しないで下さい。**

相談すること

- ❶ **次の人は服用前に医師又は薬剤師に相談して下さい。**



医師の治療を受けている人又は他の医薬品を服用している人

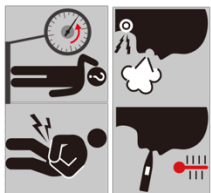


薬などによりアレルギー症状を起こしたことがある人



高齢者（65歳以上）

（一般に高齢者は、生理機能が低下していることがあります）



のどの痛み、咳及び高熱の症状のある人

（これらの症状のある人は、重篤な感染症の疑いがあり、血球数減少等の血液異常が認められることがあります。服用前にこのような症状があると、本剤の服用によって症状が増悪し、また、本剤の副作用に気づくのが遅れることがあります）、原因不明の体重減少、持続性の腹痛の症状のある人（他の病気が原因であることがあります）

- ❷ **服用後、次の症状があらわれた場合は副作用の可能性がありますので、直ちに服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。**

関係部位	症状
皮膚	発疹・発赤、かゆみ、はれ
循環器	脈のみだれ
精神神経系	気がおどくなる感じ、ひきつけ（けいれん）
その他	気分が悪くなったり、だるくなったり、発熱してのどが痛いなど体調異常があらわれる

まれに次の重篤な症状が起こることがあります。その場合は直ちに医師の診療を受けて下さい。

症状の名称	症状
シヨック（アナフィラキシー）	服用後すぐに、皮膚のかゆみ、じんましん、声のかすれ、くしゃみ、のどのかゆみ、息苦しさ、動悸、意識の混濁等があらわれる。
皮膚粘膜眼症候群（スティーブンス・ジョンソン症候群） 中毒性表皮壊死融解症	高熱、目の充血、目やに、唇のただれ、のどの痛み、皮膚の広範囲の発疹・発赤等が持続したり、急激に悪化する。
横紋筋融解症	手足・肩・腰等の筋肉が痛む、手足がしびれる、力が入らない、こわばる、全身がだるい、赤褐色尿等があらわれる。
肝機能障害	発熱、かゆみ、発疹、黄疸（皮膚や白目が黄色くなる）、褐色尿、全身のだるさ、食欲不振等があらわれる。
腎障害	発熱、発疹、尿量の減少、全身のむくみ、全身のだるさ、関節痛（節々が痛む）、下痢等があらわれる。
間質性肺炎	階段を上ったり、少し無理をしたりすると息切れがする・息苦しくなる、空せき、発熱等がみられ、これらが急にあらわれたり、持続したりする。
血液障害	のどの痛み、発熱、全身のだるさ、顔やまぶたのうらが白っぽくなる、出血しやすくなる（歯茎の出血、鼻血等）、青あざができる（押ししても色が消えない）等があらわれる。

使用前にこの説明文書を必ずお読み下さい。また、必要な時に読めるよう大切に保管して下さい。

第1類医薬品

日本薬局方 一般用
H₂プロトンポンプ阻害薬

ガスター10

- ・3日間服用しても症状の改善がみられない場合は、服用を止めて、この文書を持って医師又は薬剤師にご相談ください。
- ・2週間を超えて続けて服用しないでください。（重篤な消化器疾患を見逃すおそれがありますので、医師の診療を受けてください。）

ガスター10の特徴

「ガスター10」は、胃の不快感の原因となる胃酸の過剰分泌をコントロールし、胃粘膜の修復を早める薬で、胃酸中和型の胃腸薬とは異なるタイプの胃腸薬です。

⚠️ 使用上の注意

❌ してはいけないこと（守らないと現在の症状が悪化したり、副作用が起こりやすくなります）

1 次の人は服用しないで下さい。

- (1) フラモキシドン等のH₂プロトンポンプ阻害薬によりアレルギー症状（例えば、発疹・発赤、かゆみ、のど・まぶた・口唇等のはれ）を起こしたことがある人
- (2) 医療機関で次の病気の治療や医薬品の投与を受けている人

- ① 血液の病気、
（白血球減少、血小板減少等を起こすことがあります）
- ② 腎臓・肝臓の病気、
（腎臓・肝臓の病気を持っている場合には、薬の排泄が遅れて作用が強くなる場合があります）
- ③ 心臓の病気、
（心筋梗塞・弁膜症・心筋症等の心臓の病気を持っている場合には、心電図異常を伴う脈のみだれがあらわれることがあります）
- ④ 胃・十二指腸の病気、
- ⑤ せんそく・リウマチ等の免疫系の病気、
（胃・十二指腸の病気を受けている人は、フラモキシドンや類似の薬が処方されている可能性が高いので、重複服用に気を付ける必要があります）
- ⑥ ステロイド剤、
- ⑦ 抗生物質、
- ⑧ 抗がん剤、
- ⑨ プズール系抗真菌剤
（プズール系抗真菌剤の吸収が低下して効果が減弱します）

- (3) 医師から赤血球数が少ない（貧血）、血小板数が少ない（血が止まりにくい、血が出やすい）、白血球数が少ない等の血液異常を指摘されたことがある人
（本剤が引き金となって再び血液異常を引き起こす可能性があります）
- (4) 小児（15歳未満）及び高齢者（80歳以上）
- (5) 妊婦又は妊娠していると思われる人並びに授乳中の人
（授乳中の人は本剤を服用しないか、本剤を服用する場合は授乳を避けて下さい）

2 本剤を服用している間は、次の医薬品を服用しないで下さい。

他の胃腸薬

🗨️ 相談すること

1 次の人は服用前に医師又は薬剤師に相談して下さい。

- (1) 医師の治療を受けている人又は他の医薬品を服用している人
- (2) 薬などによりアレルギー症状を起こしたことがある人
- (3) 高齢者（65歳以上）
（一般に高齢者は、生理機能が低下していることがあります）

(4) 次の症状のある人

これらの症状のある人は、重篤な感染症の疑いがあり、血球数減少等の血液異常が認められることがあります。服用前にこのような症状があると、本剤の服用によって症状が増悪し、また、本剤の副作用に気づくのが遅れることがあります。原因不明の体重減少、持続性の腹痛の症状（他の病気が原因であることがあります）

2 服用後、次の症状があらわれた場合は副作用の可能性があるので、直ちに服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。

関係部位	症状
皮膚	発疹・発赤、かゆみ、はれ
循環器	脈のみだれ
精神神経系	気がおどくなる感じ、ひきつけ（けいれん）
その他	気分が悪くなったり、だるくなったり、発熱してのどが痛いなど 体調異常があらわれる

またに次の重篤な症状が起こることがあります。その場合は直ちに医師の診療を受けて下さい。

症状の名称	症状
シヨック (アナフィラキシー)	服用後すぐに、皮膚のかゆみ、じんましん、声のかすれ、くしゃみ、のどのかゆみ、息苦しさ、動悸、意識の混濁等があらわれる。
皮膚粘膜眼症候群 (ステイヤーランス・ ジョンソン症候群) 中毒性表皮壊死剥離症	高熱、目の充血、目やに、唇のただれ、のどの痛み、皮膚の広範囲の発疹・発赤等が持続したり、急激に悪化する。
横紋筋融解症	手足・肩・腰等の筋肉が痛む、手足がしびれる、力が入らない、こわばる、全身がだるい、赤褐色尿等があらわれる。
肝機能障害	発熱、かゆみ、発疹、黄疸（皮膚や白目が黄色くなる）、褐色尿、全身のだるさ、食欲不振等があらわれる。
腎障害	発熱、発疹、尿量の減少、全身のむくみ、全身のだるさ、関節痛（節々が痛む）、下痢等があらわれる。
間質性肺炎	階段を上ったり、少し無理をしたりすると息切れがする、息苦しくなる、空せき、発熱等がみられ、これらが急にあらわれたり、持続したりする。
血液障害	のどの痛み、発熱、全身のだるさ、顔やまぶたのうらが白っぽくなる、出血しやすくなる（歯茎の出血、鼻血等）、青あざができる（押ししても色が消えない）等があらわれる。

使用前にこの説明文書を必ずお読み下さい。また、必要な時に読めるよう大切に保管して下さい。

第1類医薬品

日本薬局方 フアモチジン錠

一般用

H₂ブロッカー-胃腸薬

ガスター10

- ・3日間服用しても症状の改善がみられない場合は、服用を止めて、この文書を持って医師又は薬剤師にご相談ください。
- ・2週間を超えて続けて服用しないでください。(重篤な消化器疾患を見逃すおそれがありますので、医師の診療を受けてください。)

ガスター10の特徴

「ガスター10」は、胃の不快感の原因となる胃酸の出過ぎをコントロールし、胃粘膜の修復を早める薬で、胃酸中和型の胃腸薬とは異なるタイプの胃腸薬です。

使用上の注意

❌ してはいけないこと 守らないと現在の症状が悪化したり、副作用が起こりやすくなります

1 次の人は服用しないで下さい。

- (1) フアモチジン等のH₂ブロッカー薬によりアレルギー症状(例えば、発疹・発赤、かゆみ、のど・まぶた・口唇等のはれ)を起こしたことがある人
- (2) 医療機関で次の病気の治療や医薬品の投与を受けている人
血液の病気、腎臓・肝臓の病気、心臓の病気、胃・十二指腸の病気、ぜんそく・リウマチ等の免疫系の病気、ステロイド剤、抗生物質、抗がん剤、アゾール系抗真菌剤
(白血球減少、血小板減少等を起こすことがあります)
(腎臓・肝臓の病気を持っている場合には、薬の排泄が遅れて作用が強くなる場合があります)
(心筋梗塞・弁膜症・心筋症等の心臓の病気を持っている場合には、心電図異常を伴う脈のみだれがあらわれることがあります)
(胃・十二指腸の病気の治療を受けている人は、フアモチジンや類似の薬が処方されている可能性が高いので、重複服用に気をつける必要があります)
(アゾール系抗真菌剤の吸収が低下して効果が減弱します)
- (3) 医師から赤血球数が少ない(貧血)、血小板数が少ない(血が止まりにくい、血が出やすい)、白血球数が少ない等の血液異常を指摘されたことがある人
(本剤が引き金となって再び血液異常を引き起こす可能性があります)
- (4) 小児(15歳未満)及び高齢者(80歳以上)
- (5) 妊婦又は妊娠していると思われる人並びに授乳中の人(授乳中の人には本剤を服用しないか、本剤を服用する場合は授乳を避けて下さい)

2 本剤を服用している間は、次の医薬品を服用しないで下さい。
他の胃腸薬

相談すること

1 次の人は服用前に医師又は薬剤師に相談して下さい。

- (1) 医師の治療を受けている人又は他の医薬品を服用している人
- (2) 薬などによりアレルギー症状を起こしたことがある人
- (3) 高齢者(65歳以上)
(一般に高齢者は、生理機能が低下していることがあります)
- (4) 次の症状のある人
のどの痛み、咳及び高熱の症状(これらの症状のある人は、重篤な感染症の疑いがあり、血球数減少等の血液異常が認められることがあります。服用前にこのような症状があると、本剤の服用によって症状が増悪し、また、本剤の副作用に気づくのが遅れることがあります)、原因不明の体重減少、持続性の腹痛の症状(他の病気が原因であることがあります)

2 服用後、次の症状があらわれた場合は副作用の可能性があるので、直ちに服用を中止し、この文書を持って医師又は薬剤師に相談して下さい。

関係部位	症状
皮膚	発疹・発赤、かゆみ、はれ
循環器	脈のみだれ
精神神経系	気がとおくなる感じ、ひきつけ(けいれん)
その他	気分が悪くなったり、だるくなったり、発熱してのどが痛いなど体調異常があらわれる

まれに次の重篤な症状が起こることがあります。その場合は直ちに医師の診療を受けて下さい。

症状の名称	症状
シヨツク(アナライキシー)	服用後すぐに、皮膚のかゆみ、じんましん、声のかすれ、くしゃみ、のどのかゆみ、息苦しさ、動悸、意識の混濁等があらわれる。
皮膚粘膜眼症候群(スティーヴンス・ジョンソン症候群)	高熱、目の充血、目やに、唇のただれ、のどの痛み、皮膚の広範囲の発疹・発赤等が持続したり、急激に悪化する。
横紋筋融解症	手足・肩・腰等の筋肉が痛み、手足がしびれる、カが入らない、こわばる、全身がだるい、赤褐色尿等があらわれる。
肝機能障害	発熱、かゆみ、発疹、黄疸(皮膚や白目が黄色くなる)、褐色尿、全身のだるさ、食欲不振等があらわれる。
腎障害	発熱、発疹、尿量の減少、全身のおくみ、全身のだるさ、関節痛(節々が痛む)、下痢等があらわれる。
間質性肺炎	階段を上ったり、少し無理をしたりすると息切れがする・息苦しくなる、空せき、発熱等がみられ、これらが急にあらわれたり、持続したりする。
血液障害	のどの痛み、発熱、全身のだるさ、顔やまぶたのうらが白っぽくなる、出血しやすくなる(歯茎の出血、鼻血等)、青あざができる(押しても色が消えない)等があらわれる。

Appendix 7

文字サイズについて

グループ	性別	年齢	評価尺度：コメント
A	女	68	<p>ちょうどいい：</p> <p>字が大きいから読みやすい；メガネなくても読みやすい。箱の方が見にくい，薬局で常備薬を選ぶとき，困る。選ぶときもこんな文書があったらいい，見にくいからいつものものを選ぶ</p>
B	女	80	<p>ちょうどいい：</p> <p>文字が大き過ぎても，紙が大きくなるので，これぐらいでいい。</p>

レオアウトの見やすさについて

グループ	性別	年齢	評価尺度：コメント
C	女	72	<p>見にくい：</p> <p>行間がほしい，文字サイズはOK</p>
C	女	78	<p>どちらでもない：</p> <p>してはいけないと相談が分かれているのが，よくわからない</p>
C	男	79	<p>見やすい：</p> <p>80歳とか65歳が分けている意味がwからない。まとめて欲しい。(売るために，こんなに書いているかな～)</p>
B	男	77	<p>とても見にくい：</p> <p>してはいけないことと相談することのマークの意味がわからない</p>

ピクトグラムの役割について(Aグループの参加者より)

性別	年齢	評価尺度：コメント
女	73	役に立った： 覚えるのには役に立った，探すときは文字の方を見ていた
男	70	役に立った： シンプルなほうがいいけど，絵は見やすい，絵を対応するのは効果的，イラストがあったほうがわかりやすい，斜線が印象的だった。
女	68	役に立った： すごく高齢な人にはいい，年が取るほど，絵が欲しい，視野が狭くなる。文字だけあると，読みたくない。文書ばかりいっぱい書いてあると，強そうに思える。
女	74	役に立った： 文字よりも絵をまずパット見ちゃう，絵があった方がいいが，意味がわからない絵もある；文字を読むのが面倒，絵が楽
男	78	あまり役に立ってない： 文書だけ読んだ。ほとんど見てない，意味がわからないイラストが入っている
女	71	役に立った： あった方がいいと思う。年取ったら，読むのが面倒
男	75	役に立った： 子ども，高齢者，妊婦さんとか絵の方が記憶に残る，イラストはいい
男	79	あまり役に立ってない： 文字ばかり並べていると，保険に入るときの感じて
男	70	とても役に立った： 覚える。妊婦とか絵で覚えた。文書を読まなくてもいいぐらいの絵が入っていれば。目がいく。空白はいい，ゆとりを感じさせる。
女	69	とても役に立った： 絵があるとすぐ探せます。
男	71	役に立った： 親しみやすい，わかりにくい絵もある。行政で統一した案があればいい
男	69	役に立った： すぐわかる
男	77	役に立った： 探す時は，ある程度予想して探すので，文字がはっきり見える方がいい。イラストの意味がわかりにくい，見慣れてないから

ピクトグラムが入っている添付文書に対する印象について(BグループとCグループの参加者より)

グループ	性別	年齢	評価尺度：コメント
B	女	80	目が入る。図解しているのはいいなあと思う。今まで見たことないが、こういうのいいなあ～。わかってても図があるとすごくわかる。お腹が痛いのか、
C	男	79	先に、目がいく。今まで見たことがない。絵はいいよ、何か書いてある読むんじゃない。流し読みには最高だ。絵は重要だと思うよ。瞬間的にわかる。でも、難しい絵もあるね。最近スマホとか、パソコンとかも絵が多いので、文字だけ流すと見づらい。
B	男	77	目に飛び込んでくる、パッとわかる。絵のサイズはOK。文字だけだと、読まなきゃ
C	男	77	項目がわかりやすい
C	男	81	赤斜線がきになる、ない方がいい。
B	女	77	親切、見やすい、バツテンがいい、すごくいい、頭に残るんですね。
B	女	75	絵で判断しやすい。絵はあった方がわかりやすい
C	男	67	絵は雰囲気の問題、全体の印象が変わる。字だけだと面倒くさい。好奇心を喚起する。ひかかれて感じ。
C	男	66	斜線がなから、絵があった方がいい、絵が見にくくなっている（この人は絵がない方を選んだ）
B	男	76	1(2)の絵の意味がわかりにくい
B	男	75	頭に入りやすい、印象的にはいい、作るのは大変だけど
B	女	68	見る気になる。ダメなことがパット見てわかるからいい。
C	女	77	絵の意味がわかりにくい
B	男	72	字が小さくても、絵があった方が見やすい、読みやすい
B	女	72	こういうイラストを共通しているといい、字が読めない人はいないけど、読むのが面倒くさい人がいるので。説明書が親切だと信頼度が高くなる

C	男	76	文字だけよりも絵が入っている方がとつきやすい，絵が適切かどうかとは別に。文字だけだと疲れてしまう
B	男	76	今の様式が変えるのが難しかったら，先のイラストがあったりするものにして，患者のためのものをもう一個作った方がいいんです。できるならば，イラストを生かして，読むということは疲れるし，面倒くさい。どこを読めばいいかの優先順位がわかりません。全部読む必要はない。
B	女	71	わかりやすい，読まなくてもいい，字を読むのが苦手
B	女	70	読まなくてわかるからいい，病院でも色線で案内しているので便利。