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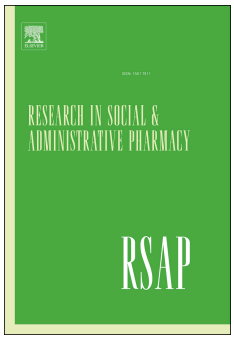

Developing alternative over-the-counter medicine label formats: How do they compare when evaluated by consumers?

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Developing alternative over-the-counter medicine label formats: how do they compare when evaluated by consumers?

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Conflict of interest

David K. Raynor is co-founder and academic advisor to Luto Research (www.luto.co.uk) which develops, refines and tests health information materials.

Developing alternative over-the-counter medicine label formats: how do they compare when evaluated by consumers?

Abstract

Background

In recent years, the Australian Therapeutic Goods Administration (TGA) has proposed implementing a standardized over-the-counter (OTC) medicine label. However, there were mixed consumer opinions regarding a label proposed in 2012 and limited evidence demonstrating the usability of the revised (2014) format.

Objective

To develop and examine the usability of alternative OTC medicine label formats for standardization, and explore consumer perspectives on the labels.

Materials and methods

Four alternative labels were developed for the exemplar medicine diclofenac. One was based on the Medicine Information label proposed by the TGA ('Medicine Information'), one was based on the U.S. Drug Facts label ('Drug Facts'), and two were based on suggestions proposed by consumers in the earlier needs analysis phase of this research (referred to as the 'Medicine Facts' and 'Consumer Desires' label formats). Five cohorts of 10 participants were recruited. Each cohort was assigned to user test one of the alternative labels or an existing label for a proprietary diclofenac product (which acted as a comparator) for diagnostic purposes. Each participant then provided feedback on all 5 labels. Each interview consisted of the administration of a user testing questionnaire, measuring consumers' ability to find and understand key points of information, and a semi-structured interview exploring consumer perspectives.

Results

Overall, all 4 alternative label formats supported consumers' ability to find and understand key points. The existing comparator label was the poorer label with respect to participants' ability to find and understand key points. Factors such as perceived usability, color, design, content, and/or content ordering impacted consumer preferences. The 'Consumer Desires' or 'Drug Facts' label formats were most often preferred by consumers for use as the standardized OTC label over the TGA proposed format.

Conclusions

All alternative label formats demonstrated satisfactory usability and could be considered for use in OTC label standardization. User testing of OTC labels and consumer feedback received as part of the testing process can assist in the refinement of OTC labeling to ensure that implemented policies are evidence-based.

Keywords

Drug labeling; user testing; nonprescription medicines; comprehension; consumers.

Introduction

Availability and access to over-the-counter (OTC) medicines is essential to support consumers in their autonomy and choice to self-manage minor ailments. Appropriate, user-friendly information must therefore accompany OTC medicines to facilitate this, notably the information included on OTC medicine packaging. This information, hereafter referred to as the OTC label or OTC labeling, encompasses both the medicine information included on the packaging and how it is presented i.e. the label's design.

A complex interplay of factors is involved in balancing the design and content included on an OTC label to yield a written medicine information source that is fit-for-purpose.[1] Various strategies help to safeguard and/or improve OTC labeling quality, such as legislation and guidelines.[2, 3] Application of guidelines such as good information design[4] result in improved OTC labeling.[1] However, label design may not always adhere to guidelines,[5, 6] and deficiencies may lead to suboptimal comprehension of OTC medicine information.[1] An example of a more specific strategy to optimize medicine labeling is the standardization of OTC labels in the United States (U.S.) using the Drug Facts label format.[7] Testing demonstrated a number of positive benefits associated with this standardized format[8] such as improvement in the time to locate information.[9, 10]

In recent years, OTC label standardization as a strategy has also been proposed for implementation in different regulatory contexts such as Australia[11, 12] and Canada.[13] The rationale for OTC label standardization, as proposed by the relevant Australian and Canadian regulatory authorities, was underpinned by the aim of promoting safer and more effective use of OTC medicines by consumers.[11, 13] If information was presented consistently, it was postulated that it would support appropriate self-selection of OTC medicines and that consumers could more easily locate information on OTC labels across different products.[11, 13]

Within the Australian context, as part of a general public consultation in 2012, the Australian Therapeutic Goods Administration (TGA) sought feedback on a proposal put forward for standardized OTC labeling in Australia.[11] However, there was a lack of published data detailing consultations with consumers that helped to inform the

details of this proposal. Consequently, in response to the initial 2012 consultation, semi-structured interviews were conducted with 38 Australian and 39 UK consumers to explore consumer opinions on OTC label standardization and the Medicine Information Box format (MIB) (which was the proposed standardized OTC label format[11] presented in the 2012 Australian TGA consultation paper).[14] Additional focus group discussions complemented the interviews and explored consumer perspectives on current non-standardized Australian OTC labels, and the U.S. Drug Facts label (on which the MIB is based[11]), in comparison to the MIB.[15] It was found that in general, consumers felt positively towards OTC label standardization, which was regarded as a strategy that could help promote ease and familiarity in retrieving information from a label.[14] However, mixed consumer opinions on the MIB format were highlighted and a plethora of suggestions for improvement were also proposed.[14, 15] Moreover, consumers also indicated a preference for the Drug Facts label format over the MIB.[15] Consequently, this emphasized the need to explore ways to redevelop and optimize the MIB format prior to its integration into updated OTC labeling policies.

Proceeding the 2012 consultation, a further public consultation on an updated proposal was conducted in 2014[12] along with a targeted consultation in 2015.[16] Despite this, a paucity of evidence exists in the published literature supporting the usability of the specific TGA OTC standardized label formats proposed in both 2012 and 2014 for implementation within an Australian context. Additionally, there is a lack of data comparing its usability with other label formats that have been developed using feedback directly obtained from consumers. Unlike how the U.S. Food and Drug Administration tested their proposed Drug Facts label with consumers,[7] the superior usability of the TGA proposed standardized format, and thus, further reassurance that the labeling policy is evidence-based from a label usability perspective, has not been clearly demonstrated in the published literature. Therefore, this study aimed to:

1. Develop and test alternative standardized OTC medicine label formats, informed by consumer opinions and good information design;
2. Compare the usability of the developed OTC label formats to an existing Australian OTC label for the exemplar medicine diclofenac; and
3. Explore consumer perspectives on all study labels.

Materials and methods

The present study forms part of a broader international collaborative project on OTC labeling improvement and standardization. Research ethics approval for the conduct of this study was obtained from the Human Research Ethics Committee of Institution 1. Participants provided written informed consent prior to participation. All participants were reimbursed for their time.

The present study comprised two stages:

1. Development of alternative standardized OTC label formats, and
2. User testing of the label formats with consumers.

Development of alternative standardized OTC label formats

Within the broader international project, a qualitative needs analysis (semi-structured interviews[14] and focus groups[15]) was conducted with consumers to explore their opinions on existing and proposed OTC labeling strategies to help inform OTC label optimization. Label development commenced after the needs analysis had been completed. The needs analysis findings were evaluated by an international panel and consensus was reached by the research team on the specific suggestions to be taken forward. Broad reasons why certain suggestions were not taken forward included:

- The suggestions were outside the scope of the study e.g. use of Braille on the packaging, pictographs;
- The suggestions were too content-specific and/or could negatively impact the safe use of the medicine e.g. deletion of important information relevant to when the product is being used; and/or
- The suggestions were only proposed by a very small number of consumers.

The needs analysis findings were used in consultation with a UK information design expert, together with reference to good information design principles[4] and use of plain English, to inform the development of alternative OTC label formats for the exemplar medicine diclofenac that could be considered for implementation as part of a label standardization policy (Table 1, Figures 1-4).

Table 1. Developed alternative standardized OTC label formats for exemplar medicine diclofenac

	Label	Brief description
Existing or proposed standardized label formats	'Medicine Information' (Figure 1)	This label was based on the design outlined in the Australian TGA consultation paper released in August 2014,[12] which appeared to integrate the findings from the initial consultation[11] (replacing the Medicine Information Box (MIB) label proposed in 2012). • Black print on white background
	'Drug Facts' (Figure 2)	This label was based on the Drug Facts standardized OTC label format implemented in the U.S.[7] Many focus group participants[15] preferred this format. • Black print on white background • Information split across 2 panels (of the box)
Novel label formats developed	'Medicine Facts' (Figure 3)	'Medicine Facts' was a consumer-proposed label title.[15] The needs analysis findings were applied in the development of this format.[14, 15] Aspects of previously implemented and tested written medicine information formats such as the U.S. Drug Facts label[7] and Australian Consumer Medicine Information[17] formats were also integrated. • Navy blue print on white background • Information split across 2 panels (of the box)
	'Consumer Desires' (Figure 4)	Findings from the needs analysis were applied to inform the development of this format.[14, 15] Some specific consumer desires[14] were integrated into this format as they were seen to have merit, but which were not reported by a large proportion of consumers. • Navy blue print on light blue background • Warnings section presented in red • Simple pictograph system highlighting indications and contraindications using ticks and crosses, respectively

A total of 4 designs were developed and finalized via consensus amongst all research team members for the exemplar study medicine diclofenac (Table 1, Figures 1-4). The MIB format developed for earlier research[14, 15] for diclofenac (one of the exemplar medicines utilized in previous studies) was adopted as the baseline label and additional label content, where necessary, was derived and/or adapted from the information available for an existing diclofenac product (Voltaren® Rapid 25 tablets).[18, 19]

Each label was incorporated and presented as part of complete OTC packaging for the fictitious brand "Viffarol" for evaluation (Figure 5 provides an example of the complete OTC packaging). The complete OTC packaging size was uniform for all Viffarol labels; when assembled, the packaging dimensions were: 115 mm (l) x 48 mm (w) x 24 mm (h). An existing label for an Australian diclofenac proprietary product (Voltaren® Rapid 25 tablets[18]; dimensions: 105 mm (l) x 45 mm (w) x 20 mm (h)) was also chosen as a comparator label format for user testing to help evaluate the relative usability of the OTC label formats. No changes were made to the existing Voltaren® Rapid 25 label.

User testing of the label formats with consumers

Once all alternative label formats were developed, user testing of the label formats was then undertaken with consumers. User testing[17] is a method of testing conducted with members of the public that is used as the standard in Europe to test patient information leaflets. It has also been advocated for use in OTC label development,[2] used in usability testing and improvement of written medicine information.[17, 20, 21] User testing was conducted with demographically matched cohorts of consumers as a diagnostic measure of the usability of the developed label formats. Both quantitative and qualitative data were obtained using a standardized user testing questionnaire (UTQ) developed specifically for the exemplar medicine diclofenac. Explicit user testing outcome measures used to ascertain the usability of the written medicine information included the ability to find and understand the information. Thus, each study participant only user tested 1 of the 5 labels to ensure that the validity of both key outcome measures was not compromised due to factors such as recall of information relevant to diclofenac.

Development of the user testing questionnaire and semi-structured interview protocol

A UTQ was developed, consisting of 13 core items that encompassed key points of information specific to the diclofenac product as agreed upon by 3 pharmacists (Authors 1-3). Some UTQ items were derived from the UTQ used in an earlier study (within the broader international collaborative project) that evaluated a label and leaflet for diclofenac (manuscript prepared for publication).

Questionnaire items were asked in an order which minimized key points corresponding to the exact order they appeared in the information across the label formats (so that respondents did not learn that the relevant information to answer a question was positioned immediately after that for the previous question). The standardized order of questions was also intended to minimize any order effects within and between cohorts.

A semi-structured interview protocol was also developed for use after the UTQ to explore consumer perspectives on the label formats (Appendix 1). Both the UTQ and semi-structured interview protocol were piloted with 2 non-medically trained people and 2 pharmacists engaged in research for face and content validity, which involved detailed individual review of all questions. Approximately 2 weeks afterwards, each person completed the entire face-to-face session as a mock participant (with the interviewer) to determine whether any further improvements to the interview process were required. Minor amendments to the wording of items included in both the UTQ and interview protocol were subsequently made to improve item clarity.

User testing- participants and setting

Study recruitment was conducted between April and October 2015 using online advertisements, recruitment flyer distribution, and by a market research company.

Consumers were eligible to participate in the study if they were:

- 18 years or older,
- Conversant in English (did not require the assistance of a translator to complete the interview tasks),
- Had purchased and used an OTC medicine (for themselves or had given it to a person under their care) within the 6 months prior to study participation,
- Had not used diclofenac (either for themselves or given to a person under their care) within the 6 months prior to study participation, and
- Had not used or given someone under their care a medicine from the same therapeutic class as diclofenac (non-steroidal anti-inflammatory drugs (NSAIDs) for pain relief) within 1 month prior to study participation.

Participants were excluded if they:

- Were a retired or practicing health care professional,
- Were currently employed in an occupation which primarily involved the use of medicine information,
- Had participated in a user testing study in the 6 months prior to study participation, or
- Had significant visual or cognitive impairment that could affect study participation.

In accordance with user testing guidelines in place in the European Union for written medicine information, satisfactory usability is achieved when a minimum of 8 out of 10 participants in a cohort are able to demonstrate their ability to both find and understand each key point of information.[20] As user testing was used diagnostically, only 10 participants per label format were required for one round of testing; where applicable, additional testing can be undertaken to evaluate necessary label revisions made as a result of any identified issues.[21] Therefore, each cohort (that consisted of 10 participants) user tested a different assigned OTC label format for diagnostic purposes and each participant then provided feedback on all 5 labels. Five cohorts of 10 participants were recruited. Each cohort was demographically matched using criteria that were adapted from a previous study.[22] These criteria acted as controlled variables per cohort to ensure an adequate spread of participant demographics and allowed for a degree of comparison between cohorts.

Each cohort was demographically matched by gender (at least 3 males and 3 females per cohort of 10), education (a maximum of 3 participants per cohort of 10 having completed a university degree or higher), occupation/use of written information (at least 2 participants per cohort of 10 unemployed or retired, or did not regularly use written information as part of their occupation), and age (at least 1 participant per cohort of 10 representing each of the following adult age brackets: 18-29, 30-39, 40-49, 50-59, 60-69, and 70+ years). Once recruited, participants were assigned a specific label to user test in order to ensure that all demographic requirements were met per cohort.

Study protocol

Data were collected via individual face-to-face interviews, lasting approximately 1 hour in total (at Institution 1). All interviews were conducted by 1 researcher (Author 1) to ensure consistency in their conduct and were audio-recorded with permission from the participants.

Each face-to-face interview consisted of 2 parts:

(i) Administration of the UTQ to test 1 assigned label format, and

(ii) A semi-structured interview component exploring consumer opinions on all label formats.

At the interviews, participants were given a copy of the participant information statement and consent form to read and sign. The assigned label for testing was provided to the participant and they were given as much reading time as required. The structured UTQ was then administered. Participants kept the label in front of them at all times. Participants were then asked for their feedback on the label they had user tested regarding aspects such as the design, content, and wording. All other labels were then presented together and participants were asked for their opinions on the different label formats. All labels could be viewed side by side by the participants. They were also requested to rank all the label formats from the most to least preferred and explain their reasoning. Finally, they were asked to select a label format they would choose to implement as a standardized OTC label format.

Data analysis

User testing data analysis

All audio recordings were reviewed after interview completion and participant responses to the UTQ were transcribed verbatim for analysis. Responses were coded according to the model answers for the UTQ items as:

- Found and understood;
- Found but not understood, or;
- Not found (understanding was therefore not applicable).

To help provide an indication of the ease in locating the key point of information, in the instances where information was found, answers were noted to be found with difficulty if the participant:

- Took more than 2 minutes to locate the complete indicative answer on the label, or;
- Two or more prompts were required to be initiated by the interviewer (Author 1) prior to the indicative answer being located in full on the label.

The above criteria for noting answers as 'found with difficulty' were adapted from a previous user testing study.[22]

All coding was completed by 1 researcher (Author 1). Coding for finding and understanding information was dichotomous. Therefore, regardless of whether an answer was found with difficulty, if the relevant information was located by the participant, it was still coded as found. Similarly, responses were coded as understood if an answer was provided that corresponded to the complete indicative answer to the questionnaire item that was agreed upon by the research team members. All answers that were not clearly found and understood as per the model answers were reviewed by another researcher (Author 3) and reconciled where necessary to ensure that agreement was reached in their coding.

Semi-structured interview data analysis

The qualitative semi-structured interviews were transcribed verbatim. Each transcript was then checked against the audio recording to ensure accuracy. Checked verbatim transcripts were thematically analyzed.[23] Matrix displays[24] were developed and used in preliminary data analysis to display the semi-structured interview data under broad themes. Themes and subthemes were then derived inductively from the data and refined.

Participant label rankings were pooled for analysis and represented numerically. A standard competition ("1224") ranking approach[25] was utilized to take into account equal label rankings nominated by some participants, where points were assigned to correspond with each rank. Five points was awarded to the label ranked 1st (most preferred) and the allocated points were decreased by 1 point with each subsequent rank to the minimum of 1 point awarded for the label ranked 5th (least preferred). These were then tallied.

Results

A total of 50 participants (Table 2) completed the study (10 participants per label format).

User testing results

User testing results for the 4 alternative OTC label formats

Overall, the label formats generally well supported consumers' ability to both find and understand the majority of key points of information for diclofenac (Table 3).

UTQ item 8 relating to sucrose proved problematic for 2 participants in each relevant cohort when the 'Medicine Facts' and 'Consumer Desires' label formats were user tested (Table 3). Sucrose was unable to be located on the label by those participants. In response to UTQ item 10, related to persistent pain and the actions to be taken, between 2 and 5 participants in each cohort had difficulty in finding the key information; in particular, participants had difficulty understanding the maximum treatment duration before needing to contact their doctor (Table 3).

User testing results for the Voltaren® Rapid 25 comparator label

Despite participants' ability to locate the majority of key points of information when user testing the comparator label Voltaren® Rapid 25, it was the label format that demonstrated poorer usability relative to the other labels. Specific problem areas were the understanding of dosage, warning about use in pregnancy, and actions to be taken in relation to UTQ item 10 (Table 3). Maximum treatment duration could not be found by 1 participant.

Feedback obtained on the user tested label format

Suggestions put forward by participants were categorised as design, content, or wording improvements. Common broad improvements suggested for the label formats included:

- More bolding of key terms or points of information,
- Increased font size, and
- Further use of color, in particular for highlighting or differentiation of information e.g. warnings information to be highlighted using the color red.

Other more label-specific suggestions for improvement have been summarized in Table 4.

338 Table 2. Summary of participant demographics

Demographic		Voltaren® Rapid 25 cohort (n=10)	'Medicine Information' cohort (n=10)	'Medicine Facts' cohort (n=10)	'Consumer Desires' cohort (n=10)	'Drug Facts' cohort (n=10)	Total (n=50)
Gender	Male	4	5	5	5	5	24
	Female	6	5	5	5	5	26
Age, years	18-29	3	3	3	3	3	15
	30-49	3	3	2	3	3	14
	50-69	2	3	3	3	3	14
	70+	2	1	2	1	1	7
Highest level of education	Year 10	3	1	2	0	0	6
	Year 12 or College	5	7	5	7	9	33
	Bachelor's degree or higher	2	2	3	3	1	11
Main language spoken at home	English	10	8	10	9	9	46
	Other	1[a]	2	3[a]	1	1	8

Demographic		Voltaren® Rapid 25 cohort (n=10)	'Medicine Information' cohort (n=10)	'Medicine Facts' cohort (n=10)	'Consumer Desires' cohort (n=10)	'Drug Facts' cohort (n=10)	Total (n=50)
Regular use of written information as part of occupation	Yes	3	8	5	4	7	27
	No	7	2	5	6	3	23
Country of birth	Australia	4	6	4	8	4	26
	Overseas	6	4	6	2	6	24

[a] Participants also specified English as a main language spoken at home (language categories were not mutually exclusive, hence cohort total may exceed 10)

341 Table 3. Summary of the user testing findings for all 5 label formats

User testing questionnaire (UTQ) item		Voltaren® Rapid 25 (n=10)		'Medicine Information' (n=10)		'Medicine Facts' (n= 10)		'Consumer Desires' (n=10)		'Drug Facts' (n=10)	
		Found (n, difficulty[a])	Under-stood	Found (n, difficulty)	Under-stood	Found (n, difficulty)	Under-stood	Found (n, difficulty)	Under-stood	Found (n, difficulty)	Under-stood
1.	What is the active ingredient found in *[insert diclofenac brand]?*	10 (0)	10	10 (0)	10	10 (0)	10	10 (0)	10	10 (0)	10
2.	You are taking *[insert diclofenac brand]* to relieve your back pain. How much should you take and how often?	10 (0)	**9**	10 (0)	10	10 (0)	10	10 (0)	10	10 (0)	10
3.	Pretend that you are pregnant. After coming home from the pharmacy, you realize you did not tell the pharmacist that you are pregnant at the moment. What should you do?	10 (0)	**9**	10 (0)	10	10 (0)	10	10 (0)	10	10 (0)	10
4.	How should you store these tablets?	10 (0)	10	10 (0)	10	10 (1)	10	10 (0)	10	10 (0)	10
5.	Pretend you have already taken SIX *[insert diclofenac brand]* tablets so far today for your pain. How many more tablets can you still take today?	10 (0)	10	10 (1)	10	10 (0)	10	10 (0)	10	10 (0)	10

User testing questionnaire (UTQ) item		Voltaren® Rapid 25 (n=10)		'Medicine Information' (n=10)		'Medicine Facts' (n= 10)		'Consumer Desires' (n=10)		'Drug Facts' (n=10)	
		Found (n, difficulty[a])	Under-stood	Found (n, difficulty)	Under-stood	Found (n, difficulty)	Under-stood	Found (n, difficulty)	Under-stood	Found (n, difficulty)	Under-stood
6.	Pretend your father has just bought some *[insert diclofenac brand]* from the pharmacy. He tells you that he forgot to tell the pharmacist that he has a stomach ulcer at the moment. What would you tell your father about taking *[insert diclofenac brand]*?	10 (0)	10	10 (0)	10	10 (1)	10	10 (0)	10	10 (0)	10
7.	SHOW CARD: A picture of Nurofen® Cold and Flu tablets Active ingredient: Ibuprofen (NSAID anti-inflammatory) Pseudoephedrine (relieves blocked noses) Pretend you are currently taking *[insert diclofenac brand]* tablets and have just come down with a cold. You have some Nurofen® Cold and Flu tablets at home. What does the box say about taking this medicine together with *[insert diclofenac brand]*?	10 (0)	10	10 (0)	10	10 (1)	10	10 (0)	10	10 (2)	10

User testing questionnaire (UTQ) item		Voltaren® Rapid 25 (n=10)		'Medicine Information' (n=10)		'Medicine Facts' (n= 10)		'Consumer Desires' (n=10)		'Drug Facts' (n=10)	
		Found (n, difficulty[a])	Under-stood	Found (n, difficulty)	Under-stood	Found (n, difficulty)	Under-stood	Found (n, difficulty)	Under-stood	Found (n, difficulty)	Under-stood
8.	Imagine you know that your body reacts badly when you have sucrose. What does the box tell you about whether you can take this medicine?	10 (1)	10	10 (0)	10	**8 (1)**	**8**	**8 (2)**	**8**	10 (1)	10
9.	What can *[insert diclofenac brand]* be used for?	10 (0)	10	10 (0)	10	10 (0)	10	10 (0)	10	10 (0)	10
10.	Pretend you have been taking *[insert diclofenac brand]* for about 4 days in a row now but the pain has not gone away or improved. What does the box say you should do?	10 (5)	**7**	10 (2)	**8**	10 (4)	**8**	10 (3)	10	10 (3)	10
11.	If you wanted to know more about this medicine, who can you contact or where can you go?	10 (1)	10	10 (0)	10	10 (0)	10	10 (0)	10	10 (0)	10
12.	What side effects should you look out for whilst taking *[insert diclofenac brand]*?	n/a (not on label)	n/a	10 (0)	10	10 (0)	10	10 (0)	10	10 (0)	10
13.	What is the longest amount of time that this medicine can be used for?	**9 (0)**	**9**	10 (0)	10	10 (0)	10	10 (0)	10	10 (0)	10

[a] The number of participants who had difficulty finding the information

343 Table 4. Summary of other potential improvements suggested by participants who user tested the label format specifically

Label	Design improvements	Content improvements	Wording improvements
Voltaren® Rapid 25	**Re-ordering and/or relocation of information** • Higher up: Directions for use, "Do not take" section • Move treatment duration to beginning of "Do not" section or together with action to be taken if symptoms persist • Group information requiring you to see the doctor together under "Precaution" e.g. allergic reaction, if symptoms persist **Other** • Include a separate box to state the ingredients • List and number dosage information	**Addition** • How it will work; common side effects; type of medications it cannot be used with; specific treatment duration; other information sources; what liquid to take medication with **Deletion** • Some warnings; statements: use only as directed, do not exceed stated dose, see doctor regarding allergic reaction, prolonged use could be harmful; maximum daily dose	**Uses** • Replace migraine with headache **Directions for use** • Dosing interval as 8 hours; 1 day as 24 hours (maximum daily dose) **Warnings and/or precautions** • Clearer, concise pregnancy warning • "If symptoms persist, stop the medicine and see your doctor" **Headings** • "Warnings" instead of "Do not take"
'Medicine Information'	**Re-ordering and/or relocation of information** • Higher up: Directions for use • Lower down: Warnings, Ingredients, all contact information • Allergy information together with "Ingredients"	**Addition** • All ingredients **Deletion** • Content repetition; sponsor/contact details	**Headings** • Reword "Uses"

Label	Design improvements	Content improvements	Wording improvements
'Medicine Facts'	**Re-ordering or relocation of information** • Higher up: Directions for use, Warnings, Inactive ingredients (after Active ingredient) • Lower down: "Do not use", Active ingredient, Uses • Combine action to be taken if symptoms persist and maximum treatment duration - include under "How to take" • Storage information above Poisons Information Centre • Sucrose to "Things to be careful of" • "Other information" on another panel	**Addition** • When to take in relation to meals; sucrose on back panel; why sucrose is highlighted **Deletion** • Statement about reading leaflet (back panel); other information except website	**Warnings and/or precautions** • Clearer statement of when to stop taking the medicine **Headings** • "Dosage" instead of "How to take" • "Filling up ingredients" instead of "Inactive ingredients"
'Consumer Desires'	**Re-ordering or relocation of information** • Higher up: Warnings • Lower down: Directions for use, Other information • Include maximum duration of use, if symptoms persist, and overdose information together under "What should I be careful of?" • Move "Other information" or "Ingredients" to side panel **Other** • White background • Ingredients listed in bullet points	**Deletion** • Statement about reading leaflet (back panel); Uses (just state pain reliever); unnecessary words	**Headings** • "Warnings" instead of "Do not use"

Label	Design improvements	Content improvements	Wording improvements
'Drug Facts'	**Re-ordering or relocation of information** • Higher up: Directions for use • Lower down: Warnings, Active ingredient, Other information • Side effects under "Warnings" • Move "When using this product" to another panel **Other** • More white background • Landscape orientation for back panel • Include maximum daily dose in a sentence together with dosage • Separate out adults and children and tabulate dosage	**Addition** • Sucrose on back panel • Elaborate on "at first" (dosage) • Warning regarding driving or drinking alcohol whilst using this medicine **Deletion** • Common side effects	**Headings** • "Inactive ingredients" instead of "Other ingredients" • "Main active ingredient" instead of just "Active ingredient" • "Side effects" as a heading **When using this product** • State not to use with other anti-inflammatories and diclofenac-containing medicines together • Advise to be aware of side effects **Directions for use** • Delete "at first" and rephrase dosage

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Consumer perspectives on the label formats

Overview- participant label rankings and preferences

The 'Consumer Desires' label format scored highest (Table 5). In the label ranking exercise, it was cited most frequently as the most preferred OTC label format (n=17), followed closely by the 'Drug Facts' label (n=15). The 'Medicine Information' label was the label least often ranked 1st (most preferred) by participants (n=4).

The majority of participants were in support of OTC label standardization as a labeling strategy. Similar to the rankings, consumers most commonly chose the 'Consumer Desires' or 'Drug Facts' label formats as their favored standardized OTC label format for implementation. Conversely, the 'Medicine Information' label format was only nominated by a few participants.

Consumer perspectives on the label formats varied considerably. Differences in factors such as perceived usability, visual appeal, use of colour, design, content amount/type, and/or order of information influenced consumer label preferences and subsequent rankings. The label-specific characteristics mentioned by consumers when comparing and ranking labels are the focus herein.

Table 5. Tallied points for each label according to the nominated ranks per cohort

		User testing participant cohorts					
		Voltaren® Rapid 25 cohort (n=10)	'Medicine Information' cohort (n=10)	'Medicine Facts' cohort (n=10)	'Consumer Desires' cohort (n=10)	'Drug Facts' cohort (n=10)	Total points per label format
Label format	Voltaren® Rapid 25 label	26	25	32	29	27	**139**
	'Medicine Information' label	27	30	24	27	31	**139**
	'Medicine Facts' label	29	32	33	29	31	**154**
	'Consumer Desires' label	34	40	37	30	31	**172**
	'Drug Facts' label	34	23	26	36	31	**150**

'Consumer Desires' label format

The majority of participants who ranked the 'Consumer Desires' as their most preferred label (14/17) were aged 18-39 years. Participants liked its visual appeal. The use of color, in particular the contraindications' section presented using red, was frequently mentioned as beneficial in highlighting the information, along with the tick cross pictograph system (utilized to help communicate the indications and contraindications information). Aspects that were liked about the 'Consumer Desires' label format included:

- Directions for use situated higher up, along with its tabulation;
- Both active and inactive ingredients being presented together;
- Distinct sectioning of information within the main label;
- Inclusion of all information on 1 main panel; and
- Use of colloquial language.

"The colored one immediately stands out to me because it's got a panel which is red with some crosses which immediately says to me 'Danger, danger. You need to read this.' So umm, I think that's, that's quite good." (P42- 'Drug Facts' cohort)

"I'm really liking this colored one with the crosses and the ticks. Umm and I like the fact that each heading is contained within its own sort of graphically designed bubble, if you like. Umm, [it] makes the information really easy to find. It's sort of like an index on the back of the box." (P42- 'Drug Facts' cohort)

Despite these positives, there were a number of shortcomings. Some participants thought that the 'Consumer Desires' label format was too busy; small print, excessive color, too much information, and minimal background space were negative characteristics raised. The question-style headings were also not favored.

'Drug Facts' label format

The majority of participants who most preferred the 'Drug Facts' label format (12/15) were 40 years or older. Participants liked the clearer, simple layout, larger font, and the ease with which it could be read. The black print on white was seen to stand out; the use of space was also seen as good. The content was liked (e.g. specification that diclofenac is a NSAID) and the categorization and separation of information made information easy to find.

Similar proportions of participants nominated the 'Drug Facts' label as the most preferred or least preferred label, which has contributed to its slightly lower total point score (Table 5). It was perceived as an unappealing, boring, or outdated design. Comparisons were made to nutrition labeling or cigarette packaging. Directions for use located at the bottom or information located on the side panel were generally not favored. Further still, separate areas of information did not stand out, for instance, when referring to the label format quickly. Participants also opposed the title "Drug Facts" as it *"makes it sound like marijuana or something" (P30- 'Medicine Information' cohort)*. Participants expressed mixed feelings regarding the information, black bullet points, and the border. The two-column format also affected perceptions on how easily the label could be read.

"That's just a really bad packaging… Whoever designed that needs to probably go back to design school." (P12- Voltaren® Rapid 25 cohort)

"I think it's a no no, just 'cause it is very hard to read. It is all black and all. It's not colour coded as this one is. So I don't think this is very helpful."(P21- 'Consumer Desires' cohort)

'Medicine Facts' label format

The 'Medicine Facts' was seen as very similar to the 'Medicine Information' label format. The navy blue print was seen as more attractive than black print. The layout was seen as easy to read, with good, clear, dark banded headings, some white space, bullet points, and sectioning.

"It's not an overly complicated box. Like, it's not millions of things going on so that does make it a bit easier to use as well." (P17- 'Medicine Facts' cohort)

Differing opinions on the amount of information was evident; it was liked but on the other hand, also seen as too much. The order of information was commented on, where it did not always correspond with consumers' preference or perceived importance of information. Furthermore, difficulty locating the dosage was reported; it *"breaks up the warnings with 'How to take Viffarol' in the middle and I just feel like it's really random that the directions are here. Like, it kind of gets lost in it." (P02- 'Medicine Information' cohort)*. Information included on the side panel was not liked, with participants believing that the information could be missed. Font size was disliked and the colour was also seen as not sharp enough.

"I don't know. It's sort of too much. It's all the same colour and it all blends down together. It's harder to find. You can see it, obviously, but it's harder to find." (P37- 'Consumer Desires' cohort)

'Medicine Information' label format

Participants liked the clear, banded headings, clear information, bullet points, and grouping of contraindications and precautions information together. The black print on white was easier to read for some than the navy blue print. Mixed opinions on font size appropriateness were seen.

On the other hand, the monochrome design was viewed as unappealing and unengaging. Participants generally did not like the order of information; in particular, the inclusion of directions for use near the bottom of the label. The amount of information was also seen as too much.

Voltaren® Rapid 25 label format

Participants liked the color (navy blue print), the order of information (specifically, that the directions for use were at the top of the label), font size, and the prominence of the storage information. The simple design, with only 3 headings utilized, and heading style were also liked.

On the other hand, the Voltaren® Rapid 25 label was seen to be lacking in content. It was criticized for having lengthy individual dot points or sentences, deficient sectioning of information, and an extensive "Do not take"[18] section.

"It [is] a lot of things to read under one heading, so… I don't find that easy to, you know, just go through." (P14- 'Medicine Facts' cohort)

General comments on label characteristics

Consumers generally preferred short headings (although headings adopting a question-style or use of laymen terms were also liked on occasion). Overall, core information included on 1 main panel (where possible) was preferred. However, of those who preferred or were comfortable with splitting information across multiple panels, information that was less important, less useful, or less often used could be included on a side panel. Where some felt indifferent or did not see inactive ingredient information as useful (e.g. if it was not understood or in the absence of allergies), others felt that complete information should be provided on the label for the purposes of transparency or as a precaution.

Discussion

To the best of the authors' knowledge, this is the first study that has developed and tested, using industry-standard user testing, labels based on TGA consultation proposals, and more importantly, alternative ones based on good information design principles and a consumer needs analysis. All developed label formats demonstrated satisfactory usability in accordance with benchmark user testing standards[20] and thus, could be considered as candidates for use as standardized OTC label formats. Their usability was also superior to the existing label for Voltaren® Rapid 25. Participants supported the standardization of OTC labeling, similar to previous studies.[14, 15] Specifically, the 2 labels most frequently preferred and nominated as the format of choice for standardization were the 'Drug Facts' and 'Consumer Desires' labels.

The 'Drug Facts' label was the superior label of the 5 in terms of usability, with all 10 participants finding and understanding all key points. This may be due to label aspects such as the larger font size and ample white space integrated into its layout in comparison to the other labels, where larger font has been previously associated with improved usability by consumers when answering questions about the information on an OTC label.[26, 27] In particular, this may explain why all participants user testing the 'Drug Facts' label identified that the product contained sucrose (for UTQ item 8), compared to the 'Medicine Facts' or 'Consumer Desires' label formats. On the other hand, on the Voltaren® Rapid 25 and 'Medicine Information' labels, only sucrose was specified as the sole additional ingredient rather than a complete list as seen in the other labels. This could explain why no issues pertaining to UTQ item 8 were detected when these labels were user tested. Overall, a few consumers in each cohort had difficulty finding the complete indicative answer for UTQ item 10 (actions to be taken in response to persistent pain). This was due to the relevant information being located in more than 1 label section. Thus, consolidating this information together in 1 section is a potential target for future label optimization.

Consumer preferences with respect to OTC labels can vary with differences exhibited in label characteristics, such as ordering of information[28] and design aspects such as print size and spacing,[29] which were also aspects commented on by the study participants. However, with respect to the 'Drug Facts' and 'Consumer Desires' labels, participant feedback received in the present study suggest a degree of consistency in specific label characteristics favored by consumers- for example, the suggested use of red to convey warnings[14] and support for the 'Drug Facts' label[15] as identified in the initial consumer needs analysis. Furthermore, suggested improvements mirrored some received in the consumer needs analysis, especially if the label format they user tested did not display these characteristics e.g. further use of bolding and color, inclusion of directions for use higher up, and active ingredient lower down in the label.[14] This order of information and use of red to highlight the contraindications were all characteristics of the 'Consumer Desires' label. On the contrary, the 'Medicine Information', the Australian TGA format proposed in 2014,[12] achieved the lowest total point score and was nominated least often as the chosen standardized format to be implemented.

When considering usability in tandem with consumer preferences and feedback given as part of the present study, a hybrid of the 'Consumer Desires' and 'Drug Facts' labels could be considered for use as an OTC standardized label format for implementation by countries seeking to adopt a label standardization strategy. Aspects of each label could address the perceived shortcomings of the other across different demographics (as these 2 labels were the most different from each other). For instance, in terms of specific characteristics, the 'Drug Facts' label could be amended to reflect the order of information on the 'Consumer Desires' label; other aspects such as the moderate use of color (e.g. the red used for warnings information was liked) and use of the tick cross pictograph system could also improve its visual appeal. The larger font size and ample white space should also be retained as these are aspects of good information design.[4]

With regards to standardization as a labeling strategy, a one-size-fits-all approach will inherently have its limitations in its ability to satisfactorily cater for the needs of the entire consumer population. Consumer preference may not always equate to a label that actually performs well, as was evident in the diversity of participant perspectives on the 5 study label formats. For instance, user testing demonstrated that the active ingredient could still be found even if not presented initially at the top of the label. Thus, the present study does not provide evidentiary support of an advantage in including the ingredients foremost, particularly when consumers generally do not prefer this approach, as voiced in both the present and previous[8, 14, 28] studies. Importantly, usability must remain the focal point for improvement of OTC labeling quality as OTC label information may not be adequately understood and can be inappropriately acted upon.[30-32] It is imperative to consult consumers in the written medicine information development process as by doing so, targets for improvement of OTC medicine information can be identified.[33-36] Interestingly, Bix et al.[37] demonstrated that adherence to labeling requirements embedded in standardized labeling regulations, such as those stipulated for the Drug Facts label, may still yield variations in the legibility of label formats. In addition, a recent study conducted in the U.S. by Bhansali et al.[38] noted that almost 80% of participants most preferred an alternative label format that included directions near the top of the label and warnings information lower down. In comparison, only approximately 14% most preferred the Drug Facts label format i.e. the order of information.[38] Since requirements for standardized tabulation of information on OTC labels have now been formally published in both Australia and Canada (after the present study had been concluded),[39, 40] this reinforces that ongoing research is important and necessary to ensure that standardization promotes the development of improved OTC labels for consumers. With standardized labeling, there is a risk of implementing a policy centered on an OTC label format that is not preferred by consumers, for whom the benefits are intended, or that would not yield optimal usability. Considering that all evidence-based label formats for the same exemplar medicine in the present study demonstrated comparable usability on the whole, this also brings into question the overall advantage of implementing a standardized label format in terms of usability.

At present, user testing of OTC medicine information is not required by law in Australia and is not routinely used to evaluate written medicine information.[41] As legislation places emphasis on the content required for inclusion on labels,[42] usability of existing OTC labels in regulatory contexts such as Australia remains largely unknown. Thus, future research on the impact of these labeling changes is critical and should feed into an iterative, consumer-centric user testing process for label optimization, as embodied in previous OTC label user testing studies.[34, 35] Moreover, there are no legislated requirements in the U.S. for the user testing of all OTC labels; instead, guidelines are available which describe how testing of OTC labels can be conducted.[43] This lack of mandated user testing may have implications on the quality of standardized OTC labels. Accordingly, a move towards legislating user testing may allow for more innovative labeling strategies that demonstrate superior usability to a standardized format. This may also more effectively take into account both consumer and manufacturer perspectives on OTC labeling.

Study limitations

This study has some limitations. It is acknowledged that the involvement of other experts, for instance, in the area of functional linguistics, would be useful to assist in label development. The options for label design are effectively unlimited in many ways, depending on how written medicine information developers opt to manipulate different parameters. Accordingly, in the present study, there was a pragmatic limitation on the number of label designs included for user testing which meant that not all possible label formats and combinations could be explored. In light of this, a range of different label characteristics was integrated across the different label formats. Also, the same packaging dimensions were used for all the developed label formats for consistency as they were developed for the same fictitious branded product. Thus, findings may differ if packaging size was altered. Optimal product-specific labeling that meets the relevant requirements for standardization should also be evaluated by other key stake-holders in addition to consumers, such as pharmaceutical manufacturers. However, it is imperative to ensure that compromises are not made to the labels that will have an adverse impact on medication safety.

Conclusions

All alternative OTC label formats developed and user tested in this study were effective in communicating key information overall and demonstrated better usability than the existing Voltaren® Rapid 25 comparator label format. This then highlights the effectiveness of implementing good information design principles in OTC label development and the need to improve existing OTC labeling. The satisfactory usability of these labels also emphasizes that consumer preferences can be utilised to help guide label development without compromising OTC label usability. Differences in factors such as design, content, and wording impacted both participants' actual and perceived usability of the OTC label formats.

As the TGA proposed 'Medicine Information' label format was least often nominated by participants as their preferred standardized OTC label format for implementation, this reinforces the importance of consulting consumers as key stakeholders in working towards the implementation of regulatory changes such as OTC label standardization. Aspects of the 'Consumer Desires' and 'Drug Facts' labels can be taken forward in refining the design of a standardized OTC label format that could be adopted in future, in line with both consumer preferences and usability testing data. In light of the recent introduction of new OTC medicine labeling policies that facilitate standardization in Australia, this study provides evidence in support of the advantages for adoption of a mandate for user testing to also be integrated into OTC labeling frameworks in future to evaluate and ensure label usability.

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Figure captions

Figure 1. ‘Medicine Information’ label format

Figure 2. ‘Drug Facts’ label format

Figure 3. ‘Medicine Facts’ label format

Figure 4. ‘Consumer Desires’ label format

Figure 5. Complete “Viffarol” packaging for the ‘Medicine Information’ label format

753 **Appendix**

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755 Appendix 1. Semi-structured interview protocol questions

Semi-structured interview protocol sections	Questions
Perspectives on the user tested label	• Firstly, what are your overall thoughts about the box that you just helped us test, in terms of how easy/hard it is to read and the information that is included on it? • Looking at the information on the box, what do you think about the amount of information that it contains? • What do you think about the layout of the information on the box? • Thinking back to how you used the box to answer the questions before, what information was easy or difficult to find and/or understand? • From your point of view, how can we improve the box in the future to improve its readability and how well it is understood?
Perspectives on all other label formats	• Firstly, what are your overall thoughts about these boxes, in terms of how easy/hard it is to read and the information that is included on it? • What do you think about the amount of information that each of these boxes contain? • What do you think about the layout of the information on the boxes? • What do you think about the headings used on these boxes? • What do you think about how the information is ordered on these boxes? • What do you think about how colour has been used on these boxes? • What do you think can be improved with these boxes to make them better in the future?
Label format rankings	• How would you rank all the boxes, from the one you most preferred to the least preferred? • Why did you rank them in this way?
Standardization-preferred label format	• If we had to choose a standard back of the pack for all over-the-counter medicines, which would you choose out of the 5 and why? • How would you feel if this was the one we rolled out onto all over-the-counter medicines in Australia? • Taking a step back from the boxes in front of you, what do you think about having standardised back of the packs/boxes for all over-the-counter medicines?

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Medicine Information

Ingredients

Each tablet contains the active ingredient:
Diclofenac potassium 25mg. Also contains sucrose.

Uses

Short term relief of pain and swelling related to:

- migraines
- back
- joints
- period pain
- sprains and strains

Warnings

Do not use if

- You are pregnant
- You have heart failure
- You have kidney problems
- You are less than 14 years old
- You have a stomach ulcer or other stomach or bowel problems
- You are allergic to any of the ingredients, or other anti-inflammatory medicines like aspirin

While using this product

- Do not take this product together with other anti-inflammatory medicines
- Do not take other medicines that also contain diclofenac
- Common side effects: feeling sick, stomach upset, feeling dizzy
- Call the Poisons Information Centre (**13 11 26**) or go to the hospital straight away if you have taken too much
- Talk to your doctor or pharmacist if your problems get worse or do not get better
- For more information: **02 9000 5000 (Aus)** or visit **www.viffarol.com.au**

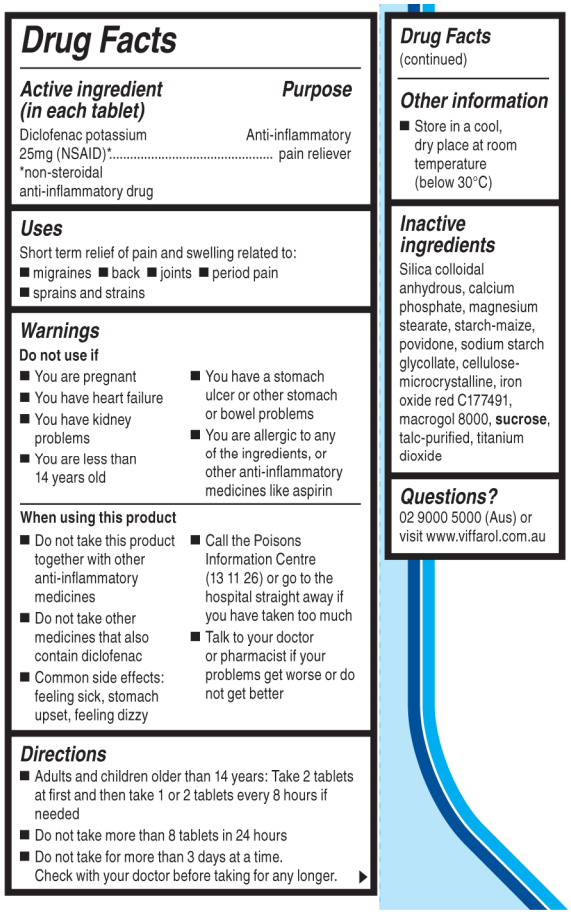
Directions for use

- Adults and children older than 14 years: Take 2 tablets at first and then take 1 or 2 tablets every 8 hours if needed
- Do not take more than 8 tablets in 24 hours
- Do not take for more than 3 days at a time. Check with your doctor before taking for any longer.

Other information

Store in a cool, dry place at room temperature (below 30°C)

Supplied by PharmVT Consumer Health Australasia Pty Ltd, 100-150 Parkside Road, NSW 2006, Australia.
Phone: 02 9000 5000.
NZ Office: Auckland, New Zealand. Phone 09 300 5000.



Drug Facts

Active ingredient (in each tablet)	Purpose
Diclofenac potassium 25mg (NSAID)*	Anti-inflammatory pain reliever

*non-steroidal anti-inflammatory drug

Uses

Short term relief of pain and swelling related to:

- migraines
- back
- joints
- period pain
- sprains and strains

Warnings

Do not use if

- You are pregnant
- You have heart failure
- You have kidney problems
- You are less than 14 years old
- You have a stomach ulcer or other stomach or bowel problems
- You are allergic to any of the ingredients, or other anti-inflammatory medicines like aspirin

When using this product

- Do not take this product together with other anti-inflammatory medicines
- Do not take other medicines that also contain diclofenac
- Common side effects: feeling sick, stomach upset, feeling dizzy
- Call the Poisons Information Centre (13 11 26) or go to the hospital straight away if you have taken too much
- Talk to your doctor or pharmacist if your problems get worse or do not get better

Directions

- Adults and children older than 14 years: Take 2 tablets at first and then take 1 or 2 tablets every 8 hours if needed
- Do not take more than 8 tablets in 24 hours
- Do not take for more than 3 days at a time. Check with your doctor before taking for any longer.

Drug Facts (continued)

Other information

- Store in a cool, dry place at room temperature (below 30°C)

Inactive ingredients

Silica colloidal anhydrous, calcium phosphate, magnesium stearate, starch-maize, povidone, sodium starch glycollate, cellulose-microcrystalline, iron oxide red C177491, macrogol 8000, **sucrose**, talc-purified, titanium dioxide

Questions?

02 9000 5000 (Aus) or visit www.viffarol.com.au

Medicine Facts

Please read the Medicine Information Leaflet inside the pack before using Viffarol.

Active ingredient	Purpose
Each Viffarol tablet contains: **Diclofenac potassium 25mg** (NSAID)* *non-steroidal anti-inflammatory drug	Anti-inflammatory pain reliever.

Uses

Short term relief of pain and swelling related to migraines, back, joints, period pain, or sprains and strains.

Do not use Viffarol if:

- You are **pregnant**
- You have heart failure
- You have kidney problems
- You are less than 14 years old
- You have a stomach ulcer or other stomach or bowel problems
- You are allergic to any of the ingredients in Viffarol, or other anti-inflammatory medicines like aspirin

How to take Viffarol

- Adults and children older than 14 years:
  - Take 2 tablets at first.
  - Then take 1 or 2 tablets every 8 hours if needed.
- Do not take more than 8 tablets in 24 hours.
- Do not take Viffarol for more than 3 days at a time. Check with your doctor before taking for any longer.

Things to be careful of when taking Viffarol

- Do not take Viffarol together with other anti-inflammatory medicines.
- Do not take other medicines that also contain diclofenac.
- Common side effects: feeling sick, stomach upset, feeling dizzy.
- Talk to your doctor or pharmacist if your problems get worse or do not get better.

Other information

Call the Poisons Information Centre (13 11 26) or go to the hospital straight away if you have taken too much.
For more information: 02 9000 5000 (Aus) or visit **www.viffarol.com.au**
Store in a cool, dry place at room temperature (below 30°C)

Viffarol *25 mg tablets*

Diclofenac Potassium

Inactive ingredients

Silica colloidal anhydrous, calcium phosphate, magnesium stearate, starch-maize, povidone, sodium starch glycollate, cellulose-microcrystalline, iron oxide red C177491, macrogol 8000, **sucrose**, talc-purified, titanium dioxide

Please read the Medicine Information Leaflet inside the pack before using Viffarol.

What is Viffarol used for?

✓ Short term relief of pain and swelling related to migraines, back, joints, period pain, or sprains and strains.

How do you take Viffarol?

Adults and children older than 14 years	- Take 2 tablets at first. - Then take 1 or 2 tablets every 8 hours if needed. Do not take more than 8 tablets in 24 hours.

Do not take Viffarol for more than 3 days at a time. Check with your doctor before taking for any longer.

Do not use Viffarol if you:

- ✗ Are **pregnant**
- ✗ Have heart failure
- ✗ Have kidney problems
- ✗ Are less than 14 years old
- ✗ Have a stomach ulcer or other stomach or bowel problems
- ✗ Are allergic to any of the ingredients in Viffarol, or other anti-inflammatory medicines like aspirin

What should I be careful of when taking Viffarol?

- ✗ Do not take Viffarol together with other anti-inflammatory medicines.
- ✗ Do not take other medicines that also contain diclofenac.
- • Common side effects: feeling sick, stomach upset, feeling dizzy.
- • Talk to your doctor or pharmacist if your problems get worse or do not get better.

Other information

Call the Poisons Information Centre (13 11 26) or go to the hospital straight away if you have taken too much.
For more information: 02 9000 5000 (Aus) or visit www.viffarol.com.au
Store in a cool, dry place at room temperature (below 30°C)

What are the ingredients in Viffarol?

Active ingredient: Each Viffarol tablet contains **Diclofenac potassium 25mg**
Inactive ingredients: silica colloidal anhydrous, calcium phosphate, magnesium stearate, starch- maize, povidone, sodium starch glycollate, cellulose-microcrystalline, iron oxide red C177491, macrogol 8000, **sucrose**, talc-purified, titanium dioxide

Developing alternative over-the-counter medicine label formats: how do they compare when evaluated by consumers?

Highlights

- Four alternative label formats for diclofenac were developed with consumer input in response to proposed changes to Australian over-the-counter (OTC) medicine labeling legislation.
- All label formats demonstrated good usability, superior to that for an existing OTC diclofenac label.
- Consumers expressed diverse opinions on the label formats' design and content.
- The proposed Therapeutic Goods Administration's (TGA) standardized label format was only "most preferred" by 4 out of 50 consumers in total.
- Both user testing data and consumer perspectives reinforced the need to optimize the TGA proposed standardized label format.