

An Investigational Study on the Legibility of Eye Drops' Labels

A. S. BOHRA AND P. TIWARI*

Department of Pharmacy Practice, National Institute of Pharmaceutical Education and Research (NIPER), S. A. S. Nagar, Punjab-160 062, India.

The safe use of medicines depends upon the ability of users to read the information on the medicine label carefully and accurately and being able to act accordingly. The label provides important information on the use of the medicines, which helps the users to make correct use of their medicines. However, legibility is often a problem encountered in the labeling of small packages like eye/ear drops. The consumers as well as health professionals find labels difficult to read because of a number of reasons such as very small letters, poor quality of printing and poor colour contrast. This study aims not only to evaluate the legibility of information on the primary label of the eye drops but also to identify the problem(s) pertaining to its legibility.

Medicines are an essential part of human life and the safety of medicines is of utmost importance in providing pharmaceutical care to the patients. The labeling of medicines also plays an important role since the safe use of the medicines depends upon the users' understanding the medicine labeling accurately. Such understanding helps the users to assimilate the information presented and act accordingly. (<http://www.mca.gov.uk/inforesources/publications/bpglabpack.pdf>. Accessed on March 12, 2004). Since the primary label is pasted on the container, it is a valuable spot for information especially to those willing to read it.

A label is a written, printed or graphic matter on or attached to a container to identify its contents and inform the consumer about its qualities, uses and hazards. (<http://www.mca.gov.uk/inforesources/publications/>

[bpglabpack.pdf](http://www.mca.gov.uk/inforesources/publications/bpglabpack.pdf). Accessed on March 6, 2004) The purpose of the label on a medicine is to identify it, to achieve appropriate handling and storage, and to allow the product to be traced if there are problems with the manufacturing, prescribing or dispensing process. It is important to mention that an appropriate label contribute to optimal therapeutic outcome and helps to avoid medication errors.

The legibility of the labels is, often, a problem encountered in the labeling of small containers. The users find difficulty in reading a label, as the letter size(s) is very small. Apart from small letter size, other factors such as narrow letters, poor printing and inappropriate colour contrast also contribute towards decreased legibility of information on the label (<http://pharmacos.eudra.org/f2/edu/g1981002.pdf>; Accessed on April 5, 2004). Eye drops are widely utilized for the treatment of various ocular diseases and this is especially relevant as many of the users are elderly patients. This

*For correspondence

E-mail: ptiwari@niper.ac.in

study aims not only to evaluate the legibility of information on the primary label of the eye drops but also to identify the problem(s) pertaining to its legibility.

This questionnaire-based study covered the top ten selling eye drops as per the ORG-IMS data (Table 1). The ten products were randomly assigned to five groups, each having two products. A total of 100 subjects (comprising two-third respondents from community and one-third from pharmacy/healthcare background) were asked to evaluate each pair of eye drops. Since the labels were in English, the working knowledge of English was a prerequisite for all the respondents.

The questionnaire used for this study consisted of two sections. The first section had four questions concerned with readability of the brand name, composition, directions for use/instructions and storage condition(s). The respondents had three options to answer each one of these questions - viz. yes, no or with difficulty. If the subjects experienced difficulty in reading the information on the label, they were asked to identify the reasons for the difficulty in reading the information and these reasons comprised the second section of the questionnaire.

Additionally, an objective scoring criteria (also referred to as Label Legibility Score or LLS) was also developed by the investigators to assess the legibility of each label on six different parameters viz. a) Letters and appearance, b) Colour contrast, c) Paper quality and texture, d) Printing quality, e) Quality of ink used for printing of the batch number/manufacturing date/expiry date and f) Proportion of unused space on the label. Appropriate weightage was attached to each of the parameters and a product could score a maximum of 7 points.

The respondents from age group of 15 to 60 y (average \pm SEM; 33.41 \pm 0.54 y) participated in this study.

TABLE 1: TOP TEN SELLING EYE DROPS

Product name	Manufacturer
Ciplox	Cipla Ltd.
Pyrimon	FDC Ltd.
Iotim	FDC Ltd.
Flur	Allergan India Ltd.
Dexcin	Syntho pharmaceuticals Ltd.
Betnesol-N	GlaxoSmithkline
Genticyn	Allergan India Ltd.
Itone	Dey's medical stores Ltd.
Locula	East India pharmaceuticals Ltd.
Refresh tears	Allergan India Ltd.

The product name (brand name) was printed in large and bold letters on most of the products. All the respondents could easily read brand name on products such as Ciplox, Dexcin, Iotim, Locula and Refresh Tears. However, 10-15% respondents had difficulty in reading the brand name on Flur and Betnesol-N. Approximately two-third of the respondents either had difficulty or could not read the composition on Genticyn label whereas nearly 40% of the respondents faced difficulty reading the compositions on Pyrimon, Timolol, Flurbiprofen and Betnesol-N.

Nearly two-third of the respondents found it difficult to read the storage conditions on the labels of Pyrimon, Ciplox, Timolol and Flur. It is important to mention that storage condition was missing from Dexcin and Genticyn label. Between 52-80% of the respondents faced difficulty in reading the directions for use/instruction on Pyrimon, Timolol, Flur and Betnesol-N.

The analysis of the reasons for the difficulty in legibility showed that the small size of the letters was the major reason in most of the labels. All the respondents complained about small letter size of the information on Genticyn label whereas these percentages for Pyrimon, Flur, Timolol ranged between 85-96%. Over two-thirds of the respondents also complained about small letter size of the information on Betnesol-N. Further, the respondents found narrow letters as reason for difficulty in reading the information especially on the labels of Pyrimon, Genticyn, Timolol and Flur. Most of the labels had good quality of printing except Genticyn. For Pyrimon and Genticyn, more than half of the respondents polled for poor colour contrast.

The respondents identified Locula and Refresh Tears eye drops to be the two best labels studied. A majority of the respondents had no difficulty in reading their brand name, composition, storage condition, and directions for use/ instruction on these two labels. The number of the respondents who identified small letter size as reason for difficulty in reading the Locula and Refresh Tears labels was very small. It is equally important to note that none of the respondents found difficulties with narrow letters, poor quality of printing and poor colour contrast on these two labels.

Similarly, Genticyn and Pyrimon were identified as the two poorest labels in this study. The respondents had difficulty in reading information on these labels and most

TABLE 2: LABEL LEGIBILITY SCORES FOR EYE/EAR DROPS

	Letters and appearance	Colour contrast	Quality and texture of paper/foil	Printing quality	Quality of ink used	Proportion of unused space	Total score
Weightage	2	1	1	1	1	1	7
Ciplox	1	1	0.5	1	1	0.5	5
Pyrimon	1	0.5	0.5	0.5	1	0	3.5
lotim	1	1	0.5	1	1	0.5	5
Flur	1	0.5	0.5	0	1	0.5	3.5
Dexcin	2	1	0.5	1	1	0.5	6
Betnesol-N	1	0	0.5	0.5	1	0.5	3.5
Genticyn	0	0	0.5	0	1	0.5	2
Itone	2	1	NA	1	1	0.5	5.5
Locula	2	1	1	1	1	1	7
Refresh Tears	2	1	0.5	1	1	1	6.5

NA- Not applicable

of the respondents complained about small letter size, narrow letters and poor quality of printing.

Based upon the scoring criteria for labels, it was found that Locula label scored a full 7 and Refresh Tears label 6.5. This scoring is in concurrence with the findings of the respondents. Likewise, the scores for Genticyn and Pyrimon were 2 and 3.5 on a scale of 7, respectively. This too is in concurrence with the options chosen by the respondents.

The ten products and their scores on the criteria used in the study are presented in Table 2. As many as six products could not score 2 on the letter and appearance criteria; four of them had poor ranking on the contrast issue, and only two products scored 100% for the quality and texture of paper used in the label.

Finally, on the basis of this study, the recommendations that have emerged for improving the legibility of labels on eye/ear drops are as follows; 1. The letter size should be proportionate depending upon the area of the label. Letters should be spaced appropriately, 2. The clumsy appearance of information on the labels should be

avoided, 3. Use of bold letters should be confined only for emphasizing particular information. Use of all capital and italic letters should be avoided, 4. Both upper and lower case lettering should be used, 5. Important information regarding the use of medicine, directions for use, warnings should be highlighted on the label by either using boxes or different colours, 6. Appropriate colour contrast should be chosen in view with the colour of the paper of the label and 7. Good quality of ink, which does not fade or smudge easily, should be used for printing the labels.

This study has evaluated the primary labels of the ten top selling brands of eye drops and the reasons responsible for the poor readability on the labels thereof. The improved labels will help in better understanding of the information and lead to desired outcomes of pharmacotherapy using eye/ear drops.

Accepted 26 October 2006

Revised 5 January 2006

Received 17 May 2005

Indian J. Pharm. Sci., 2006, 68 (5): 677-679