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RESEARCH ARTICLE

# Profile of eye drops labelling of pharmacies' prescription service in Surabaya

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## Abstract

**Background:** Drug labelling in prescription services is a critical stage because it contains information about the use of medicines. **Objective:** This study aimed to discover the drug information listed on the label of the eye drops prescription service at pharmacies in Surabaya. **Method:** An observational study with a cross-sectional design was used to conduct this research. Data collection was performed with the simulated patient method. The information on the label was examined using a checklist based on the "FIP Guidelines for The Labels of Prescribed Medicines" and the Minister of Health Regulation No. 73 of 2016. **Result:** Of 138 pharmacies visited in this study, 105 (76%) pharmacies dispensed the drug, and 83 (79%) pharmacies placed a label on the drug. The information that appeared the most was the pharmacy name (100.0%), pharmacy address (95.2%), patient name (90.4%), individual dosage instructions (100.0%), and dispensing date (88.0%). Then, the indicators that appear the least include the product name (9.6%), dosage form (2.4%), amount of drug (4.8%), expiration date (1.2%), and storage instructions (2.4%). **Conclusion:** Eye drops need to be maintained for their safety and efficacy. Hence, the period after opening needs to be included in the label.

## Introduction

The labelling of dispensed medicine is one of the stages in dispensing prescription drugs. Dispensing labels must contain information about drugs clearly and easily understood by the patient and can be used to avoid medication errors. Medication error is any failure in the treatment process that can lead to adverse drug reactions. One type of medication error is a dispensing error. Dispensing with the wrong information on the label is one of the categories of dispensing errors (Aronson, 2009; Cheung *et al.*, 2009). Research on medication errors in community pharmacies found that improper labelling (4%) occurred at the dispensing stage (Pervanas *et al.*, 2016). In addition, 92.77% of patients wanted complete drug labelling (Ressandy, 2019). There is a lack of public knowledge about the shelf life of eye drop preparations, indicated by the presence of people (38.1%) who think these preparations can be stored for more than a month after the packaging is opened (Medisa *et al.*, 2020). The results of research

on the public regarding knowledge, attitudes, and practices toward self-medication eye drops have shown that respondents always touch the bottle nozzle when using eye drops (5.2%), share eye drops with others (18.3%), and do not wash hands before using eye drops (15.6%) (Alessa *et al.*, 2022). Eye drops were chosen because they have special information to ensure their appropriate use compared to oral preparations. This is because the use of eye drops is based on which eye needs to be dropped and how many drops according to the doctor's instructions. In addition, information regarding the period after opening also needs to be included because eye drops are sterile preparations with a limited shelf life.

Indonesia has no guidelines or national standards for making prescription labels. Thus, the possible contents of the information on the label will be very diverse. A study on drug labels has been investigated in Thailand. This study found information that is mostly written on drug labels, including drug use directions (75.5%); drug

indications (67.3%); and the pharmacy name, address and telephone number (59, 2%). On the other hand, respondents did not write down the pharmacist's signature (77.6%), the patient's name (61.2%), and the date of drug delivery (46.9%) (Tungswatdirat *et al.*, 2018). The data in that study were collected using a questionnaire, so it may not describe the situation in the pharmacy. The simulated patient method was used in this study to describe the real situation in a community pharmacy setting. Thus, the aspects of drug labelling and the drug information listed on the label of the eye drops prescription service at pharmacies in Surabaya can be identified.

## Methods

### Study design

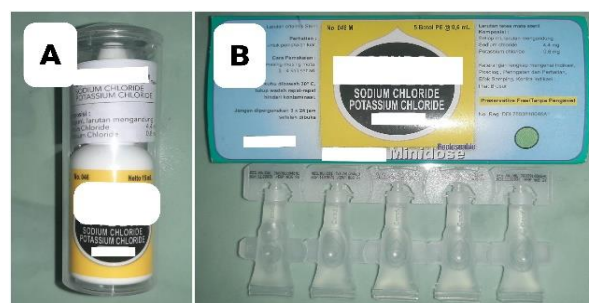
An observational cross-sectional study was designed. A simulated patient method was used for the data collection. The sample was taken using a simple random sampling technique from all pharmacies in Surabaya. The minimum sample size of 82 pharmacies was needed based on a 95% confidence level with a 5% margin of error. A checklist based on the "FIP Guidelines for the Labels of Prescribed Medicines" and the Ministry of Health directive No. 73/2016 was used to examine the information. Descriptive analysis was used to analyse the findings. The sample medicines used were eye drops for the treatment of dry eyes, prescribed for children aged four years.

## Results

The data collection process was carried out after obtaining ethical approval with letter number No.5/LE/2022 issued by the Health Research Ethics Committee of the Faculty of Pharmacy, Universitas Airlangga. A total of 138 pharmacies were visited in this study. There were 105 (76%) pharmacies that dispensed the drugs, while the labels found 83 (79%). The results of the eye drop label observations are listed in Table I. It was also found that two drugs were given in different package forms from those prescribed, resulting in different volumes of eye drops. These different packaging forms can be seen in Figure 1.

**Table I: List of information in eye drops label (n=83)**

Information	Indicators	n(%)
Pharmacy data	Pharmacy name	83 (100.0)
	Pharmacy address	79 (95.2)
	Pharmacy telephone number	71 (85.5)
	Logo	49 (59.0)
Pharmacist data	Pharmacist name	70 (84.3)
	SIPA (Pharmacist license) number	41 (49.4)
	SIA (Pharmacy license) number	27 (32.5)
Patient data	Patient's name	75 (90.4)
Drug data	Product name	8 (9.6)
	Dosage form	2 (2.4)
	Drug amount	4 (4.8)
	Individual dosage instructions	83 (100.0)
	a. Frequency of administration	83 (100.0)
	b. Number of drops	81 (97.6)
	Administration route	72 (86.7)
	Expiry date	1 (1.2)
	Storage instructions	2 (2.4)
	Date of dispensing	73 (88.0)
Prescription number	45 (54.2)	



**Figure 1: Prescribed eye drops (A) and dispensed eye drops (B)**

## Discussion

From the results of observations, it was discovered that the information mostly included in the label was the name of the pharmacy (100.0%), pharmacy address (95.2%), patient name (90.4%), individual dosage instructions (100.0%), and date of dispensing (88.0%). On the other hand, the product name (9.6%), dosage form (2.4%), amount of drug (4.8%), expiration date (1.2%), and storage instructions (2.4%) were the information least listed on the label.

Two eye drops were obtained with a mini-dose of 0.6 mL, which did not match the prescription's requested packaging forms. If this is dispensed, there will be a possibility of a less therapeutic period because the

preparations are small and the price is relatively high compared to bottle packaging.

The patient's name was one of the indicators that appeared the most. However, the resulting percentage was not optimal. It is important to include the patient's name on the label so that the drug is not accidentally exchanged with family members in the same house and with other patients at the pharmacy if there are many patients on the same day (Mekonen et al., 2014).

Most of the labels had provided correct dosing instructions with the sentence 'four times a day, one drop in each right and left eye'. However, two labels were written with wrong usage instructions. On one label said 'once a day in the right and left eye', and on one label said "four times a day in the left eye". In addition, both labels did not state the number of drops per use. These inappropriate directions were medication errors at the dispensing stage which would result in administration errors due to inappropriate doses.

This instruction is important to note because a study conducted in Japan revealed that patients only used eye drops to relieve the symptoms of dry eye. It was ineffective because the abnormal function of the corneal epithelium and tear film instability were still present, and the patient might soon experience a recurrence of symptoms (Uchino et al., 2022).

From Table I, it can be seen that there was one label that contained information on the expiry date (26-09-2024). However, the stated expiration date becomes invalid after opening the drug packaging. The sterility of eye drops needs to be maintained. Sterile preparations such as eye drops become unsterile once opened and can pose a serious risk of infection if used beyond the period after opening. Therefore, eye drops should be discarded four weeks after opening unless specified by the manufacturer (Rees, 2014). This unsterility is caused by contamination from various bacteria in the environment. Unsealing time, frequency of use, and contact with the eyelids or the surrounding environment are risk factors that can lead to contamination (Wang et al., 2021).

The storage instructions found only said 'keep out of reach of children'. In fact, some dosage forms require proper storage to maintain product stability. The stability of pharmaceutical products is important because it can maintain the therapeutic efficacy of a drug. Stability is influenced by temperature, material quality, manufacturing quality, humidity, and sunlight (Ali et al., 2016). Complete instructions such as 'Keep in a cool place (less than 30°C), away from direct sunlight and moisture' should be included on the label.

According to FIP guidelines for the labels of prescribed medicines, some indicators were not listed by pharmacy staff, including the generic name of the active ingredients, strength, and individual indication or intended use. Indications or purposes of use can be listed on the label because they have benefits in improving medication management, increasing understanding of drugs, increasing medication adherence, and possibly reducing medication errors (Garada et al., 2017).

## Conclusion

Generally, the pharmacy data listed on the label at the Surabaya City pharmacy are almost the same. As for the pharmacist data listed, it looks varied. The patient data found in this study were only the patients' names. The preparation of eye drops needs to be maintained for safety and efficacy. Therefore, the period after opening is important to be added to the label.

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