# PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

Schedule 0

# PROPERTY NAME AND DOSAGE FORM

## **PREFRIN Liquifilm Sterile Eye Drops, phenylephrine hydrochloride** 1,2 mg/ml

# Read all of this leaflet carefully because it contains important information for you

PREFRIN Liquifilm is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use PREFRIN Liquifilm carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PREFRIN Liquifilm with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

# 1. WHAT PREFRIN LIQUIFILM CONTAINS

- The active substance is phenylephrine hydrochloride 1,2 mg/ml.
- The preservative is benzalkonium chloride 0,005 % m/v.
- The other ingredients are polyvinyl alcohol (Liquifilm), sodium phosphate dibasic anhydrous, sodium phosphate monobasic, disodium edetate, sodium acetate anhydrous, sodium thiosulphate anhydrous, purified water. Sodium hydroxide or hydrochloric acid may be added to adjust the pH.

# 2. WHAT PREFRIN LIQUIFILM IS USED FOR

PREFRIN Liquifilm is a lubricating decongestant that whitens the eyes and is used for the relief of minor eye irritations caused by colds, hay fever, dust, smog, hard contact lenses, sun, swimming, wind, when no infection is present.

# 3. BEFORE YOU USE PREFRIN LIQUIFILM

# Do not use PREFRIN Liquifilm:

- If you are hypersensitive (allergic) to phenylephrine hydrochloride or any of the other ingredients of PREFRIN Liquifilm;
- If you have narrow angle glaucoma;.
- While you are wearing soft contact lenses.

# Take special care with PREFRIN Liquifilm:

- If you have arteriosclerosis (hardening of artery walls), high blood pressure, an overactive thyroid gland, enlargement of the prostate, or diabetes;
- If you are taking monoamine oxidase (MAO) inhibitors (found in some anti-depressants), or within 2 weeks from stopping MAO-inhibitor therapy;

- If you have a red, inflamed eye;
- If you have an extensive eye surface disease, special care should be taken when using eye drops with benzalkonium chloride as preservative such as PREFRIN Liquifilm;
- Do not use PREFRIN Liquifilm for a prolonged period of time and have regular eye examinations;
- Use of PREFRIN Liquifilm in children is not recommended.

## **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before using PREFRIN Liquifilm.

Safety and efficacy in pregnancy and breastfeeding have not been established.

## Driving and using machinery

PREFRIN Liquifilm may cause your pupils to dilate and short-term blurring of vision when used. Do not drive or operate hazardous machinery unless your vision is clear.

## Important information about some of the ingredients of PREFRIN Liquifilm

Do not use PREFRIN Liquifilm while your contact lenses are in your eyes. Remove your lenses before using PREFRIN Liquifilm, and wait at least 15 minutes before putting your lenses back into your eyes. A preservative called benzalkonium chloride may cause eye irritation and is also known to discolour soft contact lenses.

### Taking other medicines with PREFRIN Liquifilm

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

The following medicines may interfere with PREFRIN Liquifilm:

- Medicines to treat depression or anxiety;
- Medicines to treat high blood pressure (hypertension);
- Medicines to treat heart conditions.

# 4. HOW TO USE PREFRIN LIQUIFILM

Do not share medicines prescribed for you with any other person.

Always use PREFRIN Liquifilm exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one or two drops of PREFRIN Liquifilm in each eye, every 3 to 4 hours if needed.

After putting a drop into the eye, keep the eye closed and press your finger against the corner of your eye (the side where your eye meets your nose) for two minutes. This helps to prevent PREFRIN Liquifilm from getting into the rest of the body.

To avoid eye injury or contamination, do not let the tip of the bottle touch your eye or anything else.

If you have the impression that the effect of PREFRIN Liquifilm is too strong or too weak, talk to your doctor or pharmacist.

# If you use more PREFRIN Liquifilm than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

An ocular overdosage may rarely cause systemic effects like palpitation, changes in the way your heart beats, heart contractions, headache, paleness of the skin, trembling, increased sweating and high blood pressure. In case of an overdose in the eyes, wash the eyes with lots of water or saline solution and seek medical help.

## If you forget to take PREFRIN Liquifilm

Do not take a double dose to make up for forgotten individual doses.

# 5. POSSIBLE SIDE EFFECTS

PREFRIN Liquifilm can have side effects. Not all side effects reported for PREFRIN Liquifilm are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using PREFRIN Liquifilm, please consult your doctor, pharmacist or other healthcare provider for advice.

The following side effects may occur:

# Affecting the eyes

Enlarged pupils, dry eye, eye discharge, eye irritation, eye pain, itchy eyes, increased tearing, redness of the eye, blurred vision

# Affecting the body

Allergic reaction, including signs of eye allergy and skin allergy.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

# 6. STORING AND DISPOSING OF PREFRIN LIQUIFILM

Do not store above 25 °C. Keep bottle tightly closed when not in use. Do not use for more than

30 days after first opening. Store all medicines out of the reach of children.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 7. PRESENTATION OF PREFRIN LIQUIFILM

PREFRIN Liquifilm is supplied in sterile dropper bottles containing 15 ml solution.

### 8. IDENTIFICATION OF PREFRIN LIQUIFILM

A clear colourless solution.

#### 9. REGISTRATION NUMBER

J/15.4/84

### 10. NAME AND ADDRESS OF THE OF THE REGISTRATION HOLDER

Allergan Pharmaceuticals (Pty) Ltd 30 New Road (entrance off Bavaria Road) Randjespark Ext. 11, Midrand, 1682 Johannesburg, Gauteng SOUTH AFRICA

Telephone number: 011 545 6600

### **11. DATE OF PUBLICATION**

Date of registration: 23 December 1976 Date of the most recently revised Patient Information Leaflet as approved by the Authority: 23 December 1976

Professional Information can be accessed via <u>http://www.allergan.co.za/en-za/products</u> In case of an adverse event, please contact +27 11 545 6600 or send an email to <u>SA\_Complaints@Allergan.com</u>