PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

REFRESH Polyvinyl alcohol 14 mg/ml and **Povidone** 6 mg/ml, **Ophthalmic Solution** (eye drops).

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

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

- Keep this leaflet. You may need to read it again.
- Do not share REFRESH 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.

1. WHAT REFRESH CONTAINS

- The active substances in REFRESH are polyvinyl alcohol and povidone.
- The other ingredients are purified water and sodium chloride.

2. WHAT REFRESH IS USED FOR

REFRESH is used for the symptomatic relief of irritated dry eyes and symptoms of dry eyes. May also be used as a comfort drop while wearing hard or soft contact lenses.

3. BEFORE YOU USE REFRESH

Do not use REFRESH

If you are hypersensitive (allergic) to polyvinyl alcohol, povidone or any of the other ingredients of REFRESH.

Take special care with REFRESH

• If eye irritation, eye pain, continued redness and change in vision occurs or worsen, increases or persists for more than 24 hours, discontinue use and consult your healthcare provider.

• If solution changes colour or becomes cloudy, discontinue use.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before using REFRESH.

Driving and using machinery

REFRESH may cause temporary blurred vision which may impair the ability to drive or operate machines. Do not drive or use hazardous machinery unless your vision is clear.

Using other medicines with REFRESH

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

If you use REFRESH with another eye medicine, leave at least 15 minutes between putting in REFRESH and the other medicine.

4. HOW TO USE REFRESH

Do not share your medicines with any other person. The usual dose is one or two drops in each eye as needed.

Ensure that the container is intact before use. To open, twist off the tab. Apply one or two drops in each eye as needed, or as directed. There is no special dosage schedule for the elderly or for children.

In order to avoid contamination, the dropper should not be allowed to touch the eye or any other surface. Use immediately after opening. Do not store opened container. Discard after use.

If you are wearing soft contact lenses wait at least 15 minutes after instilling REFRESH to insert soft contact lenses back in the eye.

If you use more **REFRESH** than you should

If you use more REFRESH than you should it is unlikely to cause you any serious harm. In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use REFRESH

If you forget to use REFRESH, use a single drop in each eye that needs treatment as soon as you remember, and then revert to your regular routine. Do not use a double dose to make up for a forgotten dose.

5. POSSIBLE SIDE EFFECTS

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

The frequency of the following side effects is not known (cannot be estimated from available data).

Eye disorders

- Eye irritation
- Eye pain
- Eye discharge
- Itchiness
- Redness
- A feeling of something in the eye
- Increased tear flow
- Blurred vision

Immune System Disorder

- Hypersensitivity
- Allergic reaction

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

6. STORING AND DISPOSING OF REFRESH

- Store unopened container below 25 °C.
- Do not store opened container.
- Discard after use.
- Store all medicines out of reach of children.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).
- Do not use after expiry date stated on the label / carton

7. PRESENTATION OF REFRESH

Cardboard cartons containing 30 single-use containers per carton.

8. IDENTIFICATION OF REFRESH

A clear, colourless to slightly yellow solution.

9. **REGISTRATION NUMBER**

Z/15.4/348

10. NAME AND ADDRESS OF 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: 28 October 1992

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