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## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

Schedule 0

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**REFRESH TEARS®**, Carboxymethylcellulose sodium 5 mg/ml lubricating eye drops

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

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

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

- The active substance is carboxymethylcellulose sodium 5 mg/ml
- Other ingredients are Purite® (stabilised oxychloro complex, solution) as preservative, sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, boric acid, sodium borate decahydrate, and purified water.

### 2. WHAT REFRESH TEARS® IS USED FOR

REFRESH TEARS® is a tear substitute and contains a lubricant called carboxymethylcellulose sodium. It is used for the treatment of the symptoms of dry eye (such as burning, irritation, dryness or eye pain).

### 3. BEFORE YOU USE REFRESH TEARS®

#### **Do not use REFRESH TEARS®**

- If you are hypersensitive (allergic) to carboxymethylcellulose sodium or any of the other ingredients of REFRESH TEARS®.
- In infants and small children under 3 years.
- If the solution changes colour or becomes cloudy.

### **Take special care with REFRESH TEARS®**

- If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if your condition worsen or persists for more than 72 hours stop using the product. In these cases, consult your doctor or pharmacist.

### **Pregnancy and breastfeeding**

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

### **Driving and using machinery**

REFRESH TEARS® is not expected to cause blurred vision. If you do experience temporary blurring, do not drive or use machines until your sight is clear.

### **Using other medicines with REFRESH TEARS®**

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

If you use REFRESH TEARS® with another eye medicine, leave at least 15 minutes between putting REFRESH TEARS® and the other medicine. Use any eye ointment or eye gel last.

## **4. HOW TO USE REFRESH TEARS®**

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

Follow these instructions unless your pharmacist or doctor gave you different advice.

The usual dose is 1 drop of REFRESH TEARS® in each affected eye, 4 times a day or as needed. You do not need to remove contact lenses before using REFRESH TEARS®.

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



Always wash your hands before applying eye drops. Apply your eye drops in the following way:

1. Tilt your head back and look at the ceiling. Hold the bottle, tip lowermost over your eye.

2. Gently pull the lower eyelid down until there is a small pocket between the inside of the lower eyelid and the eyeball.
3. Squeeze the upturned dropper bottle to release a drop into your eye.

Replace and tighten the cap immediately after use.

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

It will not cause you any harm. If you are however worried, talk to your doctor or pharmacist.

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

**5. POSSIBLE SIDE EFFECTS**

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

The most common side effects are burning feeling in the eye, eye dryness, eye irritation/itching, eye discomfort and disturbed vision (affecting less than 3 in 100 people).

Less frequent effects are eyelid swelling, eye watering, redness of eyelid, redness of the eye, eye pain, foreign body sensation in the eye, hypersensitivity including eye allergy, and sticky eye (affecting less than 1 in 100 people).

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

**6. STORING AND DISPOSING OF REFRESH TEARS®**

- Store at or below 25 °C. Do not refrigerate.
- Keep the container tightly closed.
- Store all medicines out of the reach of children.
- Do not use more than 30 days after first opening.
- Do not use after the expiry date stated on the bottle.

**7. PRESENTATION OF REFRESH TEARS®**

REFRESH TEARS® is available in teal green opaque plastic dropper bottle with a screw cap, containing 15 ml of solution.

## **8. IDENTIFICATION OF REFRESH TEARS®**

REFRESH TEARS® is a clear, colourless to slightly straw-coloured solution, practically free from particulate matter.

## **9. REGISTRATION NUMBER**

37/32.5/0092

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

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

## **11. DATE OF PUBLICATION**

Date of registration: 12 November 2004

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