

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### OFTALMOL

0.5%w/v Eye Drops, Suspension

PREDNISOLONE ACETATE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What OFTALMOL is and what it is used for
2. Before you take OFTALMOL
3. How to take OFTALMOL
4. Possible side effects
5. How to store OFTALMOL

#### 1. WHAT OFTALMOL IS AND WHAT IS IT USED FOR

OFTALMOL contains a corticosteroid.

It is used to treat inflamed eyes (red and painful) for which the inflammation is not caused by an infection. The part of the eye affected will vary depending on the cause of the inflammation.

This medicine is indicated for children, adults and the elderly.

#### 2. BEFORE YOU TAKE OFTALMOL

##### **Do not use these drops if**

- you are allergic to the active substance (prednisolone) or any of the other ingredients.
- you have high pressure inside the eye or you are at risk of developing glaucoma. Your doctor will have checked for this.
- you have an eye infection.
- it is intended for long term continuous therapy in children (at the discretion of the physician).

##### **Children**

In children, continuous, long term use of these eye drops should be avoided. Check with your doctor if your child has been using this medicine for a long time. The doctor or eye specialist may decide to prescribe an alternative.

Using other medicines

**OFTALMOL can increase the effects of:**

- medicine used to treat epilepsy (barbiturates)
- medicine used to help you sleep or to relieve anxiety (sedative hypnotics)
- medicine used to treat depression (tricyclic antidepressants).

**OFTALMOL can decrease the effects of:**

- medicines such as anticholinesterases (indicated for reduced intestinal movement and for myasthenia gravis (a muscle weakening disease)).
- medicines used to treat infection of the eye caused by a virus
- medicines similar to aspirin called salicylates (indicated for inflammation, pain, fever and blood thinning).

If you are taking any of these medicines, or if you are unsure, talk to your doctor or pharmacist.

If you are pregnant, may be pregnant, or are breastfeeding

Tell your doctor or eye specialist, he/she may decide to use these drops or to prescribe you an alternative.

### **Contact lenses**

Your doctor will ask you to remove your contact lenses prior to the administration of the drops. There is no information on the effect of this product on contact lenses. Therefore do not wear contact lenses until the effects of the drops have completely worn off.

### **Driving and using machines**

As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines.

## **3. HOW TO TAKE OFTALMOL**

### **Dosage**

- The normal adult dose is 1 to 2 drops in one or both eyes as often as directed by your doctor.
- The dose for children will be decided by the doctor or eye specialist.

### **Method of administration**

If you are putting the eye drops in yourself, then follow these instructions carefully:

1. Wash your hands.
2. Use a mirror, this will help you to see what you are doing.
3. Carefully dry your eyes using a tissue, and twist off the cap from the OFTALMOL body of the unit.
4. Pull your lower eyelid down gently, and then carefully place 1 or 2 drops inside your lower eyelid.

**Make sure the dropper does not touch any parts of your eye.**

5. Close your eye and blink a few times to make sure your eye is covered by the liquid.
6. Close the eyelids. It is advisable to press gently on the inner corner of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.
7. Repeat steps 4, 5 and 6 for the other eye if necessary.

**If your eyes get worse** or are not better after a few weeks of using the eye drops, see your doctor or eye specialist or pharmacist.

This medicine should not be used for long term and frequent use without talking to your doctor or pharmacist.

***If you use more OFTALMOL than you should***

An overdose is very unlikely to occur. If you suddenly feel unwell after using the drops, tell your doctor or eye specialist or contact the nearest emergency department immediately.

***If you forget to use OFTALMOL***

You should take the missed dose as soon as you remember, unless it is nearly time for the next dose, but you should not take a double dose to make up for a missed dose.

***4. POSSIBLE SIDE EFFECTS***

Most people who are treated with these eye drops do not suffer from any side effects.

Long term, frequent use of corticosteroids can lead to clouding of the lens in the eye (cataract) or to an increase of the pressure inside the eye.

Consult your doctor if you feel any changes in your eyesight.

If any of the side effects gets serious, please seek immediate medical attention. If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

***5. HOW TO STORE OFTALMOL***

Keep out of the reach and sight of children.

Do not use the eye drops after the expiry date which is stated on the overwrap of each unit and on the carton after the letters "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze. Store in original package in order to protect from light.

Discard the bottle 28 days after opening, even if there is solution remaining.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.