

## **Package leaflet: Information for the patient**

### **Zoftacot 3.35 mg/ml eye drops, solution in single-dose container**

Hydrocortisone sodium phosphate

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Zoftacot is and what it is used for
2. What you need to know before you use Zoftacot
3. How to use Zoftacot
4. Possible side effects
5. How to store Zoftacot
6. Contents of the pack and other information

#### **1. What Zoftacot is and what it is used for**

This medicine is an eye drops solution in single-dose containers, which contains a substance called hydrocortisone. This substance is a corticosteroid which reduces inflammatory symptoms.

It is used to treat mild allergic or inflammation conditions that affect the clear lining that covers the whites of your eye(s) and the insides of your eyelids (your conjunctiva).

The eye should not be infected (see Do not use Zoftacot).

#### **2. What you need to know before you use Zoftacot**

##### **Do not use Zoftacot:**

- If you are allergic to the active substance (hydrocortisone) or any of the other ingredients of this medicine (listed in section 6).
- If you have high pressure inside the eye (ocular hypertension), known to be due to glucosteroids (family of corticosteroid medicines) or to other causes.
- If you have an eye infection caused by viruses (acute herpes or most other viruses while there are ulcers, unless the infection is being treated with an anti-infective treatment for herpes virus).
- If you have conjunctivitis with inflammation and ulcers on the clear cornea surface of the eye (keratitis) even if it is at an early stage.
- If you have an eye infection caused by bacteria (acute purulent infection, conjunctivitis, blepharitis, stye).
- If you have an eye infection caused by fungus (ocular mycosis).
- If you have a bacterial infection called tuberculosis which affects your eye (ocular tuberculosis).

#### **Warnings and precautions**

- Talk to your doctor, pharmacist or nurse before using this medicine.

- If you have a red eye that has not been diagnosed, do not use this medicine.
- If you have a viral eye infection (herpes), only use this medicine if the infection is being treated with an anti-infective treatment and close monitoring of your eyes is required.
- If you have a disease that causes thinning of the outer part of your eye (cornea and sclera), there can be a higher risk of perforation when topical corticosteroids are applied to the eye.
- If you have used or have been using a corticosteroid medicine for a long time and have an eye wound (corneal ulcer), a fungal infection may be suspected.
- Close regular monitoring of your eyes is required during your treatment. Prolonged use of corticosteroids has shown to cause an increase of the pressure inside the eye and the start of glaucoma, especially in patients who already suffer from high pressure inside the eye, or if you are known to be at risk of developing this condition with local steroid treatment (see Possible side effects), and to cause a clouding of the lens in the eye (cataract), in particular in children and older people.
- The use of corticosteroids can cause eye infections that may not normally happen (opportunistic eye infections). In addition, corticosteroids given to the eye may increase, make worse or hide signs and symptoms of these eye infections.
- You should avoid wearing contact lenses during treatment with this medicine.
- Contact your doctor if you experience blurred vision or other visual disturbances.

### **Children**

There are no data on safety and effectiveness in children.

Continuous long-term treatment with corticosteroids in children may produce adrenal suppression.

The increase of the eye pressure in children occurs more frequently, more severely, and more quickly than in adults.

### **Other medicines and Zoftacot**

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines including medicines you have without a prescription.

Some medicines may increase the effects of Zoftacot and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as ritonavir or cobicistat).

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- The use of this medicine during pregnancy is not recommended except when judged necessary by your doctor and under strict supervision.
- It is not known whether this medicine passes into breast milk. Your doctor will decide if you can use this medicine during breast-feeding or not.

### **Driving and using machines**

Temporary blurred vision or other sight problems may affect the ability to drive or use machines. Do not drive or use machines until normal vision has returned.

### **Zoftacot contains phosphates**

This medicine contains 0.227 mg phosphates in each drop.

## **3. How to use Zoftacot**

### **Dose**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 2 drops in the affected eye(s), 2 to 4 times a day, depending on the prescription. Gradually reducing the dose is recommended in order to avoid relapse. The duration of treatment usually varies from a few days to a maximum of 14 days.

The same dose is used for both adults and the elderly.

### Use in children

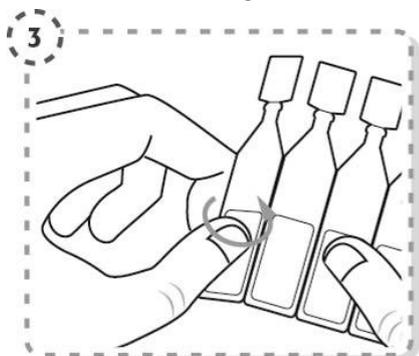
The effectiveness and the safety in children have not been established for this medicine.

### How to use the drops

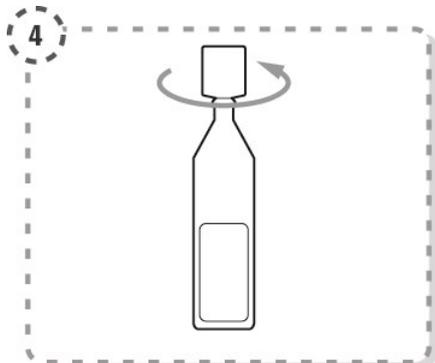
This medicine is to be used in the eye.

Please follow these instructions to use the drops:

1. Wash your hands and sit or stand comfortably.
2. Open the sachet containing 10 single-dose containers. Write down the date of first opening on the sachet.
3. Break off one single-dose container from the strip.



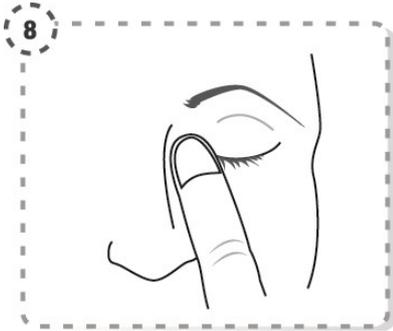
4. Twist open the top of the single-dose container as shown. Do not touch the tip after opening the container.



5. Use your finger to gently pull down the lower eyelid of your affected eye.
6. Place the tip of the single-dose container close to, but not touching your eye.
7. Squeeze the single-dose container gently so that two drops go into your eye, then release the lower eyelid.



8. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute while keeping the eye closed.



9. Repeat in your other eye if your doctor has told you to do this. Each single-dose container contains enough solution for both eyes.

10. Discard the single-dose container after use. Do not keep it to use it again.

11. Put the unopened single-dose containers back in the sachet. Put the opened sachet in the carton. The unopened containers must be used within one month after opening the sachet.

If you are using any other eye medicine, you should wait 5 minutes between using each medicine.

**If you use more Zoftacot than you should**

Rinse the eye with sterile water if you have used too much medicine in your eye and have irritation that lasts a long time.

Immediately tell your doctor or pharmacist.

**If you forget to use Zoftacot**

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

**If you stop using Zoftacot**

Do not suddenly stop using the medicine. Always tell your doctor if you are thinking about stopping the treatment.

If you have any more questions on the use of this medicine, ask your doctor, pharmacist or nurse.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Not known: frequency cannot be estimated from the available data**

- transient (short-lived) eye discomfort (burning, stinging) after use.

**The following side effects were reported with medicines of the same group (corticosteroids) when used for treating eye conditions.**

**Not known: frequency cannot be estimated from the available data**

- allergic reactions (red, itchy eyes),
- delayed wound healing,
- clouding of the lens in the eye (posterior capsular cataract),
- eye infections that may not normally happen (opportunistic viral infections like herpes, fungal infection),
- increase of pressure in your eye (glaucoma),
- dilation of the pupil (mydriasis),
- drooping eyelids (ptosis),
- inflammation inside your eye (uveitis),
- changes in the thickness of the front of the eye (cornea),
- inflammation of the cornea (crystalline keratopathy),

- blurred vision.

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance  
Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie)  
e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Zoftacot**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, sachet and single-dose container after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

**After first opening of the sachet:** use the single-dose containers within one month.

Keep the single-dose containers in the sachet to protect them from light.

Write down the date of first opening on the sachet.

**After first opening of the single-dose container:** use immediately and throw away the single-dose container after use.

After the individual single-dose container is opened, the solution inside cannot stay sterile, so you must throw away any solution remaining in the container after each use.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Zoftacot contains**

- The active substance is hydrocortisone sodium phosphate.  
1 ml eye drops, solution contains 3.35 mg of hydrocortisone sodium phosphate.
- The other ingredients are disodium phosphate dodecahydrate, sodium dihydrogen phosphate monohydrate, sodium chloride, disodium edetate, hydrochloric acid (for pH adjustment), water for injections.

### **What Zoftacot looks like and contents of the pack**

This medicine is an eye drops solution in single-dose containers.

The solution is practically clear, colourless to slightly yellow, practically free from particles, packed in a sachet of 10 units, each single-dose container holding 0.4 ml of product.

The pack size contains 10 (1 x 10), 20 (2 x 10), 30 (3 x 10) or 60 (6 x 10) single-dose containers.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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12, rue Louis Blériot

63017 CLERMONT-FERRAND Cedex 2

FRANCE

### **Manufacturer**

LABORATOIRES UNITHER

ZI de la Guérie

50 211 COUTANCES CEDEX

FRANCE

or

LABORATOIRES THEA

12, rue Louis Blériot

63017 CLERMONT-FERRAND Cedex 2

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**This leaflet was last revised in July 2018**

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharmaceuticals Ltd, telephone number +44 (0)345 521 1290.