

## Package leaflet: Information for the user

Proxal 50 micrograms/ml eye drops, solution  
Latanoprost

**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 or the doctor treating your child or pharmacist.
- This medicine has been prescribed for you or for your child 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 the doctor treating your child or pharmacist. This includes any possible side effects not listed in this leaflet.

### What is in this leaflet

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

### 1. What Proxal is and what it is used for

Proxal belongs to a group of medicines known as prostaglandin analogues. It works by increasing the natural outflow of fluid from inside the eye into the bloodstream.

Proxal is used to treat conditions known as **open angle glaucoma** and **ocular hypertension**. Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eye sight.

Proxal is also used to treat increased eye pressure and glaucoma in all ages of children and babies.

### 2. What you need to know before you use Proxal

Proxal can be used in adult men and women (including the elderly) and in children from birth to 18 years of age. Proxal has/have not been investigated in prematurely born infants (less than 36 weeks gestation).

#### Do not use Proxal

- If you or your child is allergic (causing red, itchy, swollen and watering eyes) to latanoprost or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant, think you may be pregnant or are planning to have a baby.
- If you are breast-feeding

#### Warnings and precautions

Talk to your doctor or the doctor treating your child or pharmacist before taking Proxal or before giving this to your child if you think any of the following apply to you or your child:

- If you or your child are about to have or have had eye surgery (including cataract surgery)
- If you or your child suffer from eye problems (such as eye pain, irritation or inflammation, blurred vision)
- If you or your child suffer from dry eyes

- If you or your child have severe asthma or the asthma is not well controlled
- If you or your child wear contact lenses. You can still use Proxal, but follow the instruction for contact lens wearers in Section 3
- If you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)

### **Other medicines and Proxal**

Tell your doctor or the doctor treating your child or pharmacist if you or your child are taking or have recently taken or might take any other medicines.

The effect of prostaglandins or prostaglandin derivatives (used in increased eye pressure) can be influenced by Proxal. Combining these with Proxal is not recommended, as the eye pressure may increase.

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

#### Pregnancy

Do not use Proxal if you are pregnant, think you are pregnant, or are planning to become pregnant.

#### Breast-feeding

Do not use Proxal when you are breast-feeding.

### **Driving and using machines**

When you use Proxal you might have blurred vision, for a short time. If this happens to you, **do not drive** or use any tools or machines until your vision becomes clear again.

### **Proxal contains benzalkonium chloride**

Proxal contains a preservative called benzalkonium chloride. This preservative may cause eye irritation or disruption to the surface of the eye. Benzalkonium chloride can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact with soft contact lenses.

If you or your child wears contact lenses, they should be removed before using Proxal. After using Proxal you should wait 15 minutes before putting the contact lenses back in. See the instructions for contact lens wearers in Section 3.

## **3. How to use Proxal**

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

The recommended dose for adults (including the elderly) and children is one drop once a day in the affected eye(s). The best time to do this is in the evening.

Do not use Proxal more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

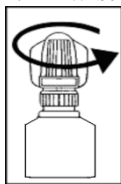
Use Proxal as instructed by your doctor or the doctor treating your child until they tell you to stop.

#### **Contact lens wearers**

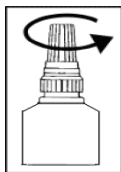
If you or your child wear contact lenses, they should be removed before using Proxal. After using Proxal you should wait 15 minutes before putting the contact lenses back into the eyes.

### **Instructions for use**

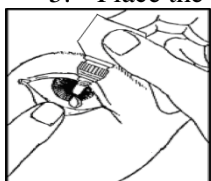
1. Wash your hands and sit or stand comfortably.
2. Twist off the outer cap (which can be thrown away).



3. Unscrew the protective inner cap. The protective cap should be retained.



4. Use your finger to gently pull down the lower eyelid of your affected eye.
5. Place the tip of the bottle close to, but not touching the eye.



6. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.
7. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.
8. Repeat in your other eye if your doctor has told you to do this.
9. Put the protective inner cap back on the bottle.

#### **If you use Proxal with other eye drops**

Wait at least 5 minutes between using {Latanoprost 50 micrograms/ml eye drops} and taking other eye drops.

#### **If you use more Proxal than you should**

If you put too many drops into the eye, it may lead to some minor irritation in the eye and the eyes may water and turn red. This should pass, but if you are worried contact your doctor or the doctor treating your child for advice.

Contact your doctor as soon as possible if you or your child swallows Proxal accidentally.

#### **If you forget to use Proxal**

Carry on with the usual dosage at the usual time. Do not take a double dose to make up for the dose you have forgotten. If you are unsure about anything talk to your doctor or pharmacist.

#### **If you stop using Proxal**

You should speak to your doctor or the doctor treating your child if you want to stop taking Proxal.

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

## **4. Possible side effects**

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

The following side effects have been reported:

*Very common: may affect more than 1 in 10 people*

- A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris. If you have mixed-colour eyes (blue-brown, grey-brown, yellow-brown or

green-brown) you are more likely to see this change than if you have eyes of one colour (blue, grey, green or brown eyes). Any changes in your eye colour may take years to develop although it is normally seen within 8 months of treatment. The colour change may be permanent and may be more noticeable if you use Proxal in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after Proxal treatment is stopped.

- Redness of the eye.
- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye).
- A gradual change to eyelashes of the treated eye and the fine hairs around the treated eye, seen mostly in people of Japanese origin. These changes involve an increase of the colour (darkening), length, thickness and number of your eye lashes.

*Common: may affect up to 1 in 10 people*

- Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis) and eye pain.

*Uncommon: may affect up to 1 in 100 people*

- Eyelid swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), blurred vision and conjunctivitis.
- Skin rash.

*Rare: may affect up to 1 in 1,000 people*

- Inflammation of the iris, the coloured part of the eye (iritis/uveitis); swelling of the retina (macular oedema), symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye (periorbital oedema) misdirected eyelashes or an extra row of eyelashes, light sensitivity (photophobia).
- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Asthma, worsening of asthma and shortness of breath (dyspnoea).

*Very rare: may affect up to 1 in 10,000 people*

- Worsening of angina in patients who also have heart disease. Chest pain.
- Sunken eye appearance (eye sulcus deepening).

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

- Fluid filled area within the coloured part of the eye (iris cyst).
- Headache.
- Dizziness.
- Palpitations.
- Muscle pain, joint pain.
- Viral infection of the eye caused by the herpes simplex virus (HSV).

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

### **Additional side effects in children**

Side effects seen more often in children compared to adults are:

- Runny itchy nose.
- Fever.

### **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 Proxal**

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 after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Keep the bottle in the outer carton in order to protect from light.

After first opening the bottle: do not store above 25°C and use within 4 weeks.

Do not use this medicine if you notice that the solution is not clear and colourless.

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 protect the environment.

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

### **What Proxal contains**

The active substance is latanoprost.

1 ml of eye drops contains 50 micrograms of latanoprost.

2.5 ml bottle of eye drops contains 125 micrograms of latanoprost.

The other ingredients are benzalkonium chloride, sodium chloride, sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, purified water. See section 2 of this leaflet for important information about benzalkonium chloride.

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

Eye drops, solution.

A clear colourless solution in a LDPE bottle with dropper, HDPE screw cap and tamper evident LDPE over seal.

Pack sizes: 1 x 2.5ml eye drops, 3 x 2.5ml eye drops, 6 x 2.5ml eye drops.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturers**

Marketing Authorisation Holder:

Actavis Group PTC ehf

Reykjavíkurvegi 76-78

220 Hafnarfjörður

Iceland

Manufacturers: Arrow Génériques SAS, 26 Avenue Tony Garnier, 69007 Lyon, France  
SIFI SpA, Via Ercole Patti 36, 95020 Lavinaio, Aci S. Antonio (CT), Italy

Juta Pharma GmbH, Gutenbergstrasse 13, 24941 Flensburg, Germany.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Czech Republic: Zeleza 50 mcg/ml, oční kapky, roztok

Denmark:	Latanoprost Arrow
Finland:	Latanoprost Arrow 50 mikrog/ml silmätipat, liuos
Germany:	Latano-Q 50 Mikrogramm/ml Augentropfen
Ireland:	Proxal 50 micrograms/ml eye drops, solution
Netherlands:	Latanoprost Aurobindo 50 microgram/ml oogdruppels, oplossing
Norway:	Glauprost 50 mikrogram/ml øyedråper, oppløsning
Poland:	Latanoprost Arrow
Slovak Republic:	Tiopromal 0.05mg/ml
Spain:	Latanoprost Arrow 50 microgramos/ml, colirio en solución
Sweden:	Latanoprost Arrow 50 mikrog/ml ögondroppar, lösning
United Kingdom:	Latanoprost 0.005% w/v eye drops, solution

**This leaflet was last revised in August 2016**