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PACKAGE LEAFLET: INFORMATION FOR THE USER

Zanopro 50micrograms/ml Eye Drops, Solution

Latanoprost

Read all of this leaflet carefully before you start using this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or the doctor treating your child or pharmacist.

In this leaflet:

1. What Zanopro is and what it is used for
2. Before you use Zanopro
3. How to use Zanopro
4. Possible side effects
5. How to store Zanopro
6. Further information

1. WHAT ZANOPRO IS AND WHAT IT IS USED FOR

Zanopro are eye drops used in patients with a condition known as open angle glaucoma which causes an increase in pressure in the eye. The active ingredient in Zanopro is one of a group of medicines known as prostaglandins. Zanopro is a medicine that lowers the pressure within your eye by increasing the natural outflow of fluid from inside the eye into the blood stream.

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

2. BEFORE YOU USE ZANOPRO

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

Do not use Zanopro
- if you are allergic (hypersensitive) to Latanoprost or any of the other ingredients of Zanopro.

Take special care with Zanopro
Talk to your doctor, or the doctor treating your child or your pharmacist before you use Zanopro or before you give 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 suffers 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 Zanopro, 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).

Tell your treating doctor or the doctor treating your child if any of the above warnings apply to you or your child, or have ever applied to you or your child in the past.

Taking other medicines
Zanopro may interact with other medicines. Please tell your doctor, the doctor treating your child or pharmacist if you or your child are taking or have recently taken any other medicines, including medicines (or eye drops) obtained without a prescription.

Pregnancy
Ask your doctor for advice before using Zanopro.

The unborn child might be affected. Zanopro should not be used during pregnancy.

Breast-feeding
Ask your doctor for advice before using Zanopro.

The child might be affected. Zanopro should not be used when breastfeeding.

Driving and using machines
As with other eye drops, if your vision is blurred when you first put your drops in, wait until this wears off before you drive or operate machinery.

Important information about some of the ingredients of Zanopro
Zanopro contains benzalkonium chloride which may cause eye irritation. Benzalkonium chloride is known to discolour soft contact lenses. Therefore, avoid contact with soft contact lenses.

If you or your child wear contact lenses, they should be removed before using Zanopro. After using Zanopro 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 ZANOPRO

Always use Zanopro exactly as your doctor or the doctor treating your child has told you. You should check with your doctor or the doctor treating your child or pharmacist if you are not sure.

The usual 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 Zanopro more than once a day, because the effectiveness of treatment can be reduced if you administer it more often.

If you have to use other eye drops you should wait for at least five minutes before using them.

Take care when squeezing the bottle, so that you insert only one drop into the affected eye.

Use Zanopro 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 Zanopro. After using Zanopro you should wait 15 minutes before putting the contact lenses back into the eyes.

Instruction for use

Follow the steps below to help you use Zanopro properly:

1. Wash your hands and sit or stand comfortably.
2. Twist off the cap.
3. Use your finger to gently pull down the lower eyelid of your affected eye.
4. Place the tip of the bottle close to, but not touching your eye.
5. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.
6. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.
7. Repeat in your other eye if your doctor has told you to do this.
8. Replace cap on the bottle

If you use more Zanopro than you should
Be careful when you are squeezing the bottle so that you only put one drop into the affected eye. 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 Zanopro accidentally.

If you forget to use Zanopro
Do not use a double dose to make up for a forgotten dose. If you forget to use your eye drops at the usual time, wait until it is time for your next dose. Do not put an extra drop into your eye to make up for the one you may have missed.

If you stop using Zanopro
You should speak to your doctor or the doctor treating your child if you want to stop using Zanopro.

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

4. POSSIBLE SIDE EFFECTS

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

The frequency at which side effects occur is categorised as follows:

Very common	affects more than 1 user in 10
Common	affects 1 to 10 users in 100
Uncommon	affects 1 to 10 users in 1,000
Rare	affects 1 to 10 users in 10,000
Very rare	affects less than 1 user in 10,000
Not known	frequency cannot be estimated from the available data

The following side effects have been reported:

Very common:
- eye colour discolouration (turning browner and darker);
- red and streaming eyes, a burning, prickling, itching and stinging feeling in the eyes; it may feel as if there is something in your eye(s);
- increase in number of – or darkening, thickening or lengthening of – eyelashes and fine hair on the eyelids.

Common:
- transient punctate epithelial erosions, mostly without symptoms
- inflammation of the eyelid edges
- sore eyes

Uncommon:
- swollen and puffy eyelids
- dry eyes
- inflammation of the cornea
- blurred vision
- conjunctivitis
- skin rash

Rare:
- certain forms of eye inflammation (iritis, uveitis)
- swelling and damage to the cornea (corneal oedema)
- swelling around the orbit of the eye (periorbital oedema)
- in-grown eyelashes, which may occasionally lead to eye irritation (uncommon)
- sudden onset of tight-chestedness caused by muscle spasms and swelling of the airway linings, often with coughing and coughing up mucus (asthma); worsening of asthma and shortness of breath (dyspnoea)
- skin rash of the eyelids
- dark discolouration of the eyelid skin
- macular oedema

Very rare:
- chest pain
- worsening of pre-existing tight-chestedness (angina pectoris) can occur

Other side effects which have been reported since Latanoprost was marketed (frequency not known):
- headache
- dizziness
- palpitations
- muscle ache and painful joints.
- iris cyst
- developing a viral infection of the eye caused by the herpes simplex virus (HSV)

Side effects seen more often in children compared to adults are runny itchy nose and fever.

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

5. HOW TO STORE ZANOPRO

Keep out of the reach and sight of children.

Do not use Zanopro after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

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

After first opening the bottle: do not store above 25°C. Four weeks after the first opening this product should be disposed of, even if it has not been completely used up.

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.

6. FURTHER INFORMATION

What Zanopro contains
The active substance is latanoprost.

1 ml of eye drops contains 50 micrograms of latanoprost.

2.5 ml of eye drops, solution (content of a bottle) contains 125 micrograms of latanoprost.

One drop contains approximately 1.5 micrograms latanoprost.

The other ingredients are benzalkonium chloride, sodium dihydrogen phosphate monohydrate, disodium hydrogen phosphate anhydrous, sodium chloride, purified water.

What Zanopro looks like and contents of the pack
Zanopro is a clear, colourless eye drop solution in an LDPE bottle with LDPE dropper with HDPE tamper-proof screw cap.

Each bottle of Zanopro contains 2.5 ml eye drops solution corresponding to approximately 80 drops of solution.

Zanopro is available in pack sizes of 1 × 2.5 ml, 3 × 2.5 ml and 6 × 2.5 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:
HBM Pharma s.r.o., Sklabinská 30, 036 80 Martin, Slovak Republic

Pharma Stulln, Werkstr. 3, D-92551 Stulln, Germany

STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany

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

Austria	Latanoprost STADA 0,005% Augentropfen
Belgium	Latanoprost EG oogdruppels, oplossing
Denmark	Latanoprost STADA
Finland	Oftastad
France	LATANOPROST EG 0,005%, collyre en solution
Germany	Latanoprost STADA 50 Mikrogramm/ml Augentropfen
Ireland	Zanopro 50 micrograms/ml eye drops, solution
Luxembourg	Latanoprost EG collyre en solution
Poland	Latanoprost Premier-Research
Portugal	Latanoprost Ciclum
Romania	Latanoprost STADA HF 50 micrograme/ml, picături oftalmice, soluție
Sweden	Latanoprost STADA
Netherlands	Latanoprost CF 50 microgram/ml oogdruppels, oplossing

This leaflet was last approved in April 2013.

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