

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Zanopro Plus 50micrograms/ml and 5mg/ml Eye Drops, Solution

Latanoprost / Timolol

**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 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. See section 4.

#### What is in this leaflet

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

#### 1. What Zanopro Plus is and what it is used for

Zanopro Plus is a medicine for the treatment of **increased intraocular pressure** (pressure inside the eye).

Zanopro Plus is a drug combination containing two active substances: latanoprost (a prostaglandin derivative) and timolol maleate (a beta-blocker).

Fluid known as aqueous humour is produced inside the eye. This fluid is then drained back into the bloodstream, thereby maintaining the required pressure within the eye. If this outflow is obstructed, pressure within the eye increases.

Among other things, beta-blockers reduce pressure inside the eye, by reducing the production of aqueous humour. Prostaglandins promote the outflow of aqueous humour.

#### Zanopro Plus is used:

- to reduce inner eye pressure in patients with open-angle glaucoma (damage to the optic nerve, caused by excessive pressure within the eye).
- to reduce inner eye pressure in patients for whom the effect of beta-blockers or prostaglandin derivatives alone is not sufficient.

#### 2. What you need to know before you use Zanopro Plus

**Do not use Zanopro Plus** eye drops, solution

- if you are **allergic** to latanoprost or timolol, beta-blockers or any of the other ingredients of Zanopro Plus (listed in section 6).
- if you have now or have had in past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- if you have serious heart problems or heart rhythm disorders.
- if you are pregnant (or trying to become pregnant)
- if you are breast feeding

## Warnings and precautions

Before you use this medicine, tell your doctor if you have now or have had in the past

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure
- disturbances of heart rate such as slow heart beat
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- diabetes as timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as timolol may mask signs and symptoms
- any kind of eye surgery (including cataract surgery)
- eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision)
- dry eyes
- angina (particularly a type known as Prinzmetal angina)
- severe allergic reactions that would usually require hospital treatment
- suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)

Wearing contact lenses: You can still use ZanoPro Plus but follow the instructions for contact lens wearers in section "ZanoPro Plus contains benzalkonium chloride".

Tell your doctor before you have an operation that you are using ZanoPro Plus as ZanoPro Plus may change effects of some medicines used during anaesthesia.

## Other medicines and ZanoPro Plus

ZanoPro Plus can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines (including using eye drops).

Medicines can affect each other and **interactions** may occur. You must bear this in mind if you are taking or using any of the following types of medicine:

► **Calcium antagonists** (e.g. in coronary heart disease or for high blood pressure)

**Guanethidine** (for high blood pressure)

**Beta-blockers** (for high blood pressure)

**Antiarrhythmics** (medications that normalise the heart rhythm)

**Digitalis glycosides** (for heart failure)

**Parasympathomimetic agents** (e.g. for the treatment of glaucoma)

Taking/using ZanoPro Plus together with the above medicines can cause low blood pressure and/or slow down the heart rate.

► **Medicines that act in a similar way to ZanoPro Plus**

If used at the same time as ZanoPro Plus, the effect of other medicines with a similar action to ZanoPro Plus may be increased. For this reason, ophthalmic use (i.e. in the eye) of two beta-blockers or two prostaglandin derivatives is not recommended.

► **Clonidine**

If you are using the active substance clonidine to reduce inner eye pressure together with ZanoPro Plus and you suddenly stop using clonidine, your blood pressure may rise. If you are also using beta-blockers at the same time to lower your blood pressure, your blood pressure may - due to this reverse effect - rise even further.

► **Quinidine** (used to treat heart conditions and some types of malaria)

► **Antidepressants** known as fluoxetine and paroxetine

## Children and adolescents

ZanoPro Plus is not recommended for children or adolescents.

### Elderly patients

Zanopro Plus is also suitable for the treatment of elderly patients.

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

#### Pregnancy

**Do not use** Zanopro Plus if you are pregnant unless your doctor considers it necessary. Tell your doctor immediately if you are pregnant, think you are pregnant or are planning to become pregnant.

#### Breast-feeding

**Do not use** Zanopro Plus if you are breast-feeding. Timolol and latanoprost may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

### **Driving and using machines**

After putting in Zanopro Plus eye drops, your vision may become temporarily impaired.

If you should experience **blurred vision** – particularly after just putting in Zanopro Plus eye drops – you should

- not drive any vehicles.
- not use any tools or machines.

### **Zanopro Plus contains benzalkonium chloride**

Benzalkonium chloride may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before putting them back in.

Benzalkonium chloride is known to discolour soft contact lenses.

### **3. How to use Zanopro Plus**

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

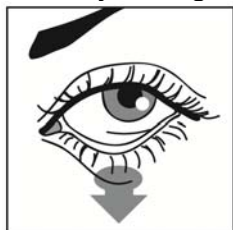
Unless otherwise prescribed by the doctor, the **usual dose** is:

Adults, including elderly patients: **insert one drop once a day into each affected eye.**

If you are using other eye drops in addition to Zanopro Plus, these should be used at least 5 minutes apart.

#### Directions for use

1. Wash your hands and sit or stand in a comfortable position.
2. Remove the outer protective cap from the bottle.
3. Use your fingertip to gently pull down the lower lid of the affected eye.



4. Place the tip of the bottle close to, but not touching the eye. Carefully squeeze the bottle until one drop falls into your eye. Please make sure that you do not squeeze the bottle too hard, so that no more than one drop falls into the affected eye.



5. Let go of your eyelid.
6. After using Zanopro Plus press a finger into the corner of your eye, by the nose for 2 minutes.



This helps to stop ZanoPro Plus getting into the rest of the body.

If prescribed by your doctor, repeat the procedure in your other eye. If the drop should miss your eye, apply another drop.

7. Close the bottle.

#### **If you use more ZanoPro Plus than you should**

If too many drops have gone into your eye, **irritation and redness** may occur.

Tell a **doctor immediately** if you or anyone else has **swallowed** the eye drops by mistake, or if you have been using the drops more often than prescribed.

Keep the pack of this medicine ready, so that the doctor can find out more about the medication.

He/she will then decide what to do next.

#### **If you forget to use ZanoPro Plus**

If you have forgotten to use your eye drops, continue your treatment as normal at the next dose. The daily dose of one drop into the affected eye should not be exceeded.

Do **not** use a **double dose** to make up for a forgotten dose.

#### **If you stop using ZanoPro Plus**

Do not interrupt or stop your treatment with ZanoPro Plus without talking to your doctor first.

If you do not use ZanoPro Plus regularly or if you frequently forget to use it, the **success of your treatment may be at risk**.

Increased intraocular pressure (pressure within the eye) can damage the optic nerve and worsen your eyesight. Blindness may occur. Normally, you can barely feel increased intraocular pressure. The disorder can only be diagnosed via an examination by an eye specialist. If you suffer from increased intraocular pressure, regular eye tests are necessary, together with measurements of inner eye pressure. Pressure within the eye should be measured at least every 3 months. Visual field measurements and optic nerve examinations should be performed at least once a year.

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

#### **4. Possible side effects**

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

You can usually carry on taking the eye drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using ZanoPro Plus without speaking to your doctor.

Listed below are the known side effects of using eye drops containing the active substances latanoprost and timolol. The most important side effect is the possibility of a gradual, permanent change in your

eye colour. It is also possible that eye drops containing the active substances latanoprost and timolol might cause serious changes in the way your heart works. If you notice changes in your heart rate or heart function you should speak to a doctor and tell them you have been using ZanoPro Plus.

The frequency of possible side effects listed below is defined using the following convention.

**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. The colour change may be permanent and may be more noticeable if you use ZanoPro Plus 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 ZanoPro Plus treatment is stopped.

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

- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye) and eye pain.

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

- Headache.
- Redness of the eye, eye infection (conjunctivitis), blurred vision, watery eyes, inflammation of the eyelids, irritation or disruption of the surface of the eye
- Skin rashes or itching (pruritus)

#### **Other side effects**

*The following side effects have been seen with latanoprost:*

Infections and Infestations:

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV)

Immune System Disorders:

- Symptoms of allergic reaction (swelling and redness of the skin and rash).

Nervous System Disorders:

- Dizziness.

Eye Disorders:

- Changes to the eyelashes and fine hairs around the eye (increased number, length, thickness and darkening), changes to the direction of eyelash growth, swelling around the eye, swelling of the coloured part of the eye (iritis/uveitis), swelling at the back of the eye (macular oedema), inflammation/irritation of the surface of the eye (keratitis), dry eyes, , fluid filled cyst within the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus), eye disorder affecting the cornea which is characterized by a breakdown or damage of the epithelium of the cornea in a pinpoint pattern (punctate epithelial erosions), swelling and fluid retention in the cornea (corneal oedema) and corneal erosion (damage to the front layer of the eyeball).

Heart (Cardiac) Disorders:

- Worsening of angina, awareness of heart rhythm (palpitations).

Breathing (Respiratory) Disorders:

- Asthma, worsening of asthma, shortness of breath.

Skin Disorders:

- Darkening of the skin around the eyes.

Muscle and Skeletal Disorders:

- Joint pain, muscle pain.

#### General Disorders:

- Chest pain.

Like other medicines applied into eyes, Zanopro Plus is absorbed into the blood. The timolol portion of this combination may cause similar side effects as seen with 'intravenous' and/or 'oral' as applicable beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example, taken by mouth or injected. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

- Generalized allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airway which may cause difficulty swallowing or breathing. Hives or itchy rash, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction.
- Low blood glucose levels.
- Difficulty sleeping (insomnia), depression, nightmares, memory loss.
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations like pins and needles, and headache.
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed), double vision.
- Whistling/ringing in the ears (tinnitus).
- Slow heart rate, chest pain, palpitations, oedema (fluid build up), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build up), a type of heart rhythm disorder, heart attack, heart failure.
- Low blood pressure, Raynaud's phenomenon, cold hands and feet.
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough.
- Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash.
- Muscle pain not caused by exercise.
- Sexual dysfunction, decreased libido.
- Muscle weakness/tiredness.

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.

#### 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

FREEPOST, IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.

Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.imb.ie](http://www.imb.ie), E-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie).

If you get any side effects talk to your doctor. This includes any possible side effects not mentioned in this leaflet.

#### **5. How to store Zanopro Plus**

Keep out of the **sight and reach of children**.

Do not use this medicine after the **expiry date** which is stated on the bottle label and carton after “EXP”. The expiry date refers to the last day of that month.

**Please note the following storage instructions:**

Unopened bottles: Store in a refrigerator at 2°C - 8°C.

After the first opening of the bottle: Do not store above 25°C.

Once opened, you must discard the bottle - with any remaining contents - after 4 weeks. Otherwise, there is a risk of eye infection.

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

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

### **What Zanopro Plus contains**

The **active substances** are: latanoprost and timolol maleate

1 ml eye drops contains 50 micrograms of latanoprost and 6.8 mg of timolol maleate, equivalent to 5.0 mg timolol.

The **other ingredients** are:

Sodium chloride, benzalkonium chloride, sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dodecahydrate, purified water, sodium hydroxide for pH adjustment and hydrochloric acid for pH adjustment.

### **What Zanopro Plus looks like and contents of the pack**

Zanopro Plus is a **clear, colourless liquid** packed in a transparent dropper bottle with a screw cap.

#### Zanopro Plus is available in the following pack sizes:

1 dropper bottle containing 2.5 ml eye drops,

3 dropper bottles, each containing 2.5 ml eye drops,

6 dropper bottles, each containing 2.5 ml eye drops.

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:

S.C. Rompharm Company S.R.L., Eroilor Street, no. 1A, Otopeni 075100, Ilovo District, Romania

PharmaCoDane ApS, Marielundvej 46 A, 2730 Herlev, Denmark

Centrafarm Services B.V., Nieuwe Donk 9, 4879 AC Etten-Leur, The Netherlands

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

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

STADA Production Ireland Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

Denmark	Latanostad Comp
Austria	Latanoprost/Timolol STADA 50 Mikrogramm/ml + 5 mg/ml Augentropfen
Spain	Latanoprost / Timolol STADA 50 microgramos/ml + 5 mg/ml colirio en solución
Finland	Oftastad comp
Ireland	Zanopro Plus 50 micrograms/ml and 5 mg/ml eye drops, solution
Poland	Latanoprost + Timolol STADA
Portugal	Latanoprost + Timolol Ciclum
Romania	Latanoprost/Timolol STADA HEMOFARM 50 micrograme/ml + 5 mg/ml, picături oftalmice, soluție
Slovak Republic	LATIMOSTAD

**This leaflet was last revised in February 2014.**