

**Package leaflet:
Information for the user**



**2.5mg/ml eye drops, solution
5mg/ml eye drops, solution**
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.

Important information about the administration of this product

Eysano eye drops are contained within a novel multidose eye drop bottle, which allows for the solution not to contain any preservatives. Due to the design of the container, administration with these eye drops is not the same as standard eye drop bottles.

- Prior to first use, practice using the drops away from the eye. Slowly squeeze the bottle to deliver one drop in the air to get used to the pressure and time required to deliver one drop.
- Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard, or more than one drop may come out.
- After use and prior to recapping, the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid on the tip. This is necessary in order to ensure delivery of subsequent drops.
- If more than one type of eye drop is used, leave at least 5 minutes between administration of each eye drop solution.

Please read the full instructions on the correct use of this product in **Section 3** of the leaflet ("How to use Eysano"), before using these eye drops.

What is in this leaflet

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

1. What Eysano is and what it is used for

Eysano contains a substance called timolol which belongs to a group of medicines called beta-blockers. Timolol lowers the pressure in your eye(s). It is used to treat chronic open-angle and secondary glaucoma, when the pressure in the eye is raised, in adults.

Eysano eye drops, solution is a sterile solution that does not contain a preservative.

2. What you need to know before you use Eysano

Do not use Eysano if:

- you are allergic to timolol, beta-blockers or any of the other ingredients of this medicine (listed in section 6).
- you have now or have had in the 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).
- you have a slow heartbeat, heart failure or disorders of heart rhythm (irregular heartbeats).
- you have "cardiogenic shock" - a serious heart condition caused by very low blood pressure, which may result in the following symptoms: dizziness and lightheadedness, fast pulse rate, white skin, sweating, restlessness, loss of consciousness.

If you are not sure whether you should use Eysano talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor before using Eysano 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.
- closed-angle glaucoma, a condition in which the pressure inside your eye becomes too high.
- low blood pressure.
- disturbances of heart rate such as slow heartbeat.
- 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.
- muscle weakness.
- tumor of the adrenal gland (pheochromocytoma).
- blood and body fluid abnormality (metabolic acidosis).
- pain in the legs when walking due to poor circulation in the legs (claudication).
- reduced kidney function.
- you wear soft contact lenses. Timolol has not been studied in patients wearing contact lenses. If you wear contact lenses, you should consult your doctor before using Eysano.

If you have a history of contact hypersensitivity to silver, you should not use this product.

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

If you suspect that Eysano is causing an allergic reaction or hypersensitivity (for example, skin rash or redness and itching of the eye) contact your doctor immediately.

Children and adolescents

Eysano should generally be used with caution in young patients. In newborns, infants and toddlers Eysano should be used with extreme caution. If coughing, wheezing, abnormal breathing or abnormal pauses in breathing (apnoea) occur, the use of the medicine should be stopped immediately. Contact your doctor as soon as possible. A portable apnoea monitor may also be helpful.

Other medicines and Eysano

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

Eysano 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.**

It is important to tell your doctor before using Eysano if you are taking one or more of the following medicines:

- Eye drops containing adrenaline.
- A calcium antagonist, such as nifedipine, verapamil or diltiazem, often used to treat high blood pressure, angina, an abnormal heartbeat or Raynaud's syndrome.
- Guanethidine, a medicine often used to treat high blood pressure.
- Parasympathomimetic medicine, which may have been prescribed to help you pass urine. Parasympathomimetics are also a particular type of medicine which is sometimes used to help restore normal movements through the bowel.
- Digoxin, a medicine used to relieve heart failure or treat abnormal heartbeat.
- Quinidine, used to treat heart conditions and some types of malaria.
- Antidepressants known as fluoxetine and paroxetine.
- Antiarrhythmics (including amiodarone).
- Clonidine, a medicine used to treat high blood pressure.
- Other beta-blockers taken by mouth or used as eye drops, because they belong to the same group of medicines as Eysano and could have an additive effect.
- Insulin and other oral anti-diabetic medicines.

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 for advice before taking this medicine.

Use in pregnancy

Do not use Eysano if you are pregnant unless your doctor considers it necessary.

Use in breast-feeding

Do not use Eysano if you are breast-feeding. Timolol may get into your milk.

Driving and using machines

There are possible side effects associated with Eysano, such as dizziness, tiredness and changes in your eyesight, such as blurred vision, drooping of the upper eyelid (making the eye stay half closed), double vision which may affect your ability to drive and/or operate machinery. Do not drive and/or operate machinery until you feel well and your vision is clear.

Eysano contains phosphate buffer

Each ml of Eysano 2.5mg/ml solution contains 12.72mg phosphates.

Each ml of Eysano 5mg/ml solution contains 11.78mg phosphates.

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.

3. How to use Eysano

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The doctor will decide how many drops you should take each day and how long you should use them.

The recommended dose is one drop in the affected eye(s) once or twice (one in the morning and one in the evening) each day.

Do not change your recommended dose without talking to your doctor.

Do not allow the tip of the bottle to touch the eye or areas around the eye. It could cause injury to your eye. The eye drops solution may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision.

To avoid possible contamination of the bottle, keep the tip of the bottle away from contact with any surface.

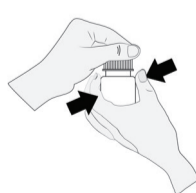
Instructions for use

Before instillation of the eye drops:

- Wash your hands before opening the bottle.
- Do not use this medicine if you notice that the tamper-proof seal on the bottle neck is broken before you first use it.
- At the first use, after cap removal, without positioning the eyedropper above the eye, slowly squeeze the bottle to deliver one drop in the air to get used to the pressure and time required to deliver one drop. In case of difficulties of delivering one drop at a time, this step might be repeated.
- Choose the position that you find most comfortable for the instillation of the drops (you can sit down, lie on your back, or stand in front of a mirror).

Instillation:

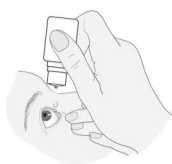
1. Hold the bottle directly below the cap and turn the cap to open the bottle. Do not touch anything with the tip of the bottle to avoid contamination of the solution.



2. Tilt your head backwards and hold the bottle above your eye.
3. Pull the lower eyelid down and look up. Squeeze the bottle gently in the middle and let a drop fall into your eye. Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard.



If you are not sure how to administer your medicine, ask your doctor, pharmacist or nurse.



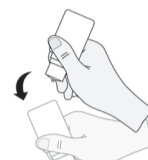
4. Blink a few times so that the drop spreads over the eye.



5. After using Eysano, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop the eye drops getting into the rest of your body.



6. Follow the instructions 2-5 for dropping also into the other eye.
7. After use and prior to recapping, the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid on the tip. This is necessary in order to ensure delivery of subsequent drops.



There might remain a small amount of solution in the bottle at the end. This is accounted for by an overfill of all bottles ensuring that 5ml solution can always be dispensed.

Do not use the eye drops for longer than 28 days after first opening the bottle.

Use in children and adolescents

Before your child starts to use Eysano, your child's doctor will have carried out a detailed medical examination and decided whether or not this medicine is suitable. Your child, especially a newborn, should be closely monitored for one to two hours after the first dose and carefully monitored for any signs of side effects.

Method of administration for use in children and adolescents

One drop only of Eysano should be instilled into the affected eye(s) each time. Follow the "Instructions for use" above when administering the eye drops.

Duration of treatment for use in children and adolescents

Your child's doctor will decide for how long the eye drops will be needed.

If you use more Eysano than you should

If you put too many drops in your eye or swallow any of the drops, you may:

- have a headache.
- feel dizzy or light-headed.
- have difficulty breathing.
- have chest pain.
- feel that your heart rate has slowed down.

If this happens, contact your doctor immediately.

If you forget to use Eysano

It is important to take Eysano as prescribed by your doctor.

- If you miss a dose, use the drops as soon as possible.
- If it is almost time for the next dose, skip the missed dose and take the next dose at the usual time.
- Do not take a double dose to make up for a forgotten dose.

If you stop using Eysano

If you want to stop using this medicine talk to your doctor first. 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.

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

Serious side effects

See your doctor immediately if you notice any of the following side effects for which you may need urgent medical treatment:

Rare (may affect up to 1 in 1,000 people)

- Severe sudden life-threatening allergic reaction with sudden rash, swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airway which may cause difficulty breathing or swallowing, and fainting (within minutes to hours) due to hypersensitivity (anaphylactic reaction).
- Paralysis, speech disorders, loss of consciousness due to reduced blood supply to the brain, interference with the blood supply to the brain which may lead to a stroke.
- 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.
- Difficulty breathing, shortness of breath, wheezing, cough.
- Very slow pulse.
- Sudden decreased vision after surgery for glaucoma.
- Rash on the face, kidney inflammation, fever, joint and muscle pain due to connective tissue disease. A condition called lupus (systemic lupus erythematosus).
- Increases in signs and symptoms of myasthenia gravis (a muscle disorder which causes muscle weakness and fatigue of the eye muscles and/or of the muscles used in swallowing, chewing and breathing).
- Raynaud's phenomenon (white, "dead" fingers and toes).
- Limping and leg pain when walking because there is a reduced blood supply to your legs.
- In men, a condition which affects your penis called Peyronie's disease. The signs may be Peyronie's disease, pain or hardening of the tissue of your penis.

Other side effects

Common (may affect up to 1 in 10 people)

- Blurred vision, signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation of the surface of the eye, irritation or pain in the eye, dry eyes, decreased corneal (layer at the front of the eye) sensitivity, corneal erosion (damage to the front layer of the eyeball), feeling of a foreign object in the eye, secretion
- Headache, dizziness

Uncommon (may affect up to 1 in 100 people)

- Fainting, general weakness, fatigue
- Depression
- Abnormal vision
- Nausea, indigestion

Rare (may affect up to 1 in 1,000 people)

- General allergic reactions including localized and generalized rash, itchiness
- Double vision, drooping of the upper eyelid (making the eye stay half closed) and separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye
- Low blood pressure
- Chest pain, palpitations, oedema (fluid build-up)
- Difficulty sleeping (insomnia), nightmares, memory loss
- Decreased sex drive
- Diarrhoea, dry mouth
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis
- Ringing sound in the ears
- Unusual sensations like tingling or pins and needles
- Cold hands and feet

Not known (frequency cannot be estimated from the available data)

- Hallucination

Like other medicines applied into eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with intravenous and/or oral beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example, taken by mouth or injected. The following additional side effects were seen within the class of beta-blockers when used for treating eye conditions:

- Low blood glucose levels
- Corneal erosion (damage to the front layer of the eyeball), tearing and redness in the eyes
- Heart failure
- Severe allergic reactions with swelling and difficulty breathing
- Skin rash and itching
- Taste disturbances, abdominal pain, vomiting
- Muscle pain not caused by exercise
- Sexual dysfunction

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 the Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eysano

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

This medicine does not require any special storage conditions.

Do not use the eye drops for longer than 28 days after first opening the bottle. Write down the date you opened the bottle in the space on the bottle label and box.

Make sure the bottle is properly closed.

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 Eysano contains

The active substance is timolol.

Eysano is available in two strengths:

- Each ml of Eysano 2.5mg/ml solution contains 3.417mg of timolol maleate (equivalent to 2.5mg of timolol).
 - Each ml of Eysano 5mg/ml solution contains 6.834mg of timolol maleate (equivalent to 5mg of timolol).
- The other ingredients are: sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, sodium hydroxide (for pH adjustment), water for injections.

What Eysano looks like and contents of the pack

Eysano 2.5mg/ml eye drops, solution is presented as a clear, colourless aqueous solution in a white opaque 11ml LDPE bottle and white Novelia nozzle (HDPE and silicone) with a white HDPE cap.

Eysano 5mg/ml eye drops, solution is presented as a clear, colourless aqueous solution in a white opaque 11ml LDPE bottle and white Novelia nozzle (HDPE and silicone) with a white HDPE cap.

Pack sizes: 1 or 2 bottles of 5ml solution in a cardboard box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Aspire Pharma Ltd
Unit 4, Rotherbrook Court
Bedford Road, Petersfield
Hampshire, GU32 3QG
United Kingdom

Manufacturer

Pharmathen S.A.,
6 Dervenakion
15351 Pallini Attiki
Greece

and
EXCELVISION
27 st. La Lombardière,
ZI La Lombardière,
ANNONAY 07100
France

This leaflet was last revised in: 11/2019

1010347-P8.4



MMM