

XYLASE-T 0.005% / 0.5%W/V EYE DROPS

Latanoprost /Timolol

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. 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 become serious, or if you notice any side effects not listed in this leaflet, please inform your healthcare provider.

In this leaflet:

1. What Xylase-T eye drop is and what it is used for
2. What you need to know before you use Xylase-T eye drops
3. How to use Xylase-T eye drops
4. Possible side effects
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6. Contents of the pack and other information

1. WHAT XYLASE-T EYE DROP IS AND WHAT IT IS USED FOR

Xylase-T eyedrop is used for the treatment of **increased intraocular pressure** (pressure inside the eye). Xylase-T 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 blood stream, thereby maintaining the required pressure within the eye increase. Xylase-T 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) and 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 XYLASE-T EYE DROPS

Do not use XYLASE-T eye drops

- If you are **allergic** to latanoprost or timolol, beta-blockers or any of the other ingredients of Xylase-T.
- 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 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 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 • Any kind of eye surgery (including cataract surgery)

• Eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision. • Dry eyes.

• Wear contact lenses. You can still use Xylase-T but follow the instructions for contact lens wearers in section "Xylase-T contains".

• Angina (particularly a type known as Prinzmetal angina).

• Severe allergic reactions that would usually require hospital treatment. • You have suffered or are currently suffering from a viral infection of the eye caused by the Herpes Simplex Virus (HSV).

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

Other medicines and Xylase-T

Xylase-T 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 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 Xylase-T together with the above medicines can cause low blood pressure and/or slow down the heart rate.

Medicines that act in a similar way as Xylase-T

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

Children and adolescents

Xylase-T is not recommended for children or adolescents.

Elderly patients

Xylase-T is also suitable for the treatment of elderly patients.

Pregnancy and breast-feeding and fertility

Pregnancy: Do not use Xylase-T if you are pregnant unless your doctor considers it necessary.

Breast-feeding: Do not use XYLASE-T if you are breast-feeding. Latanoprost/Timolol may get into your milk.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or breast-feeding

Driving and using machines

After putting in Xylase-T eye drops, your vision may become temporarily impaired. If you should experience **blurred vision** – particularly after just putting in Xylase-T eye drops – **you should not** drive any vehicle nor use any tool or machine

3. HOW TO USE XYLASE-T EYE DROPS

Always use 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: One drop once a day into each affected eye. If you are using other eye drops in addition to Xylase-T, 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 Xylase-T press a finger into the corner of you eye, by the nose for 2 minutes. This helps to stop Xylase-T 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.

4. POSSIBLE SIDE EFFECTS OF XYLASE-T EYE DROPS

Like all medicines, this medicine can cause side effects although not everybody gets them. You can usually carry on taking the eyedrops unless the effects are serious. If you are worried, talk to a doctor or pharmacist. Do not stop using Xylase-T 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 Xylase-T

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

Very common (*may affect up to 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 Xylase-T 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 Xylase-T treatment is stopped.

Common (*may affect up to 1 in 100 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 1 in 1000 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).

Reporting of side effects

If you experience any of the side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Fidson Healthcare Plc. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE XYLASE-T EYE DROPS

Keep all medicines out of the 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 30°C

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

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 Xylase-T Eyedrops contains:

The active ingredients are Latanoprost 0.005% and Timolol maleate 0.5%.

What Xylase-T looks like and contents of the pack

Xylase-T Eye Drops come in a 5 mL, 10 mL bottle with a screw cap, placed in an outer

carton with insert.

SUPPLIER AND MANUFACTURER

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