

**MODULE 1 - ADMINISTRATIVE INFORMATION AND PRESCRIBING
INFORMATION**

1.3 PRODUCT INFORMATION

1.3.1 SPC, Labelling and Package Leaflet

PACKAGE LEAFLET: INFORMATION FOR THE USER

MONOPOST UNIDOSE 50 micrograms/ml eye drops, solution in single-dose container

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 pharmacist or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT MONOPOST UNIDOSE IS AND WHAT IT IS USED FOR

MONOPOST UNIDOSE belongs to a group of medicines known as prostaglandins. It lowers the pressure within your eye by increasing the natural outflow of fluid from inside the eye into the bloodstream.

MONOPOST UNIDOSE 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MONOPOST UNIDOSE

Do not use MONOPOST UNIDOSE

- If you are allergic (hypersensitive) to latanoprost or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, or pharmacist or nurse before using MONOPOST UNIDOSE if you think any of the following apply to you:

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

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- If you have severe asthma or your asthma is not well controlled.
- If you wear contact lenses. You can still use MONOPOST UNIDOSE, 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).

Children

MONOPOST UNIDOSE has not been investigated in children (below 18 years).

Other medicines and MONOPOST UNIDOSE

MONOPOST UNIDOSE may interact with other medicines. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

Do not use MONOPOST UNIDOSE when you are pregnant or breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

When you use MONOPOST UNIDOSE 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.

Important information about some of the ingredients of MONOPOST UNIDOSE

MONOPOST UNIDOSE contains macrogolglycerol hydroxystearate (derived from castor oil) which may cause skin reactions.

3. HOW TO USE MONOPOST UNIDOSE

Usual dose

- Always use MONOPOST UNIDOSE exactly as this leaflet tells you or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- The usual dose for adults (including the elderly) is one drop once a day in the affected eye(s). The best time to do this is in the evening.
- Do not use MONOPOST UNIDOSE more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.
- Always use MONOPOST UNIDOSE exactly as your doctor has told you, until your doctor tells you to stop. Check with your doctor, or pharmacist or nurse if you are not sure.

Contact lens wearers

If you wear contact lenses, you should remove them before using MONOPOST UNIDOSE. After using MONOPOST UNIDOSE you should wait 15 minutes before putting your contact lenses back in.

Instructions for use

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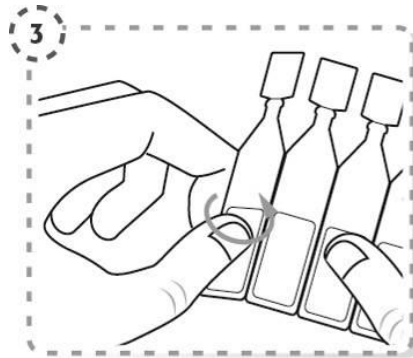
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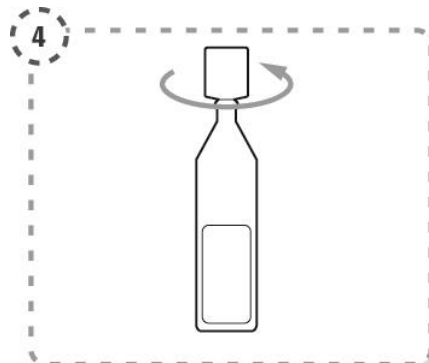
The drops are supplied in single-dose units. Use the solution from one single dose unit for administration to the affected eye(s) immediately after opening the container. Since sterility cannot be maintained after opening, throw away the container immediately after using the solution. Open a new single-dose unit every time you use MONOPOST UNIDOSE.

These instructions tell you how to use the drops:

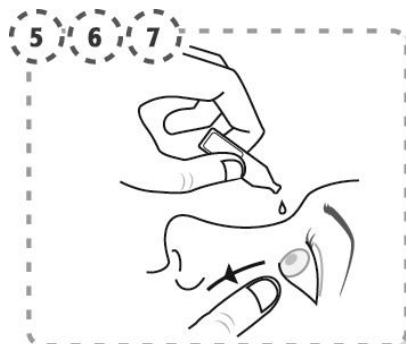
1. Wash your hands and sit or stand comfortably.
2. Open the sachet. Write down the date of first opening on the sachet.
3. Break off one single-dose container from the strip.



4. Twist open the top of the single-dose container as shown. Do not touch the tip after opening the container.



5. Use your finger to gently pull down the lower eyelid of your affected eye.
6. Place the tip of the single-dose container close to, but not touching your eye.
7. Squeeze the single-dose container gently so that only one drop goes into your eye, then release the lower eyelid.

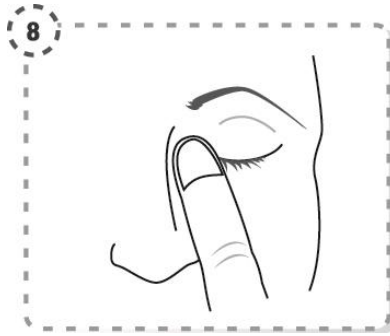


8. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.

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9. Repeat in your other eye if your doctor has told you to do this. Each single-dose container contains enough solution for both eyes.

10. Throw away the single-dose container after use. Do not keep it to use it again. Since sterility cannot be maintained after the individual single-dose container is opened, a new container must be opened prior to each use.

If you use MONOPOST UNIDOSE with other eye drops

Wait at least 5 minutes between using MONOPOST UNIDOSE and using other eye drops.

If you use more MONOPOST UNIDOSE than you should

If you put too many drops into your eye, you may have some minor irritation in your eye and your eyes may water and turn red. This should pass, but if you are worried talk to your doctor.

Contact your doctor as soon as possible if you swallow MONOPOST UNIDOSE accidentally.

If you forget to use MONOPOST UNIDOSE

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

If you stop using MONOPOST UNIDOSE

Talk to your doctor if you want to stop using MONOPOST UNIDOSE.

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

4. POSSIBLE SIDE EFFECTS

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

The following are known side effects of using MONOPOST UNIDOSE:

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).

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- 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 MONOPOST UNIDOSE 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 MONOPOST UNIDOSE 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), eye pain, sensitivity to light (photophobia), conjunctivitis.

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, inflammation of the coloured part of the eye (uveitis), swelling of the retina (macular oedema).
- Skin rash.
- Chest pain (angina), awareness of heart rhythm (palpitations).
- Asthma, shortness of breath (dyspnoea).
- Chest pain.
- Headache, dizziness.
- Muscle pain, joint pain.
- Nausea, vomiting.

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

- Inflammation of the iris (iritis), 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, fluid filled area within the coloured part of the eye (iris cyst).
- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Worsening of asthma.
- Severe itching of the skin.
- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

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

- Worsening of angina in patients who also have heart disease, sunken eye appearance (eye sulcus deepening).

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Reporting of side effects

If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MONOPOST UNIDOSE

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, sachet and single-dose container. The expiry date refers to the last day of that month.

Store below 25°C.

After first opening of the sachet: use the single-dose containers within 10 days.

After first opening of the single-dose container: use immediately and throw away the single-dose container after use.

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 MONOPOST UNIDOSE contains

The active substance is latanoprost.

1 ml eye drops solution contains 50 micrograms of latanoprost.

The other ingredients are: macroglycerol hydroxystearate 40, sorbitol, carbomer 974P, macrogol 4000, disodium edetate, sodium hydroxide (for pH-adjustment), water for injections.

What MONOPOST UNIDOSE looks like and contents of the pack

This medicine is an eye drops, solution in single-dose container. The solution looks slightly yellow and cloudy. It contains no preservative.

The single-dose containers are packed in a sachet of 5 or 10 units, each single-dose container holding 0.2 ml of solution.

A pack size contains 5 (1 sachet of 5), 10 (2 sachets of 5), 10 (1 sachet of 10), 30 (6 sachets of 5), 30 (3 sachets of 10), 90 (18 sachets of 5) or 90 (9 sachets of 10) single-dose containers.

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Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

LABORATOIRES THEA

12 RUE LOUIS BLERIOT

63017 CLERMONT-FERRAND CEDEX 2

FRANCE

Manufacturer

EXCELVISION

27, RUE DE LA LOMBARDIERE

ZI LA LOMBARDIÈRE

07100 ANNONAY

FRANCE

Or

LABORATOIRE UNITHER

1 RUE DE L'ARQUERIE

50200 COUTANCES

FRANCE

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

Belgium, Bulgaria, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland,
Italy, Latvia, Luxembourg, The Netherlands, Norway, Poland, Portugal, Spain,

SwedenMONOPROST

IrelandMONOPOST UNIDOSE

Austria, Czech Republic, Lithuania, Romania, Slovak Republic, Slovenia,

United KingdomMONOPOST

EstoniaMONOPRO

This leaflet was last revised in 12/2023.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharma Ltd, telephone number +44 (0) 345 521 1290