Package leaflet: Information for the patient

Travoprost Mylan 40 micrograms/ml eye drops

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

1. What Travoprost Mylan is and what it is used for

Travoprost Mylan eye drops contains travoprost, one of a group of medicines called prostaglandin analogues. It works by reducing the pressure in the eye. It may be used on its own or with other drops e.g. beta-blockers, which also reduce pressure.

Travoprost is used to reduce high pressure in the eye in adults, adolescents and children from 2 months old onward. This pressure can lead to an illness called glaucoma.

2. What you need to know before you use Travoprost Mylan

Do not use Travoprost Mylan:
- if you are allergic to travoprost or any of the other ingredients of this medicine (listed in section 6).

Ask your doctor for advice if this applies to you.

Warnings and precautions:
- Travoprost Mylan may increase the length, thickness, colour and/or number of your eyelashes. Changes in the eyelids including unusual hair growth or in the tissues around the eye have also been observed.
- Travoprost Mylan may change the colour of your iris (the coloured part of your eye). This change may be permanent. A change in the colour of the skin around the eye may also occur.
- If you have had cataract surgery, talk to your doctor before you use Travoprost Mylan.
- If you have current or previous history of an eye inflammation (iritis and uveitis), talk to your doctor before you use Travoprost Mylan.
- Travoprost Mylan may rarely cause breathlessness or wheezing or increase the symptoms of asthma. If you are concerned about changes in your breathing pattern when using Travoprost Mylan advise your doctor as soon as possible.
- Travoprost may be absorbed through the skin. If any of the medicinal product comes into contact with the skin, it should be washed off straight away. This is especially important in women who are pregnant or are attempting to become pregnant.
- If you wear soft contact lenses, do not use the drops with your lenses in. After using the drops wait 15 minutes before putting your lenses back in.

Children and adolescents
Travoprost can be used in children from 2 months to <18 years at the same dose as for adults. Use of Travoprost Mylan is not recommended to those children under 2 months of age.

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

Pregnancy, breast-feeding and fertility
Do not use Travoprost Mylan if you are pregnant. If you think that you may be pregnant speak with your doctor right away. If you could become pregnant you must use adequate contraception whilst you use Travoprost Mylan.

Do not use Travoprost Mylan if you are breast feeding, Travoprost Mylan may get into your milk.

Ask your doctor for advice before taking any medicine.

Driving and using machines
You may find that your vision is blurred for a time just after you use Travoprost Mylan. Do not drive or use machines until this has worn off.

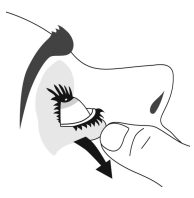
Travoprost Mylan contains benzalkonium chloride
This medicine contains 150 micrograms of benzalkonium chloride in each millilitre (ml).
Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel an abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Travoprost Mylan

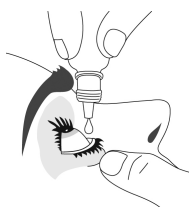
Always use this medicine exactly as your doctor or the doctor treating your child has told you. You should check with your doctor, the doctor treating your child or pharmacist if you are not sure.

The recommended dose is
One drop in the affected eye(s), once a day - in the evening.
Only use Travoprost Mylan in both eyes if your doctor told you to. Use it for as long as your doctor or the doctor treating your child told you to.

1. Immediately before using a bottle for the first time, tear off the overwrap sachet and take out the bottle. Write the date of opening on the carton or bottle label in the space provided
2. Wash your hands
3. Twist off the cap
4. After cap is removed, if tamper evident snap collar is loose, remove before using the product
5. Hold the bottle, pointing down, between your thumb and fingers
6. Tilt your head or your child's head gently back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here.



7. Bring the bottle tip close to the eye. Use a mirror if it helps.
8. Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
9. Gently squeeze the bottle to release one drop of Travoprost Mylan at a time



10. After using Travoprost Mylan, keep the eyelid closed, apply gentle pressure by pressing a finger into the corner of your eye, by the nose for at least 1 minute. This helps to stop Travoprost Mylan getting into the rest of the body
11. If you use drops in both eyes, repeat the steps for your other eye
12. Close the bottle cap firmly immediately after use
13. Only use one bottle at a time.

If a drop misses your eye, try again.

If you or your child are using other eye preparations such as eye drop or eye ointment, wait for at least 5 minutes between putting in Travoprost Mylan and the other eye preparations.

If you or your child use more Travoprost Mylan than you should
Rinse all the medicine out with warm water. Do not put in any more drops until it is time for your next regular dose.

If you forget to use Travoprost Mylan
Continue with the next dose as planned. Do not use a double dose to make up for a forgotten dose. Never use more than one drop in the affected eye(s) in a single day.

If you stop using Travoprost Mylan
Do not stop using Travoprost Mylan without first speaking to your doctor or the doctor treating your child, the pressure in your eye or your child's eye will not be controlled which could lead to loss of sight.

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

Description	Travoprost_40mcg_1ml_2.5ml			Date: 08 Nov 24		Time: 21:20	
Component Type	Leaflet	Site Barcode/ DataMatrix	N/A	No. of colours	1	Page Count	1 of 2
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TrackWise/GLAMS Job No.	3653993	Artwork Proof No.	1	Equate CMYK with			
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Sign-offs							
							V3 MAY 2023

4. Possible side effects

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

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

The following side effects have been seen with travoprost containing eye drops

Very common (may affect more than 1 in 10 people):
Effects in the eye: eye redness.

Common (may affect up to 1 in 10 people):
Effects in the eye: changes in the colour of the iris (coloured part of the eye), eye pain, eye discomfort, dry eye, itchy eye, eye irritation.

Uncommon (may affect up to 1 in 100 people):
Effects in the eye: corneal disorder, eye inflammation, iris inflammation, inflammation inside the eye, eye surface inflammation with/out surface damage, sensitivity to light, eye discharge, eyelid inflammation, eyelid redness, swelling around the eye, eyelid itching, blurred vision, increased tear production, infection or inflammation of the conjunctiva (conjunctivitis), abnormal turning outward of the lower eyelid, clouding of the eye, eyelid crusting, growth of eyelashes.

General side effects: increased allergic symptoms, headache, irregular heartbeat, cough, stuffy nose, throat irritation, darkening of skin around the eye (s), skin darkening, abnormal hair texture, excessive hair growth.

Rare (may affect up to 1 in 1,000 people):
Effects in the eye: perception of flashing lights, eczema of the eyelids, abnormally positioned eyelashes that grow back toward the eye, eye swelling, reduced vision, halo vision, decreased eye sensation, inflammation of the glands of the eyelids, pigmentation inside the eye, increase in pupil size, eyelash thickening, change in eyelash colour, tired eyes.

General side effects: eye viral infection, dizziness, bad taste, irregular or decreased heart rate, increased or decreased blood pressure, shortness of breath, asthma, nasal allergy or inflammation, nasal dryness, voice changes, gastrointestinal discomfort or ulcer, constipation, dry mouth, redness or itching of the skin, rash, hair colour change, loss of eyelashes, joint pain, musculoskeletal pain, generalised weakness.

Not known (frequency cannot be estimated from the available data):
Effects in the eye: inflammation of the back of the eye, eyes appear more inset.

General side effects: depression, anxiety, insomnia, sensation of false movement, ringing in ears, chest pain, abnormal heart rhythm, increased heartbeat, worsening of asthma, diarrhoea, nose bleeds, abdominal pain, nausea, vomiting, itching, abnormal hair growth, painful or involuntary urination, increase in prostate cancer marker.

Additional side effects in children and adolescents
The following side effects were seen more frequently in children and adolescents compared to adults:
- eye redness
- growth of eyelashes.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at 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 Travoprost Mylan

Keep this medicine out of the sight and reach of children.

Do not use this medicine if you notice that the tamper evident seal has been broken or **damaged before you first open it**.

Do not use this medicine after the expiry date which is stated on the bottle and the carton after 'Exp'. The expiry date refers to the last day of that month.

Keep the bottle in the sealed sachet to protect from moisture until after first opening of the bottle.
This medicine does not require any special temperature storage conditions.

You must throw away the bottle 4 weeks after you first opened it, to prevent infections, and use a new bottle. Write down the date you opened it in the space on the carton box or bottle label.

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 Travoprost Mylan contains
The active substance is travoprost. Each ml of solution contains 40 micrograms of travoprost.
The other ingredients are: benzalkonium chloride, macrogolglycerol hydroxystearate 40, trometamol, disodium edetate, boric acid [E284], mannitol, sodium hydroxide (for pH adjustment) [E 524] and water for injection or purified water

What Travoprost Mylan looks like and contents of the pack
Travoprost Mylan is a clear, colourless solution, in a transparent plastic bottle with a white plastic screw cap inside a protective plastic/aluminium sachet. Each bottle contains 2.5 ml of Travoprost Mylan eye drop solution (eye drops).
Travoprost Mylan is available in cartons of 1 or 3 bottles.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mylan,
Station Close, Potters Bar, EN6 1TL,
United Kingdom.

Manufacturers
Balkanpharma-Razgrad Ad,
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Jadran - Galenski Laboratorij d.d.,
Svilno 20, Rijeka 51000, Croatia.

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

This leaflet was last revised in August 2024.

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