

Package leaflet: Information for the patient

Iricryn 0.3 mg/ml eye drops, solution bimatoprost

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

1. What Iricryn is and what it is used for

Iricryn is an antiglaucoma preparation. It belongs to a group of medicines called prostamides.

Iricryn is used to reduce high pressure in the eye. This medicine may be used on its own or with other drops called beta-blockers which also reduce pressure.

Your eye contains a clear, watery liquid that feeds the inside of the eye. Liquid is constantly being drained out of the eye and new liquid is made to replace this. If the liquid cannot drain out quickly enough, the pressure inside the eye builds up. This medicine works by increasing the amount of liquid that is drained. This reduces the pressure inside the eye. If the high pressure is not reduced, it could lead to a disease called glaucoma and eventually damage your sight.

This medicine does not contain a preservative.

2. What you need to know before you use Iricryn

Do not use Iricryn

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

Warnings and precautions

Talk to your doctor or pharmacist before using Iricryn, if:

- you have any breathing problems
- you have liver or kidney problems
- you have had a cataract surgery in the past
- you have or have had low blood pressure or low heart rate
- you have had a viral infection or inflammation of the eye
- you wear contact lenses (see section 3)

During treatment, Iricryn may cause a loss of fat around the eye, which may cause your eyelid crease to deepen, your eye to appear sunken (enophthalmos), your upper eyelid to droop (ptosis), the skin around your eye to tighten (involution of dermatochalasis) and the lower white part of your eye to become more visible (inferior scleral show). The changes are typically mild, but if pronounced, they can affect your field of vision. The changes may disappear if you stop taking Iricryn. Iricryn may also cause your eyelashes to darken and grow, and cause the skin around the eyelid to darken too. The colour of your iris may also go darker. These changes may be permanent. The change may be more noticeable if you are only treating one eye.

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

Patients with a disruption of the ocular epithelial surface are at greater risk of developing bacterial keratitis. It is important to avoid allowing the tip of the bottle to contact the eye or surrounding structures, to avoid eye injury and contamination of the solution (see also section 3 - Instructions for use).

Children and adolescents

Bimatoprost has not been tested in children under the age of 18 and therefore Iricryn should not be used by patients under 18 years.

Other medicines and Iricryn

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

Pregnancy and breastfeeding

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

Bimatoprost may get into breast milk so you should not breast-feed while you are taking Iricryn.

Driving and using machines

Your sight may become blurred for a short time just after using Iricryn. You should not drive or use machines until your sight is clear again.

Iricryn contains phosphates

This medicine contains 0.95 mg phosphates in each millilitre. 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 Iricryn

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

Iricryn should only be applied to the eye.

The recommended dose is one drop of Iricryn once daily, in the evening, in each eye that needs treatment.

If you use Iricryn with another eye medicine, wait at least five minutes between using Iricryn and the other eye medicine. Eye ointments should be administered last.

Iricryn has not been studied in patients wearing contact lenses. Contact lenses should be removed prior to installation and may be reinserted 15 minutes following administration.

Do not use more than once a day as the effectiveness of treatment may be reduced.

Iricryn is a sterile solution that does not contain a preservative.

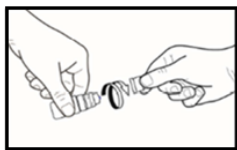
Before instillation of the eye drops:

- When using for the first time, before delivering a drop to the eye, you should first of all practise using the dropper bottle by squeezing it slowly to deliver one drop into the air, away from the eye.
- When you are confident that you can deliver one drop at a time, you should 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).

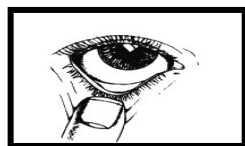
Instructions for use

1. Wash your hands carefully before using this medicine.
2. If the packaging or bottle is damaged do not use the medicine.
3. When using the medicine for the first time, unscrew the cap after making sure that the sealed ring on the cap has not been broken. You should feel a slight resistance until this tamper-proof ring breaks off (*see picture 1*).
4. If the tamper-proof ring is loose throw it away because it may fall into the eye and make injuries.
5. Tilt your head back and gently pull down your lower eyelid to form a pouch between your eye and eyelid (*see picture 2*).
6. **Avoid contact between the tip of the bottle and your eye, eyelids or fingers.** Instill one drop into the pouch by pressing slowly on the bottle (*see picture 3*). Squeeze the bottle gently in the middle and let a drop fall into your eye. 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.
7. Compress the tear duct for about 2 minutes (by pressing a finger against the corner of the eye by the nose) and close your eye(s) and keep it/them closed during this time. This ensures that the drop is absorbed by the eye and that the amount of medicine draining through the tear duct to the nose will probably be reduced.
8. Repeat steps 5, 6 and 7 in your other eye if your doctor has told you to do this.
9. 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. After instillation screw the cap on the bottle (*see picture 4*).

If a drop misses your eye, try again. Wipe off any excess that runs down the cheek.



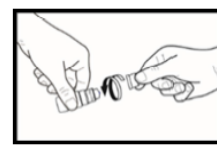
Picture 1.



Picture 2.



Picture 3.



Picture 4.

If you use more Iricryn than you should

If you use more Iricryn than you should, it is unlikely to cause you any serious harm. Put your next dose in at the usual time. If you are worried, talk to your doctor or pharmacist.

If you forget to use Iricryn

If you forget to use Iricryn, use a single drop as soon as you remember, and then go back to your regular routine. Do not take a double dose to make up for a forgotten dose.

If you stop using Iricryn

Iricryn should be used every day to work properly. If you stop using Iricryn the pressure inside your eye may go up, therefore talk to your doctor before stopping this treatment.

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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Very common side effects

These may affect one or more users in 10

Affecting the eye

- Slight redness (up to 24% of people)

Affecting the eye region:

- Loss of fat in the eye region which can lead to deepening of your eyelid crease, sunken eye (enophthalmos), drooping eyelid (ptosis), tightening of the skin around your eye (involution of dermatochalasis), and the lower white part of your eye to become more visible (inferior scleral show).

Common side effects

These may affect 1 to 9 users in 100

Affecting the eye

- Small breaks in the surface of the eye, with or without inflammation
- Irritation
- Itchy eyes
- Pain
- Dryness
- A feeling that something is in your eye
- Longer eyelashes
- Darker skin colour around the eye
- Red eyelids

Uncommon side effects

These may affect 1 to 9 users in 1000

Affecting the eye

- Tired eyes
- Sensitivity to light
- Darker iris colour
- Itchy and swollen eyelids
- Tears
- Swelling of the see-through layer which covers the surface of the eye
- Blurred vision

Affecting the body

- Headaches
- Hair growth around the eye

Side effects where the frequency is not known

Affecting the eye

- Sticky eyes
- Ocular discomfort

Affecting the body

- Asthma
- Worsening of asthma
- Worsening of the lung disease called chronic obstructive pulmonary disease (COPD)
- Shortness of breath
- Symptoms of allergic reaction (swelling, redness of the eye and rash of the skin)
- Dizziness
- Increased blood pressure
- Skin discoloration (periocular)

In addition to the side effects for bimatoprost 0.3 mg/ml preservative-free formulation, the following side effects have been seen with the preserved multi-dose formulation of bimatoprost 0.3 mg/ml and may occur in patients taking bimatoprost 0.3 mg/ml preservative-free formulation:

- Burning sensation in the eye
- An allergic reaction in the eye
- Inflamed eyelids
- Difficulty in seeing clearly
- Worsening vision
- Darker eyelashes
- Retinal bleeding
- Inflammation within the eye
- Cystoid macular oedema (swelling of the retina within the eye leading to worsening vision)
- Iris inflammation
- Eyelid twitching
- Eyelid shrinking, moving away from surface of the eye
- Nausea
- Skin redness around the eye
- Weakness
- An increase in blood-test results that show how your liver is working

Other side effects reported with eye drops containing 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.

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

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 Iricryn

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

This medicine does not require any special storage condition.

After first opening of the bottle - store below 25°C and discard after 90 days.

Iricryn should be used within 90 days after the bottle is first opened. Therefore, you must throw away the bottle 90 days after you first opened it, even if some solution is left. To help you remember, write down the date that you opened it in the space on the carton.

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 Iricryn contains

- The active substance is bimatoprost.
Each ml of solution contains 0.3 mg bimatoprost.
- The other excipients are disodium phosphate dodecahydrate, citric acid monohydrate, sodium chloride, hydrochloric acid, dilute (for pH-adjustment), water for injections.

What Iricryn looks like and contents of the pack

Iricryn is a transparent, colourless solution.

This medicine is available in white LDPE bottles, each containing 3 ml or 9 ml of solution, with multidose HDPE dropper applicator and tamper-proof HDPE screw-cap and the carton box.

Pack sizes: cartons containing 1 bottle of 3 ml solution or 1 bottle of 9 ml solution.

Not all pack sizes may be marked.

Marketing Authorisation Holder

Farmaprojects S.A.

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Barcelona

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Spain

Manufacturer

Rafarm S.A.

Thesi Pousi Xatzi Agiou Louka

Paiania, 190 02

Greece

This medicine is authorised in the Member States of the European Economic Area under the following names:

Latvia: Iricryn 0,3 mg/ml, acu pilieni šķīdums

France: Iricryn 0,3 mg/mL, collyre en solution

Italy: Iricryn

Portugal: Iricryn

Austria: Iricryn 0,3 mg/ml Augentropfen, Lösung

Denmark: Iricryn

Finland: Iricryn

Norway: Iricryn

Sweden: Iricryn 0.3 mg/ml eye drops, solution

This leaflet was last revised in.