

Package leaflet: Information for the user

Itoco 20 mg/ml eye drops, solution

dorzolamide

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

1. What Itoco is and what it is used for

Itoco contains dorzolamide which belongs to a group of medicines called "carbonic anhydrase inhibitors". Itoco is in the form of eye drops without preservatives.

Itoco is used in order to reduce elevated pressure in the eye (eyes) and in therapy of glaucoma. Itoco can be used as the only eye medicine, or with other medicines lowering the pressure in the eyes (called beta-adrenolytics).

2. What you need to know before you use Itoco

Do not use Itoco

- If you are allergic to dorzolamide or any of the other ingredients of this medicine (listed in section 6).
- If you have abnormal blood pH (hyperchloraemic acidosis), severe kidney impairment or problems, or a prior history of kidney stones.

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

Warnings and precautions

Talk to your doctor or pharmacist before using Itoco.

Tell your doctor or pharmacist about any medical problems you have now or have had in the past, including eye problems and eye surgeries, and about any allergies to any medications.

If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately.

If you suspect that Itoco is causing an allergic reaction (for example, skin rash, severe skin reaction, or itching), stop using this medicine and contact your doctor immediately.

If you wear contact lenses, you should consult your doctor before using Itoco.

Children

Dorzolamide (containing preservatives) has been used in studies in infants and children under 6 years of age with increased pressure in the eye (s) or with the diagnosis of glaucoma. For further information, talk to your doctor.

Elderly

In studies with dorzolamide, the effects of it were similar in both elderly and younger patients.

Use in patients with liver impairment

Tell your doctor about any liver problems you now have or have suffered from in the past.

Other medicines and Itoco

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines (including eye drops). This is especially important if you are using another carbonic anhydrase inhibitor such as acetazolamide (used to treat glaucoma or with other medicines to reduce edema (excess fluid retention) or medicines containing sulfonamide (used, for example, in the treatment of infections).

Pregnancy, breast-feeding and fertility

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 taking this medicine.

Pregnancy

You should not use this medicine during pregnancy. Tell your doctor if you are pregnant or intend to become pregnant.

Breast-feeding

You should not use this medicine during breast-feeding. Tell your doctor if you are breast-feeding or intend to breast-feed.

Fertility

There are no data suggesting an effect of treatment with dorzolamide on human fertility.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Itoco can cause side effects such as dizziness and blurred vision which may affect your ability to drive car or used machines. Wait to drive or use machines until you feel good or your vision is clear. You are responsible for assessing whether you are fit to drive a motor vehicle or perform work that requires increased attention. One of the factors that can affect your ability in these respects, the use of drugs is due to their effects and/or side effects.

Descriptions of these effects and side effects can be found in other sections. Therefore read all information in this leaflet for guidance. If you are not sure, talk to your doctor or pharmacist.

3. How to use Itoco

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

The appropriate dosage and duration of treatment will be established by your doctor.

When this medicine is used alone, the recommended dose is one drop in the affected eye(s) in the morning, in the afternoon and in the evening.

If your doctor has recommended you use this medicine with a beta-blocker eye drop to lower eye pressure, then the recommended dose is one drop of Itoco in the affected eye(s) in the morning and in the evening.

If you are using Itoco with another eye drop, the drops should be instilled at least 10 minutes apart. Eye ointments should be administered last.

Do not change the dose of the medicine without consulting your doctor.

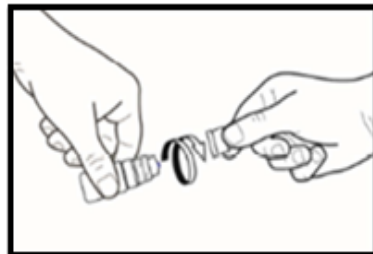
Do not allow the tip of the bottle to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the bottle, wash your hands before using this medicine and keep the tip of the single dose container away from contact with any surface.

Before instillation of the eye drops:

- When using for the first time, before delivering a drop to the eye, you should first of all practice 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, choose the position most comfortable for the instillation of the drops (you can sit down, lie on his back, or stand in front of a mirror).

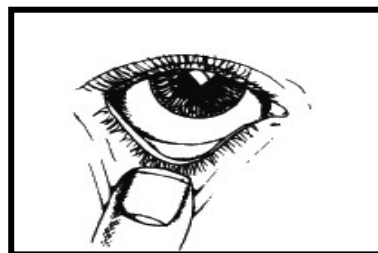
Instructions for use:

1. Wash hands carefully before using this medicine.
2. If the packaging or bottle is damaged the medicine should not be used.
3. When using the medicine for the first time, the cap should be unscrewed 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*).



Picture 1

4. If the tamper-proof ring is loose it should be thrown away because it may fall into the eye and make injuries.
5. Tilt his head back and gently pull down his lower eyelid to form a pouch between his eye and eyelid (*see picture 2*). Avoid contact between the tip of the bottle and eye, eyelids or fingers to prevent contamination of the solution.



Picture 2

6. One drop should be instilled into the pouch by pressing slowly on the bottle. Squeeze the bottle gently in the middle and let a drop fall into his eye. There might be a few seconds delay between squeezing and the drop coming out (*see picture 3*). Do not squeeze too hard, if you are not sure how to administer this medicine, ask doctor, pharmacist or nurse.



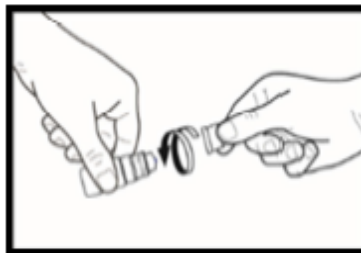
Picture 3

7. Close your eye and press the inner corner of the eye with your finger for about two minutes (*see picture 4*). This helps to stop the medicine from getting into the rest of the body.



Picture 4

8. Repeat steps 5, 6 and 7 with the other eye if the 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 the cap on the bottle should be screwed (*see picture 5*).



Picture 5

If a drop misses the eye, try again.

If you use more Itoco than you should

If you have dropped too many drops in the eye, have swallowed some of the contents of the bottle or if, for example, a child ingested the drops accidentally contact a doctor or hospital for risk assessment and advice.

If you forget to use Itoco

It is important to take this medicine as prescribed by your doctor. If you forget to use this medicine, use it as soon as possible.

However, if it is almost time for the next dose of this medicine, skip the forgotten dose and instill the next one according to the regimen prescribed by your doctor.

Do not take a double dose to make up for a forgotten dose.

If you stop using Itoco

If it is necessary to stop using this medicine contact your doctor immediately.

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 develop allergic reactions, such as hives, swelling of the face, lips, tongue and (or) throat, causing difficulty in breathing and swallowing or severe skin reactions with blistering or peeling, stop using this medicines and contact a doctor immediately or go to your nearest emergency department.

The following side effects have been reported with dorzolamide:

Very common (may affect more than 1 in 10 people)

- Burning and stinging of the eyes.

Common (may affect up to 1 in 10 people)

- Diseases of the cornea with eye pain and blurred vision (superficial punctate keratitis), tearing, secretion with eye itching (conjunctivitis), irritation/inflammation of the eyelids, blurred vision.
- Headache.
- Nausea.
- Bitter taste in the mouth.
- Tiredness.

Uncommon (may affect up to 1 in 100 people)

- Inflammation of the iris and ciliary body of the eye (iridocyclitis).

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

- Tingling and numbness of the hands and legs.
- Transitory shortsightedness (resolving after discontinuation of this medicine), formation of liquid under the retina (detachment of the choroid after filtration surgery), eye pain, formation of crusts on the eyelid, low pressure in the eye, corneal oedema (with symptoms of vision disorders), irritation of the eye with redness,
- Renal stones.
- Dizziness.
- Nasal bleeding, throat irritation.
- Dry mouth.
- Local rash (contact dermatitis), severe skin reactions with blistering or peeling (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Allergic reactions such as rash, hives, itching. In rare cases possible swelling of the lips, eyes and mouth, breathlessness and more rarely wheezing.

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

- Shortness of breath.

- Foreign body sensation in eye (feeling that there is something in your eye).
- Forceful heartbeat that may be rapid or irregular (palpitations).
- Increased heart rate.
- Increased blood pressure.

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 Itoco

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

This medicine does not require any special storage conditions.

Once opened, store below 30°C.

Bottle 5 ml

Discard 60 days after the first opening of the bottle, even if there is some solution left.

Bottle 10 ml

Discard 90 days after the first opening of the bottle, even if there is some solution left.

To help you remember the date you first opened the bottle, write down the date 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 further information

What Itoco contains

- The active substance is dorzolamide. Each ml contains dorzolamide hydrochloride equivalent to 20 mg dorzolamide.
Each drop (about 35 µl) contains 0.70 mg of dorzolamide.
- The other ingredients are hydroxyethylcellulose, mannitol (E421), sodium citrate (E331), sodium hydroxide (E524) (for pH adjustment), purified water.

What Itoco looks like and contents of the pack

Itoco is a clear, colourless, viscous solution.

This medicine is available in white LDPE bottles with multidose HDPE dropper applicator with a silicon valve and with tamper-proof HDPE screw-cap, and the carton box.

Pack sizes:

1 bottle x 5 ml

3 bottles x 5 ml

1 bottle x 10 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Farmaprojects S.A.
Calle Provença 392 6 Planta
08025 Barcelona
Spain

Manufacturer

Warszawskie Zakłady Farmaceutyczne Polfa S.A.
ul. Karolkowa 22/24, 01-207 Warszawa
Poland

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

Czech Republic: Dorzolamide Polpharma
Italy: Dimaz
Ireland: Itoco 20 mg/ml eye drops, solution
Portugal: Dimaz
France: Ofriri 20 mg/mL, collyre en solution
Austria: Itoco 20 mg/ml - Augentropfen, Lösung
Denmark: Itoco
Finland: Itoco
Norway: Dimaz
Sweden: Dimaz

This leaflet was last revised in June 2023