

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine.

- 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. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Proglau is and what it is used for
2. Before you use Proglau
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1. WHAT PROGLAU IS AND WHAT IT IS USED FOR

Dorzolamide is an ophthalmic topical inhibitor of carbonic anhydrase that lowers the pressure in the eyeball.

Therapeutic Indications

Proglau is indicated to lower high pressure in the eye(s) (high intraocular pressure) and to treat glaucoma.

Proglau may be used alone or in association with other medicines to lower the pressure in the eyes (so-called beta-adrenergic blockers). High ocular pressure may damage the optical nerve, which can result in vision deterioration and possible blindness. In general, few symptoms may suggest that you have high ocular pressure. A medical exam is necessary to identify that situation. If you experience an ocular pressure increase, regular medical exams and evaluations of the ocular pressure will be necessary.

2. BEFORE YOU USE PROGLAU

Do not use Proglau

- If you are allergic (hypersensitive) to the active substance (dorzolamide) or to any of the other ingredients of Proglau.
- If you have severe kidney problems.

Take special care with Proglau

Talk to your doctor or pharmacist about any medical problems you may have, or have had, including eye problems and eye surgeries and about any allergies to any medications.

If you experience eye irritation or other recent problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately. If you suspect that dorzolamide is causing an allergic reaction (for example, skin rash or itching) stop its use and contact your doctor, as soon as possible.

Proglau contains benzalkonium chloride as preservative. This substance may deposit on soft contact lenses. If you wear contact lenses, talk to your doctor before applying Proglau.

Use in children

The use of Proglau is not recommended in children.

Use in elderly

According to the developed studies, the effects of dorzolamide are similar in both elderly and young patients.

Use in patients with liver diseases

Tell your doctor if you have or have had liver diseases.

Using Proglau with other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including eye drops and medicines obtained without a medical prescription, particularly any whose active substance is acetylsalicylic acid.

Pregnancy and breast-feeding

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor if you are pregnant or planning to get pregnant.

You should not use Proglau during pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or if you intend to breast-feed.

You should not use Proglau during the breast-feeding period.

Driving and using machines

Possible side effects such as dizziness and visual disturbances, may affect your ability to drive and/or operate machinery (see "Possible Side Effects").

Important information about some of the ingredients of Proglau

Proglau contains benzalkonium chloride. This substance may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. This substance may discolour soft contact lenses.

3. HOW TO USE PROGLAU

Always use Proglau exactly as your doctor has told you. You should check with your doctor or pharmacist if you have any doubts.

Posology and mode of administration

When Proglau is used alone, the 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 to use Proglau with a beta-blocker medicine, in the form of eye drops, also to lower the eye pressure, then the dose should be one drop of Proglau in the affected eye(s) in the morning and in the evening.

If you are using Proglau with other eye drops, Proglau should be instilled at least 10 minutes apart.

Do not change the dosage that your doctor recommended without asking him for advice first. If you have to stop the treatment, contact your doctor immediately.

Eye drops instillation:

1. To open the bottle, unscrew the cap by twisting it clockwise;
2. Tilt your head back and pull your lower eyelid down slightly to form a small pocket between the eyelid and your eye;
3. Invert the bottle and slightly press it until a single drop is instilled into the eye, as recommended by your doctor. Do not touch your eye or eyelid with the dropper tip;
4. Repeat steps 2 and 3 for the other eye, in case your doctor has recommended you to do so;

5. Screw the cap back on by twisting it until it is firmly touching the bottle. Do not screw the cap too tight.

Do not allow the tip of the container to touch the eye or areas around the eye.

Do not allow the tip of the container to touch any object that may contaminate the solution of Proglau.

Duration of the treatment

Your doctor shall tell you the duration of your treatment with Proglau. Do not stop the treatment beforehand, as it may not be effective.

If you use more Proglau than you should

If you swallow the content of the bottle, you should contact your doctor immediately.

If you forget to use Proglau

You should instillate this medicine in the schedule recommended by your doctor. If you miss a dose, apply it as soon as possible and proceed according to the usual posology. However, if it is almost time for the next dose, skip the missed dose and apply the dose according to the regular schedule. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The following side effects may occur:

The patients may feel, in their eyes: burning and prickling feeling, blurred vision, itching, lacrimation, red eye(s), ocular pain, blurred cornea, eyelid swelling or thickening.

After you apply the eye drops, you may feel a bitter taste in your mouth.

Other side effects include headaches, nausea, tiredness, dizziness, sensation of tingling, kidney stones, nasal haemorrhage, dry mouth, irritated throat and allergic-type reactions including skin eruptions, urticaria, itching and shortness of breath.

Rarely, other side effects may occur and some of them may be severe. Ask your doctor or pharmacist for more information on the side effects; both of them have a more complete list.

If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PROGLAU

- Keep out of the reach and sight of children.

- Do not store above 25°C.

- Keep the bottle tightly closed.

- Do not use Proglau after the expiry date which is stated on the outer carton.

- Use Proglau within 28 days, after first opening the bottle.

- 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 Proglau contains

The active substance is dorzolamide, in the form of hydrochloride. Each ml of eye drops, solution contains 20 mg of dorzolamide.

1 drop of Proglau is approximately 0.031 ml (0.62 mg of dorzolamide).

The other ingredients are: mannitol (E421), sodium citrate dihydrate, hydroxyethylcellulose, benzalkonium chloride, sodium hydroxide and water for injection.

What Proglau looks like and contents of the pack

Proglau is presented in the pharmaceutical form of eye drops, solution and is available in 5 ml bottles, in packages of 1, 3 and 6 units. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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