

Package leaflet: Information for the user

Brolene® 0.1% w/v Eye Drops Solution

Propamidine isetionate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

In this leaflet:

1. What Brolene Eye Drops are and what they are used for
2. What you need to know before you use Brolene Eye Drops
3. How to use Brolene Eye Drops
4. Possible side effects
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6. Contents of the pack and other information

1. What Brolene Eye Drops are and what they are used for

Brolene Eye Drops contain a medicine called propamidine isetionate. This belongs to a group of medicines called disinfectants and antifungals. It works by stopping the growth of bacteria, allowing your body to fight off the infection.

It is used for minor infections of the eye or eyelid. Signs include sore, red or inflamed eyes, stickiness or a crust on the eyelids.

2. What you need to know before you use Brolene Eye Drops

Do not use this medicine and tell your doctor or pharmacist if:

- × You are allergic (hypersensitive) to propamidine isetionate or any of the other ingredients of Brolene Eye Drops (listed in Section 6 below). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat, tongue or around the eyes.
- × You wear contact lenses. You should not wear contact lenses while using these drops.

Do not use this medicine if the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Brolene Eye Drops.

Pregnancy and breast-feeding

Talk to your doctor before using this medicine if you are pregnant, might become pregnant or think you may be pregnant. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking or using any medicine.

Driving and using machines

You may have blurred eyesight straight after using this medicine. If this happens, do not drive or use any tools or machines until you can see clearly.

Important information about some of the ingredients of Brolene Eye Drops

This medicine contains 0.005 mg benzalkonium chloride in each drop (0.05 ml) which is equivalent to 0.1 mg/ml.

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 abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Brolene Eye Drops

Always use Brolene Eye Drops exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

How to use this medicine

- Wash your hands
- Remove the cap from the bottle
- Tilt your head back



Squeeze one or two drops inside the lower lid without touching your eye

- Close your eye
- Wipe away any excess liquid from the eyes with a clean tissue.
- Always put the cap back on the bottle as soon as you have used it.

How much to use

- One or two drops in the affected eye up to four times a day
- Use for at least 2 days
- If your symptoms worsen or do not improve after 2 days, talk to your doctor or pharmacist

If you forget to use Brolene Eye Drops

If you forget a dose, use your drops as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, Brolene Eye Drops can cause side effects, although not everybody gets them.

Stop using Brolene Eye Drops and see a doctor as soon as possible if:

- You get any kind of skin problem, such as a rash or itching around your eyes or they become more red
- You get eye pain or irritation, such as a stinging or burning sensation.

Reporting of side effects

If you get any side effects, talk to your doctor, 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 Brolene Eye Drops

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

Do not use Brolene Eye Drops after the expiry date which is stated on the label and carton. The expiry refers to the last day of that month.

Do not store above 25°C.

Brolene Eye Drops are sterile when you buy them, so you must not keep them for more than four weeks after opening the bottle (or if the drops are being used in a hospital environment, they should only be used for 7 days after first opening).

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. Contents of the pack and other information

What Brolene Eye Drops contains

- The solution contains 0.1% w/v of the active substance, propamidine isetionate

- The other ingredients are ammonium chloride, sodium chloride, benzalkonium chloride solution, sodium hydroxide and water for injections

What Brolene Eye Drops looks like and contents of the pack

Brolene Eye Drops is a liquid supplied in a 10 ml plastic dropper bottle with a tamper-proof cap. An auto-drop device may also be supplied as a separate item.

Marketing Authorisation Holder and ManufacturerMarketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Zentiva k.s., U Kabelovny 130, 102 37 Prague 10, Czech Republic

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in April 2022.