

Package Leaflet: Information for the user
Brolene® 0.1%w/v Eye Drops Solution
(propamidine isetionate)

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Brolene Eye Drops carefully to get the best results from it.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact a doctor if your symptoms worsen or do not improve after 2 days
- 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

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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 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

Brolene Eye Drops contains benzalkonium chloride. This may cause your eyes to become irritated.

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.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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IRL – Dublin 2 Tel: +353 1 6764971

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5 How to store Brolene Eye Drops

- Keep this medicine out of the sight and reach of children.
- Store below 25°C.
- Do not use this medicine after the expiry date which is stated on the label and carton.
The expiry date refers to the last day of that month.

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).

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 Further 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, 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.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, B98 0RE, UK.

The manufacturer is:

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

Brolene is a registered trademark of Sanofi.

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited,

Tel: +44 (0)1527 505414 for help.