PACKAGE LEAFLET: **Pregnancy and breast-feeding** I. What Brolene Eye Drops are and **INFORMATION FOR THE USER** Talk to your doctor before using this what they are used for medicine if you are pregnant, might become **Brolene® 0.1% w/v Eye Drops** pregnant or think you may be pregnant. Brolene Eye Drops contain a medicine called Propamidine isetionate If you are breast-feeding or planning propamidine isetionate. This belongs to a to breast-feed, talk to your doctor or group of medicines called disinfectants and pharmacist before taking or using any STADA antifungals. It works by stopping the growth medicine. of bacteria, allowing your body to fight off the infection. Driving and using machines Is this leaflet hard You may have blurred eyesight straight to see or read? Phone 01484 848164 It is used for minor infections of the eve or after using this medicine. If this eyelid. Signs include sore, red or inflamed happens, do not drive or use any tools for help eyes, stickiness or a crust on the eyelids. or machines until you can see clearly. 2. Before you use Brolene Eye Drops Read all of this leaflet carefully because Important information about some of the it contains important information for ingredients of Brolene Eye Drops Do not use this medicine and tell vou. \mathbf{X} Brolene Eye Drops contains benzalkonium This medicine is available without your doctor or pharmacist if: prescription. However, you still need to use Brolene Eye Drops carefully to get the best chloride You are allergic (hypersensitive) to This medicine contains 0,0025 mg propamidine isetionate or any of the benzalkonium chloride in each drop (0.05 results from it. other ingredients of Brolene Eye Drops ml), which is equivalent to 0.05 mg/ml. Keep this leaflet. You may need to read it (listed in Section 6 below) Benzalkonium chloride may be absorbed again. Signs of an allergic reaction include: by soft contact lenses and may change the Ask your pharmacist if you need more a rash, swallowing or breathing colour of the contact lenses. You should information or advice problems, swelling of your lips, face, remove contact lenses before using this You must contact a doctor if your throat, tongue or around the eyes. medicine and put them back 15 minutes symptoms worsen or do not improve after Do not use this medicine if the above apply afterwards. 2 days to you. If you are not sure, talk to your Benzalkonium chloride may also cause eye If any of the side effects gets serious, or doctor or pharmacist before using Brolene irritation, especially if you have dry eyes or if you notice any side effects not listed Eye Drops. disorders of the cornea (the clear layer at the in this leaflet, please tell your doctor or front of the eye). If you feel abnormal eye pharmacist. Take special care with Brolene Eye Â sensation, stinging or pain in the eye after Drops if: using this medicine, talk to your doctor. In this leaflet: You wear contact lenses. You should 1. What Brolene Eye Drops are and what not wear contact lenses while using 3. How to use Brolene Eye Drops they are used for these drops. 2. Before you use Brolene Eye Drops If you are not sure if the above apply to you, Always use Brolene Eye Drops exactly as talk to your doctor or pharmacist before How to use Brolene Eye Drops your doctor or pharmacist has told you. You 4. Possible side effects using Brolene Eye Drops. should check with your doctor or pharmacist 5. How to store Brolene Eve Drops if you are not sure. Turn Over 6. Further information

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 vour eve
- · 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 Our 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 stop using Brolene Eye Drops

Do not stop using Brolene Eye Drops just because your eye(s) feel better. If you stop, your infection may come back.

If you have any further questions on 2 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 a stinging or burning sensation in
- vour eve

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 leaffet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
- 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 in a safe place where children cannot see or reach it.

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

Store below 25°C

Brolene Eye Drops are sterile when you buy them, so you must not keep them for more (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 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 tamperproof cap. An auto-drop device may also be supplied as a separate item

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder STADA, Linthwaite, Huddersfield, HD7 5QH, UK Email: thorntonross@medinformation.co.uk

<u>Manufacturer</u> 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.

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