Package leaflet: Information for the user

Brolene Antibiotic® 0.5% w/v Eye Drops Chloramphenicol

Is this leaflet hard to see or read?

Phone 0800 035 2525 for help

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 Antibiotic Eye Drops carefully to get the best results from them.

- 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 Antibiotic Eye Drops are and what they are used for

Brolene Antibiotic Eye Drops contain a medicine called chloramphenicol. This belongs to a group of medicines called antibiotics. It works by stopping the growth of bacteria, allowing your body to fight off the infection.

Brolene Antibiotic Eye Drops are used to treat minor infections of the eye or eyelid caused by bacteria (bacterial conjunctivitis). Signs include sore, red or inflamed eyes, sticky discharge or crust on the lids.

2. Before you use Brolene Antibiotic Eye Drops

Do not use this medicine and tell your doctor if:

- You are allergic (hypersensitive) to chloramphenicol or any of the other ingredients of Brolene Antibiotic 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 and worsening of redness, itching or swelling of the eye or eyelid.
- You or anyone in your family have had any problems with your blood, including 'aplastic anaemia'

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 Antibiotic Eye Drops.

Warnings and Precautions

Take special care with Brolene Antibiotic Eye Drops

Check with your doctor before taking your medicine if:

- You have problems with your eyesight
- You have severe pain within the eye
- Your eyes are sensitive to light
- You have eye inflammation and a rash on your face or scalp
- Your eye looks cloudy
- The pupil of your eye looks unusual
- You think that you have a foreign object in your eye
- You have recently had conjunctivitis
- You have glaucoma
- Your eyes produce fewer tears (dry eye syndrome)
- You have had eye surgery or laser treatment in the last 6 months
- You have an eye injury
- You are using other eye drops or eye ointment
- You wear contact lenses. You should not wear contact lenses while using these eye drops and for at least 24 hours after completing your treatment.

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

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Brolene Antibiotic Eye Drops can affect the way some other medicines work. Also some medicines can affect the way Brolene Antibiotic Eye Drops work.

In particular, tell your doctor if you are taking any of the following:

- Medicines for cancer
- Medicines for the immune system such as azathioprine.

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.

You should not breast-feed if you are taking Brolene Antibiotic Eye Drops. This is because small amounts may pass into mothers' milk.

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.

Brolene Antibiotic Eye Drops contains Borax and Boric acid

3. How to use Brolene Antibiotic Eye Drops

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

Using this medicine

- Use the eye drops during waking hours only
- Do not use for more than 5 days without talking to your doctor

How to use this medicine

- Wash your hands
- Remove the cap from the bottle
- Tilt your head back
- Squeeze one drop inside the lower lid without touching your eye with the bottle
- Close your eye
- Wipe away any excess liquid from the eye with a clean tissue
- Always put the cap back on the bottle as soon as you have used it

How much to use

Adults, Elderly and Children over 2 years of age

- One drop in the affected eye every two hours for the first 2 days (48 hours)
- After the first 2 days, one drop in the affected eye every four hours
- Talk to your doctor or pharmacist if your symptoms do not improve within 2 days or if your eyes get worse
- Keep using the eye drops for 5 days even if your symptoms improve

If you forget to use Brolene Antibiotic Eye Drops

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

If you stop using Brolene Antibiotic Eye Drops

Keep using the eye drops for 5 days even if your symptoms improve. Do not stop using Brolene Antibiotic Eye Drops just because your eye(s) feel better. If you stop, your infection may come back.

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 Antibiotic Eye Drops can cause side effects, although not everybody gets them.

Stop using Brolene Antibiotic 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 bruise more easily than usual or you get infections more easily or frequently than usual. You may also feel tired or weak
- You notice any swelling of your face, lips or tongue, itching or rash with swelling of skin.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

• Stinging or burning in your eyes. This should only last for a short time and occurs immediately after using the eye drops

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 the Yellow Card Scheme

at: www.mhra.gov.uk/yellowcard or search for the 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 Antibiotic 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 in the fridge (between $2^{\circ}C$ and $8^{\circ}C$) and protect from light.

Brolene Antibiotic Eye Drops are sterile when you buy them. Discard any drops remaining after 5 days of use.

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. Contents of the pack and other information

What Brolene Antibiotic Eye Drops contains

- The solution contains 0.5% w/v of the active substance, chloramphenicol
- The other ingredients are borax, boric acid and water for injections

What Brolene Antibiotic Eye Drops looks like and contents of the pack

Brolene Antibiotic Eye Drops is a clear to light yellow liquid supplied in a 10 ml plastic dropper bottle.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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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.

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