

Active ingredients: Propamidine isethionate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Brolene. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Brolene.

Where to find information in this leaflet:

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- 2. What should I know before I use Brolene?
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1. Why am I using Brolene?

Brolene contains the active ingredient propamidine isethionate.

Brolene is a type of antibiotic used to treat eye infections.

Your doctor, however, may recommend Brolene for another purpose.

 Ask your doctor or pharmacist if you have any questions about why it has been recommended to you.

2. What should I know before I use Brolene?

Warnings

Do not use Brolene if:

- you are allergic to propamidine isethionate, or any of the ingredients listed at the end of this leaflet.
- if you have allergies to other substances, such as foods, preservatives or dyes.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Always check the ingredients to make sure you can use this medicine.

 Do not use Brolene when you are wearing soft or gaspermeable contact lenses.

Check with your doctor or pharmacist:

- if you take any medicines for any other condition
- If you have not told your doctor or pharmacist about any of the above, tell them before you use Brolene.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Your doctor or pharmacist will discuss the risks and benefits of using it if you are pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

It is not known whether Brolene passes into breast milk. Your doctor or pharmacist will discuss the risks and benefits of using it if you are breastfeeding or planning to breastfeed.

Use in infants

Brolene should not be used in infants except on medical advice

What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Brolene, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while using Brolene.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Brolene.

3. How do I use Brolene?

How much to use

- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.
- The standard dose for Brolene is one to two drops three to four times a day.
- Your doctor may have recommended a different dose.
- Ask your doctor or pharmacist if you are unsure of the correct dose for you.
- If you use the wrong dose, Brolene may not work as well and your problem may not improve.

When to use Brolene

 If you are not sure when to use it, ask your doctor or pharmacist.

How to use Brolene

- It is best to clean the eye with either saline solution or water that has previously been boiled
- Wash your hands
- Tilt your head backwards
- Pull down on the lower eyelid
- Put one or two drops inside the lower eyelid without touching the nozzle to your eye or eyelid
- Close your eye and wipe away any excess drops with a clean tissue

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Replace cap immediately

How long to use Brolene

If there is no improvement after using Brolene within 24-48 hours, or if the infection has not cleared completely after using Brolene for 7 days, discontinue use and see your doctor. Brolene should not be used for more than a week at a time, unless recommended by a doctor.

Ask your doctor or pharmacist if you are not sure how long to use the medicine.

If you use too much Brolene

If you think that you have used too much Brolene, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

4. What should I know while using Brolene?

Things you should do

- Remind any doctor, optometrists, dentists or pharmacist you visit that you are using Brolene.
- If vision is disturbed or symptoms become worse during therapy, discontinue use and see your doctor.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Brolene.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using this medicine.
- If you become pregnant while using Brolene, tell your doctor or pharmacist.

Things you should not do

- Do not use more than the recommended dose unless your doctor or pharmacist tells you to.
- To avoid passing on the infection, do not share this medicine with anyone else.
- Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

If you forget to use Brolene

If you forget to use Brolene, put some in as soon as you remember and then go on as before.

If it is almost time for your next dose, skip the dose you missed and use the next dose when you are meant to.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for hints.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Brolene affects your vision. Sometimes blurring of vision can occur. Do not drive or operate machinery until your vision is clear.

If you continue to have problems seeing clearly, stop using Brolene and see your doctor.

Looking after your medicine

Store below 25#C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

 Brolene should be discarded 4 weeks after first opening, because of the risk of contamination.

5. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Brolene.

Less serious side effects

These are mild side effects of this medicine and are usually short-lived.

Less serious side effects	What to do
Skin-related skin troubles such as a rash or itching around the eyes Eye disorders eyes getting redder	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Serious/rare side effects

Serious side effects	What to do
eye pain or if irritation occurs, in the form of a stinging or burning sensation	Stop using Brolene and tell your doctor immediately.
swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or Medsafe in New Zealand https://www.medsafe.govt.nz/safety/report-a-problem.asp#Medicine. By reporting side effects, you can help provide more information on the safety of this medicine.

6. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Brolene contains

Active ingredient (main ingredient)	propamidine isethionate 1 mg/mL
Other ingredients (inactive ingredients)	 ammonium chloride benzalkonium chloride sodium chloride water sodium hydroxide

Brolene does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Brolene looks like

Brolene Eye Drops are a colourless solution available in 10mL bottles.

AUST R 27486

Who distributes Brolene

Brolene is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Brolene is supplied in New Zealand by:

sanofi-aventis new zealand limited

56 Cawley Street

Ellerslie

Auckland

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