

Data Sheet

BROLENE[®]

NAME OF THE MEDICINE

Brolene Eye Drops

Non-proprietary name: propamidine isethionate
Chemical formula: 1,3-di-(4-aminophenoxy)propone di-(2-hydroxyethene-sulfate)
Molecular formula: C₁₇H₂₀N₄O₂.2C₂H₆O₄S
Molecular weight: 564.6
CA S number: 140-63-6

Brolene Eye Ointment

Non-proprietary name: dibromopropamidine isethionate
Chemical formula: 3,3'-dibromo-4,4'-(propane-1,3-diybisoxo)dibenzimidine bis(2-hydroxyethanesulphonate)
Molecular formula: C₁₇H₁₈Br₂N₄O₂.2C₂H₆O₄S
Molecular weight: 722
CAS number: 614-87-9

DESCRIPTION

Brolene Eye Drops are a colourless solution containing 1 mg/mL propamidine isethionate in a sterile, aqueous vehicle, the resultant solution being isotonic with lacrimal secretion. Excipients include benzalkonium chloride 0.05mg/mL as preservative, ammonium chloride, sodium chloride and sodium hydroxide.

Brolene Eye Ointment is a deep yellow, smooth ointment containing 1.5 mg/g dibromopropamidine isethionate in an eye ointment base B.P. Excipients include phenethyl alcohol 5mg/g as preservative, paraffin-soft yellow, paraffin-liquid and lanolin.

PHARMACOLOGY

Class

Propamidine and dibromopropamidine are members of the aromatic diamidine group of compounds which possess bacteriostatic properties against a wide range of organisms.

Site and Mode of Action

Propamidine and dibromopropamidine exert rapid and intense anti-bacterial action against pyogenic cocci, antibiotic-resistant staphylococci and some Gram-negative bacilli. Activity is retained in the presence of organic matter such as pus and lacrimal secretion.

INDICATIONS

Brolene Eye Drops are for the treatment of eye infections such as acute and chronic conjunctivitis, and for the prevention of infection resulting from minor injuries to the eye caused by foreign bodies, etc. Useful for the initial treatment of ophthalmia neonatorum.

Brolene Eye Ointment is particularly suitable for the treatment of eyelid infections such as blepharitis and for the treatment of minor injuries to the eyes, particularly for night-time application. A useful indication is to relieve 'sticky eyes' very commonly experienced with babies.

CONTRAINDICATIONS

Hypersensitivity to propamidine or any other component of the preparations.

PRECAUTIONS

Brolene Eye Drops should be discarded four weeks after first opening the bottle for domiciliary use or seven days after opening for hospital use.

Brolene Eye Ointment should be discarded one month after first opening the tube.

If no improvement is observed within two days, medical advice should be obtained and a different anti-bacterial preparation used where necessary.

Brolene should not be used while wearing soft or gas-permeable contact lenses.

Not to be used in eye infections in infants except on medical advice.

Use in Pregnancy

Safety of use in pregnancy has not been established. Use only if considered essential by a physician.

Use in Lactation

Use during lactation only if considered essential by a physician.

Effects on Ability to Drive or Operate Machinery

Brolene may cause blurring on instillation. If blurring occurs, patients should not drive or operate hazardous machinery until vision is clear.

ADVERSE EFFECTS

Hypersensitivity may occur.

There is always the possibility, though rare, of a skin sensitisation reaction resulting from the use of Brolene; in such an event, treatment should be discontinued immediately.

Eye pain or irritation, usually in the form of a stinging or burning sensation, may also occur. In such cases, use should be discontinued immediately and a physician should be consulted.

DOSAGE AND ADMINISTRATION

Before the application of Brolene, it is advisable, where practical, to cleanse the affected eye with warm water or saline solution which has previously been boiled.

Brolene Eye Drops should be instilled into the infected eye at the rate of one or two drops four times a day for not more than a week.

Brolene Eye Ointment should be applied to the eyelids or conjunctival sacs two or three times daily for not more than one week.

OVERDOSAGE

Contact the Poisons Information Centre on 0800 POISON or 0800 764 766 for advice.

PRESENTATION AND STORAGE CONDITIONS

*Brolene Eye Drops (plastic dropper bottle): 10 mL

Brolene Eye Ointment (collapsible tube): 5 g

Store below 25°C.

Protect from light.

Brolene Eye Drops should be discarded one month after first opening the bottle.

Brolene Eye Ointment should be discarded one month after first opening the tube.

MEDICINE CLASSIFICATION

Pharmacy Only Medicine

NAME AND ADDRESS OF THE SPONSOR

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*Marketed presentation