PRODUCT INFORMATION

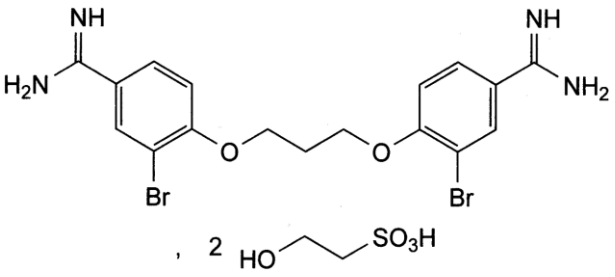
BROLENE®

NAME OF THE MEDICINE

Ointment

Non-proprietary name: Dibromopropamidine isethionate

Structural formula



Chemical formula:	3,3'-dibromo-4,4'-(propane-1,3-diybisoxy)dibenzimidine bis(2-hydroxyethanesulphonate)
Molecular formula:	$C_{17}H_{18}Br_2N_4O_2.2C_2H_6O_4S$
Molecular weight:	722
CAS number:	614-87-9

Drops

Non-proprietary name:	Propamidine isethionate
Chemical formula:	1,3-di-(4-aminophenoxy)propone di-(2-hydroxyethene-sulfate)
Molecular formula:	$C_{17}H_{20}N_4O_2.2C_2H_6O_4S$
Molecular weight:	564.6
CAS number:	140-63-6

DESCRIPTION

Ointment

Dibromopropamidine isethionate 1.5mg/g in an eye ointment base. Excipients include phenethyl alcohol 5mg/g as preservative, yellow soft paraffin, paraffin-liquid and lanolin.

Drops

Propamidine isethionate 1mg/mL in a sterile (aqueous) vehicle, isotonic with the lacrimal secretion. Excipients include benzalkonium chloride 0.05mg/mL as preservative, ammonium chloride, sodium chloride and sodium hydroxide.

ACTIONS

Propamidine and dibromopropamidine possess inhibitory activity against a range of organisms, mainly gram-positive, as well as acanthamoeba.

INDICATIONS

1. Treatment of mild acute conjunctivitis.
2. Acanthamoeba keratitis (for use under medical supervision).

CONTRAINDICATIONS

Hypersensitivity to the active substance or any of the excipients.

PRECAUTIONS

Brolene should be discarded 4 weeks after first opening for domiciliary use or 7 days after opening for hospital use, because of the risk of contamination.

If vision is disturbed or symptoms become worse during therapy, use should be discontinued and a physician should be consulted.

Discontinue use and seek medical advice if infection does not improve within 24-48 hours or clear completely in 7 days. There is always the possibility, although rare, of a sensitisation reaction resulting from the use of Brolene preparations; in such an event, treatment should be immediately discontinued.

Do not use Brolene when 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

Safety of use in lactation has not been established. 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.

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 to cleanse the affected eye with warm water or saline solution which has previously been boiled.

The ointment should be applied to the conjunctival sacs 2 or 3 times daily for not more than 1 week.

The drops should be instilled into the affected eye at the rate of 1 or 2 drops 3 or 4 times daily, for not more than 1 week.

A suggested method is to use the ointment at bedtime and the eye drops during the day. If Brolene is effective, there will be an obvious improvement within 2 days. If this has not occurred, further medical advice should be obtained.

OVERDOSAGE

For information on the management of overdose, contact the Poison Information Centre on 13 11 26 (Australia).

PRESENTATION AND STORAGE CONDITIONS

Eye ointment: 5 g◆

Eye drops (plastic dropper bottle): 10 mL

Store below 25°C

NAME AND ADDRESS OF THE SPONSOR

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113
AUSTRALIA

POISON SCHEDULE OF THE MEDICINE

S2

Date of TGA approval: 12 September 1997

Date of most recent amendment: 17 August 2017

◆ Non-marketed presentation