DATA SHEET

1 PRODUCT NAME

Brolene eye drops, solution, 0.1%.

Brolene eye ointment, 0.15% (non-marketed).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Brolene eye drops contain 1 mg/mL propamidine isetionate in a sterile, aqueous vehicle, the resultant solution being isotonic with lacrimal secretion.

Brolene eye ointment contains 1.5 mg/g dibromopropamidine isetionate in an eye ointment base B.P.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Brolene Eye Drops are a colourless solution.

Brolene Eye Ointment is a deep yellow, smooth ointment.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC 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.

4.2 DOSE AND METHOD OF 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.

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substance or any of the excipients. For the full list of excipients, see section 6.1.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Brolene should be discarded 4 weeks after first opening for domicillary 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.

Paediatric Use

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

4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

None known.

4.6 FERTILITY, PREGNANCY AND LACTATION

Pregnancy

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

Breast-feeding

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

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

4.8 UNDESIRABLE 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 OVERDOSE

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: ophthalmologicals, other antiinfectives, ATC code dibromopropamidine: S01AX14, ATC code propamidine: S01AX15.

Brolene Eye Drops

Non-proprietary name:	propamidine isetionate
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

Brolene Eye Ointment

Non-proprietary name:	dibromopropamidine isetionate
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

Mechanism of Action

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

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.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICAL SAFETY DATA

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Brolene eye drops: benzalkonium chloride 0.05mg/mL as preservative, ammonium chloride, sodium chloride and sodium hydroxide.

Brolene eye ointment: phenethyl alcohol 5mg/g as preservative, yellow soft paraffin, paraffin-liquid and lanolin.

6.2 INCOMPATIBILITIES

Not known.

6.3 SHELF LIFE

Brolene eye drops: 24 months from the date of manufacture stored at or below 25°C. Brolene Eye Drops should be discarded 4 weeks after first opening the bottle.

Brolene eye ointment: 36 months from the date of manufacture stored at or below 25°C. Brolene Eye Ointment should be discarded 4 weeks after first opening the tube.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light.

For storage conditions after first opening of the medicine, see section 6.3.

6.5 NATURE AND CONTENTS OF CONTAINER

Brolene eye drops (plastic dropper bottle): 10 mL.

♦Brolene eye ointment (collapsible tube): 5 g.

♦Non-marketed presentation

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE

Pharmacy Only Medicine.

8 SPONSOR

sanofi-aventis new zealand limited
Level 8, 56 Cawley Street
Ellerslie, Auckland, New Zealand

9 DATE OF FIRST APPROVAL

Brolene eye drops: 31 December 1969.

Brolene eye ointment: 31 December 1969.

10 DATE OF REVISION OF THE TEXT

09 August 2017.

SUMMARY TABLE OF CHANGES

Below highlights the main differences between the current and the new formatted Data Sheet document:

Section	Updated text
Throughout the data sheet	The Data Sheet has been updated to SPC-style format. Medicine names updated to match INNs. In text references updated for consistency.
4.3 Contraindications	Updated for clarity.
4.4 Special warnings and precautions for use	Section text updated throughout. 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.
4.6 Fertility, pregnancy and lactation	Safety of use in lactation has not been established.
4.8 Undesirable effects	Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

Section	Updated text
4.9 Overdose	For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).
5.1 Pharmacodynamic properties	Pharmacotherapeutic group: ophthalmologicals, other antiinfectives, ATC code dibromopropamidine: S01AX14, ATC code propamidine: S01AX15.
6.3 Shelf life	Brolene eye drops: 24 months from the date of manufacture stored at or below 25^{o}C. Brolene Eye Drops should be discarded 4 weeks after first opening the bottle. Brolene eye ointment: 36 months from the date of manufacture stored at or below 25^{o}C. Brolene Eye Ointment should be discarded 4 weeks after first opening the tube.
9 Date of first approval	Brolene eye drops: 31 December 1969. Brolene eye ointment: 31 December 1969.
10 Date of revision of the text	09 August 2017.