Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Brolene 0.15 % w/w Eye Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dibrompropamidine Isetionate 0.15 % w/w.

Excipients: contains Wool fat 9.7% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye ointment.
A pale yellow, smooth, sterile ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an anti-infective for use in local infections of the superficial structures of the eye due to microorganisms sensitive to its action.

4.2 Posology and method of administration

For ocular use.

Adults, elderly persons, and children: Cleanse the affected area and apply the ointment topically to the eyelid or conjunctival sac once or twice daily, for not more than 2 days.

4.3 Contraindications

Hypersensitivity to any component of the preparation.

Use of contact lenses.

4.4 Special warnings and precautions for use

If there is no significant improvement within 2 days medical advice should be sought.

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 discontinued immediately. Should erythema or other evidence of increased inflammation occur application should cease immediately and medical opinion should be sought.

If problems of visual acuity occur or its symptoms are detected, the doctor should be consulted immediately.

Brolene Ointment contains wool fat, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

Brolene Eye Ointment may cause transient blurring of vision on instillation. Patients should be warned not to drive or operate machinery unless vision is clear.

4.8 Undesirable effects

Eye disorders:
Not known: Eye pain or irritation, usually in the form of a stinging or burning sensation. In such cases use should be discontinued immediately. If symptoms persist medical advice should be sought.

Immune system disorders:
Not known: Hypersensitivity may occur, in which case treatment should be discontinued immediately.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Topical overdose is not applicable. Oral ingestion of a full 5g tube is unlikely to cause any toxic effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dibrompropamidine is a member of the aromatic diamidine group of compounds, which possess bacteriostatic properties against a wide range of fungi and bacteria. These diamidines exert antibacterial action against pyrogenic cocci, antibiotic resistant staphylococci and some gram-negative bacilli. The activity of the diamidines is retained in the presence of organic matter such as pus and blood.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

There is no other information available which could be of relevance to the prescriber in recognising the safety profile of Brolene and which is not included in the relevant sections of this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, white soft
Paraffin liquid
Wool fat
Phenyl Ethanol
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 18 months.
Opened: 4 weeks.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Printed, internally lacquered aluminium tube with screw capped nozzle fitted with a polythene cap, containing 5g of ointment.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi-Aventis Ireland Ltd. T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0540/094/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

March 2018