Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Brolene 0.1% w/v Eye Drops Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Propamidine isetionate 0.1% w/v.

Excipients: contains Benzalkonium Chloride solution 0.01% v/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution (eye drops).
A clear, colourless, sterile, aqueous solution.

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.

The usual dosage is 1-2 drops into the affected eye up to four times daily.

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 discontinue 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.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

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 Drops 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

Hypersensitivity may occur, in which case 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 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
IMB Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971
Fax: +353 1 6762517.
Website: http://www.imb.ie/; e-mail: imbpharmacovigilance@imb.ie

4.9 Overdose

Topical overdose is not applicable. Oral ingestion of a full 10ml bottle is unlikely to cause any toxic effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Propamidine is a member of the aromatic diamidine group of compounds which possess bacteriostatic properties against a wide range of organisms. 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 tissue fluids, pus, and semen.

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

Ammonium chloride
Sodium chloride
Benzalkonium chloride solution
Water for injections
Sodium hydroxide (for pH adjustment)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 2 years.
Opened: The drops should be discarded 28 days after first opening for domiciliary use or after 7 days when used under hospital conditions.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Low density polyethylene bottle and plug with high density polyethylene tamperproof cap containing 10ml of solution, packaged in a cardboard carton.

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

PA0540/094/001

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

April 2014