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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution (eye drops).
Product imported from the United Kingdom:
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.

Brolene contains a preservative called benzalkonium chloride. This may cause eye irritation or disruption to the surface of the eye. Benzalkonium chloride can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact with soft contact lenses. If you wear contact lenses, you should remove them before using Brolene. After using Brolene you should wait 15 minutes before putting your contact lenses back in.

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.

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

The shelf-life expiry date of this product is the date shown on the bottle and outer carton of the product as marketed in the country of origin.

In-use shelf-life: 28 days (7 days in hospital environment).

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

One plastic bottle containing 10 ml of solution in an outer cardboard carton.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/176/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th June 2012

10 DATE OF REVISION OF THE TEXT