Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Golden Eye 0.1% w/v Eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains 0.1% w/v propamidine isetionate.

Excipient with known effect: Benzalkonium chloride

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops solution
A clear colourless eye drop 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 topical ophthalmic administration.

Adults (Elderly and Children):
For the treatment of minor infections, one or two drops up to four times daily

4.3 Contraindications

i. Hypersensitivity to any component of the preparation.
ii. Soft or gas permeable contact lenses

4.4 Special warnings and precautions for use

If improvement does not occur within 2 days, medical opinion should be sought.
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.
Golden Eye 0.1% w/v Eye Drops Solution contains benzalkonium chloride which may cause eye irritation.
Contact lenses should not be worn while using the drops.
The patient should wait 24 hours after finishing using the drops before starting to use contact lenses again. This is important if soft contact lenses are used as benzalkonium chloride, an ingredient in the drops, is known to discolour soft contact lenses.

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 a physician.

4.7 Effects on ability to drive and use machines

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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal products 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; Email: medsafety@hpra.ie

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antiinfectives, ATC code: S01A X 15
Propamidine is a member of the aromatic diamidine class of compounds which possess bacteriostatic properties against a wide range of organisms.
These diamidines exert antibacterial action against pyogenic 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 serum.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Benzalkonium chloride solution
Purified water
Hydrochloric acid (for pH adjustment)
Sodium hydrochloride (for pH adjustment)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 3 years
Once opened: Discard within 4 weeks of first opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Polypropylene dropper bottle (10ml) fitted with a polypropylene nozzle or a polyethylene (LDPE) dropper bottle (10ml) fitted with a low density polyethylene nozzle and a high density polyethylene tamper evident cap.

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

Cambridge Healthcare Ireland Limited
20 Holles Street
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA22695/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd March 1993

Date of last renewal: 2nd March 2008

10 DATE OF REVISION OF THE TEXT

January 2023