

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Golden Eye 0.15% w/w Eye Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains 0.15% w/w dibromopropamide isetionate

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye ointment

A smooth uniform off-white translucent greasy 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 topical ophthalmic administration.

Adults (Elderly and Children):

Apply topically once or twice daily.

4.3 Contraindications

Hypersensitivity to any component of the preparation.

Contact lenses should not be worn during treatment with this product.

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.

4.5 Interaction with other medicinal products and other forms of interactions

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

Eye ointment will cause blurring of vision on application. 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 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 not applicable. Oral ingestion of a full 5 gram tube is unlikely to cause any toxic effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Biguanides and Amidines, ATC code: S01A X 14

Dibrompropamidine is a member of the aromatic diamidine class of compounds which possess bacteriostatic properties against a wide range of fungi and bacteria.

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 pus and blood.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin

Dispersed polyethylene in mineral oil (Plastibase 50W)

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

A white pigmented, collapsible multi-laminate tube incorporating an aluminium foil barrier with inner polyethylene coating with a polyethylene elongated nozzle with a screw cap containing 5 g 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

Cambridge Healthcare Ireland Limited
20 Holles Street
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA22695/001/002

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

April 2019