

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0148/022/001

Case No: 2028850

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Allergan Pharmaceuticals Ireland

Castlebar Road, Westport, Co. Mayo, Ireland

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Bleph-10 Liquifilm Topical Ophthalmic Solution 10.0 %w/v, eye drops solution

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **01/04/2007**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bleph-10 Liquifilm Topical Ophthalmic Solution 10.0 % w/v, eye drops solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sulfacetamide Sodium 10.0 % w/v

Excipient: Contains benzalkonium chloride 0.005% w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

A clear colourless to slightly straw coloured solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of conjunctivitis, corneal ulcer, and other superficial ocular infections from susceptible microorganism.

As an adjunct to systemic sulfonamide therapy of trachoma.

4.2 Posology and method of administration

Topical installation into conjunctival sac.

Application every two to three hours or as directed by the physician.

4.3 Contraindications

Use in patients hypersensitive to any ingredient of the formulation, or other sulfonamide preparation.

4.4 Special warnings and precautions for use

1. The solutions are incompatible with silver preparations.
2. Prolonged use of anti-infective may result in the development of superinfection due to organisms, including fungi, resistant to that anti-infective.
3. The anti-infective present may be toxic if absorbed from open surfaces.
4. Sulfonamides are inactivated by the aminobenzoic acid present in purulent exudates.
5. As with all sulfonamide preparations, severe sensitivity reactions, e.g. Steven-Johnson's syndrome, fever, skin rash, GI disturbances and bone marrow depression have been identified in individuals with no prior history of sulfonamide hypersensitivity. A significant percentage of staphylococcal isolates are completely resistant to sulfa drugs.

4.5 Interaction with other medicinal products and other forms of interaction

Bleph-10 solution is incompatible with silver preparations.

4.6 Pregnancy and lactation

Safety and effectiveness of Bleph-10 during pregnancy and lactation has not been established. The product should only be used where the benefits are judged to outweigh any risks to the baby.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Sodium sulfacetamide may cause local irritation, stinging and burning. While the irritation may be transient, occasionally, use of the medication has to be discontinued.

4.9 Overdose

For known symptoms of overdosage and particulars of its treatment: Refer to Undesirable Effects, Special Precautions and Warnings for Use listed above.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active ingredient, sulfacetamide sodium (a sulfonamide), exerts a bacteriostatic effect against a wide range of gram-positive and gram-negative microorganisms by restricting, through competition with para-aminobenzoic acid, the synthesis of folic acid which bacteria require for growth.

5.2 Pharmacokinetic properties

Sulfacetamide sodium is a member of the sulfonamide group which competitively inhibits the bacterial enzyme responsible for the incorporation of para-aminobenzoic acid into dihydropteroic acid, a precursor of folic acid. Microorganisms that are affected are those that synthesize their own folic acid. Sulfacetamide sodium has a wide range of antibacterial activity against gram-positive and gram-negative microorganisms such as *Streptococcus pyogenes*, *Streptococcus pneumoniae*, some strains of *Bacillus anthracis* and *Corynebacterium diphtheriae*. *Haemophilus influenzae*, *H. ducreyi*, *Brucella*, *Vibrio cholerae*, *Yersinia pestis*, *Nocardia*, *Actinomyces*, *Calymmatobacterium granulomatis*, and *Chlamydia trachomatis*.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvinyl alcohol
Benzalkonium chloride
Disodium edetate
Sodium Dihydrogen Phosphate Monohydrate
Sodium thiosulfate
Sodium phosphate, dibasic, heptahydrate
Polysorbate 80
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Purified water

6.2 Incompatibilities

Bleph-10 Solution is incompatible with silver preparations

6.3 Shelf Life

18 months unopened
Discard one month after opening

6.4 Special precautions for storage

Do not store above 25°C.
Keep container in outer carton.
Do not use if solution is discoloured (dark brown)

6.5 Nature and contents of container

Bleph-10 Solution will be marketed in 10 ml and 15 ml dropper bottles and tips made from low density polyethylene. Caps are made from medium impact polystyrene. A safety seal is placed around the bottle cap to insure integrity of the product.

Not all pack sizes may be marketed.

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

Allergan Pharmaceuticals Ireland
Castlebar Road,
Westport,
Co. Mayo,
Ireland.

8 MARKETING AUTHORISATION NUMBER

PA 148/22/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1977

Date of last renewal: 1st April 2007

10 DATE OF REVISION OF THE TEXT

April 2007