IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0148/021/001
Case No: 2031031

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

Blephamide Liquifilm Topical Opthalmic Suspension

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 **21/12/2006** until **31/03/2007**.

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

Blephamide LiquifilmTopical Ophthalmic Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	Percent (w/v)
Sulfacetamide sodium	10.00
Prednisolone acetate	0.20
Phenylephrine hydrochloride	0.12

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Eye Drops Suspension
An off-white to slightly yellow, microfine suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of nonpurulent blepharitis and blepharoconjunctivitis (seborrheal, staphylococcal, allergic), and nonpurulent conjunctivitis (allergic and bacterial).

4.2 Posology and method of administration

One drop two to four times daily, depending upon the severity of the condition.
In general, during early or acute stages of blepharitis, Blephamide produces results most rapidly and most efficiently with instillation directly into the eye, with the excess spread on the lid.
When the condition is confined to the lid, however, Blephamide may be applied directly to the site of the lesions.

4.3 Contraindications

Contraindicated inpatients hypersensitive to any ingredient and in ocular infections due to micro-organisms resistant to sulphacetamide. It is also contraindicated in the presence of ocular viral infections, such as superficial (or epithelial) herpes simplex keratitis (dendritic keratitis), vaccinia or varicella, fungal infections of the ocular structures or tuberculosis of the eye.

4.4 Special warnings and precautions for use

In diseases due to microorganisms resistant to sulfacetamide, infection may be masked, enhanced or activated by the steroid. Prolonged use may result in the overgrowth of non-susceptible organisms, or may aid in the establishment of secondary ocular infections from fungi or viruses from ocular tissue, or may suppress the host immune response in ocular tissues and thus increase the possibility of secondary infections. If the infection does not respond promptly, Blephamide should be discontinued until the infection has been controlled by other means.

Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.

Fungal infections of the cornea are particularly prone to develop coincidentally with long term steroid application. When signs of chronic ocular inflammation persist following prolonged corticosteroid dosing, the possibility of fungal infections of the cornea should be considered. Fungal culture should be taken when appropriate.

Prolonged or continued use of corticosteroids may increase intraocular pressure. Therefore intraocular pressure must be frequently controlled particularly in patients with a history of presence of glaucoma.
Topical corticosteroids should not be used for longer than one week except under ophthalmic supervision with regular checks of intraocular pressure.
Prolonged use of anti-infective may result in the development of superinfection due to organisms, including fungi, resistant to that anti-infective. Sulphonamides are inactivated by the aminobenzoic acid present in purulent exudates. The anti-infective may be toxic if absorbed from open surfaces.

Use of ocular corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye. As with all sulphonamide preparations, severe sensitivity reactions, e.g. Stevens-Johnson syndrome, fever, skin rash, GI disturbances and bone marrow depression have been identified in individuals with no prior history of sulphonamide hypersensitivity. A significant percentage of staphylococcal isolates are resistant to sulpha drugs.

4.5 Interaction with other medicinal products and other forms of interaction

Blephamide suspension is incompatible with silver preparations.

4.6 Pregnancy and lactation

Pregnancy:
There are no adequate and well controlled studies in pregnant women, therefore this product should be used in pregnancy only if the potential benefit outweighs the potential risk to the foetus.

Nursing mothers:
It is not known whether topical administration could results in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when this product is administered to a nursing woman taking into consideration the importance of the drug to the mother.

Use in children:
Safety and effectiveness in paediatric patients below the age of two years has not been established.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

The most often from the presence of the anti-infective component are allergic sensitizations.

Those reactions associated with the corticosteroid component include glaucoma with optic nerve damage, visual acuity of field defects, posterior subcapsular cataract formation, secondary ocular infection, perforation of the globe and delayed wound healing.

Occasionally keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperaemia, a loss of accommodation and ptosis have been reported following local use of corticosteroids, however, a casual relationship was not determined.

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

Sodium sulphacetamide is a potent bacteriostatic agent (effective against a variety of pathogens). The prednisolone content in the formulation effectively counters the allergic and inflammatory manifestations of blepharitis. The phenylephrine component rapidly whitens the engorged vessels in the eye and lid.

5.2 Pharmacokinetic properties

After absorption, prednisolone acetate hydrolyses rapidly to the active metabolite prednisolone.

After use of 50 µl of a 1% suspension of prednisolone acetate in human eyes, the following active drug concentrations were found in aqueous:

Minutes	ng/ml
0-30	49.6
31-60	171.4
61- 90	301.9
91-120	669.6
121-180	659.9
181-240	453.0
241-360	251.5
361-720	132.9
721-1080	99.5
1081-1320	28.4

There are no pharmacokinetic or bioavailability data concerning sulfacetamide sodium in Blephamide or other comparable preparations.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvinyl alcohol
Polysorbate 80
Phenylmercuric nitrate
Sodium phosphate monobasic monohydrate
Sodium phosphate dibasic heptahydrate
Edetate disodium
Phenazone (Antipyrine)
Sodium thiosulfate pentahydrate
Hydrochloric acid
Purified water

6.2 Incompatibilities

Incompatible with silver preparations.

6.3 Shelf Life

The shelf-life expiry date for this product shall not exceed 1 year from the date of its manufacture.
Discard 28 days after opening.

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate or freeze.
Keep container in outer carton to protect from light.

6.5 Nature and contents of container

5 ml and 10 ml plastic controlled dropper bottles containing an off-white to slightly yellow microfine suspension. Bottles and tips are made from low density polyethylene, caps are made of polystyrene, and all components contain a white colorant. Each unit of the drug has a safety seal around the bottle cap to insure integrity of the product.

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

To prevent contamination, do not touch the dropper tip to any surface.
Store in an upright position.
Keep bottle tightly closed when not in use.

7 MARKETING AUTHORISATION HOLDER

Allergan Pharmaceuticals (Ireland) Ltd,
Castlebar Road,
Westport,
County Mayo

8 MARKETING AUTHORISATION NUMBER

PA 148/21/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1977

Date of last renewal: 1st April 2002

10 DATE OF REVISION OF THE TEXT

December 2006