IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0365/046/002
Case No: 2077742

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

UCB Pharma Limited

208 Bath Road, **Slough**, **Berkshire SL1 3WE**, **United Kingdom**

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

Betnesol - N 0.1% / 0.5% Eye Ointment

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 **10/02/2010**.

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

Betnesol - N 0.1% / 0.5% Eye Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone Sodium Phosphate 0.10% w/w
Neomycin Sulphate 0.50% w/w (equivalent to 3500 IU/g)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye ointment
A smooth off-white translucent ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the short-term treatment of steroid responsive inflammatory conditions of the eye when prophylactic antibiotic treatment is also required, after excluding the presence of viral and fungal disease.

4.2 Posology and method of administration

Adults (including the elderly) and children

The frequency of dosing depends on the clinical response. If there is no clinical response within 7 days of treatment, the ointment should be discontinued.

Treatment should be the lowest effective dose for the shortest possible time. Normally, Betnesol-N Ointment should not be given for more than 7 days, unless under expert supervision. After more prolonged treatment (over 6 to 8 weeks), the ointment should be withdrawn slowly to avoid relapse.

An extrusion of the ointment about 1/4 inch long may be introduced beneath the lower lid two or three times daily and/or at night.

4.3 Contraindications

Viral, fungal, tuberculous or purulent conditions of the eye. Use is contraindicated if glaucoma is present or herpetic keratitis (e.g. dendritic ulcer) is considered a possibility. Use of topical steroids in the latter condition can lead to an extension of the ulcer and marked visual deterioration.

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

A patient information leaflet should be supplied with this product.

Topical corticosteroids should never be given for an undiagnosed red eye as inappropriate use is potentially blinding.

Treatment with corticosteroid/antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement, since prolonged use may lead to occult extension of infection due to the masking effect of the steroid. Prolonged use may also lead to skin sensitisation and the emergence of resistant organisms.

Prolonged use may lead to the risk of adrenal suppression in infants.

Treatment with corticosteroid preparations should not be repeated or prolonged without regular review to exclude raised intraocular pressure, cataract formation or unsuspected infections.

Aminoglycoside antibiotics may cause irreversible, partial or total deafness when given systemically or when applied topically to open wounds or damaged skin. This effect is dose related and is enhanced by renal or hepatic impairment. Although this effect has not been reported following topical ocular use, the possibility should be considered when high dose topical treatment is given to small children or infants.

4.5 Interaction with other medicinal products and other forms of interaction

None relevant to topical use.

4.6 Pregnancy and lactation

Safety for use in pregnancy and lactation has not been established. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

There is a risk of foetal ototoxicity if aminoglycoside antibiotic preparations are administered during pregnancy.

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 hazardous machinery unless vision is clear.

4.8 Undesirable effects

Hypersensitivity reactions, usually of the delayed type, may occur leading to irritation, burning, stinging, itching and dermatitis.

Topical corticosteroid use may result in corneal ulceration, increased intraocular pressure leading to optic nerve damage, reduced visual acuity and visual field defects.

Intensive or prolonged use of topical corticosteroids may lead to formation of posterior subcapsular cataracts.

In those diseases causing thinning of the cornea or sclera, corticosteroid therapy may result in thinning of the globe leading to perforation.

Mydriasis, ptosis and epithelial punctate keratitis and glaucoma have also been reported following ophthalmic use of corticosteroids.

4.9 Overdose

Long-term intensive topical use may lead to systemic effects.

Oral ingestion of the contents of one tube (3g) of ointment is unlikely to lead to any serious adverse effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: S01C A05.

Betamethasone is a glucocorticoid which has topical anti-inflammatory activity. Neomycin is a broad spectrum aminoglycoside antibiotic.

5.2 Pharmacokinetic properties

Not applicable as the ointment is applied topically to the eye.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Liquid paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 24 months.
Opened: 4 weeks.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze.

6.5 Nature and contents of container

Collapsible aluminium tubes with fine-bore extended nozzle tube fitted with a natural polyethylene cap containing 3 grams 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

UCB Pharma Limited
208 Bath Road
Slough
Berkshire
SL1 3WE
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 365/46/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 August 1993

Date of last renewal: 13 August 2008

10 DATE OF REVISION OF THE TEXT

February 2010