

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0002/033/001

Case No: 2055949

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

Bristol-Myers Squibb Pharmaceuticals Ltd

Swords, Co. Dublin, Ireland

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

Kenacomb Otic 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 **16/12/2008** until **04/06/2009**.

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

Kenacomb Otic Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1g of ointment contains: triamcinolone acetonide 0.1% w/w, neomycin sulphate (equivalent to neomycin) 0.25% w/w (1625 units), gramicidin 0.025% w/w, and nystatin 2% w/w (100,000 units).

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Ointment.

A smooth, shiny amber to yellow coloured homogenous ear ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the topical management of corticosteroid sensitive cutaneous conditions infected or likely to be infected by organisms sensitive to the anti-infectives present.

4.2 Posology and method of administration

Adults and Older Children:

Apply a small amount directly from the tube into the aural canal two to four times daily or as directed by physician.

Elderly, young children and infants:

Corticosteroids should be used sparingly and for short periods of time, in view of the naturally thinner skin.

4.3 Contraindications

In tuberculous and viral lesions of the skin. Also in fungal lesions not susceptible to nystatin.

In patients with hypersensitivity to any of the components.

Should not be used for facial rosacea, acne vulgaris or perioral dermatitis.

Should not be applied to the external auditory canal in patients with known or suspected perforated eardrums.

4.4 Special warnings and precautions for use

Prolonged use of anti-infective may result in the development of superinfection due to organisms, including fungi, resistant to that anti-infective.

Continuous treatment for longer than three weeks should be avoided in patients under the age of three years because of

the possibility of adrenocortical suppression and growth retardation.

Application to denuded surfaces or in cases of otitis media increases the degree of systemic absorption and risk of toxicity.

The product should be used with caution and in small amounts in the treatment of skin infections following extensive burns, trophic ulceration and other conditions where absorption of neomycin is possible.

The product should be used with care in patients with established hearing loss. Neomycin may cause irreversible partial or total deafness when given systemically or when applied topically, particularly to open wounds or damaged skin. This effect is dose related, is enhanced by renal and/or hepatic impairment and is more likely in the elderly.

Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement since in this situation occult extension of infection may occur due to the masking effect of the steroid.

Extended or recurrent application may increase the risk of contact sensitisation and should be avoided.

There have been a few reports in the literature of the development of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to rule out systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable

4.6 Pregnancy and lactation

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 intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus. There are theoretical risks of neomycin-induced ototoxicity; therefore the product should be used with caution only when the benefit outweighs the potential risk.

It is not known whether any of the components of Kenacomb topical preparations are excreted in breast milk.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Side effects include irritation, impaired healing, petechiae and ecchymoses, facial erythema, increased sweating, hirsutism, acneiform eruptions, lupus erythematosus - like lesions, thinning or atrophy of skin, purpura, striae, telangiectasia, sensitivity reactions, ototoxicity and nephrotoxicity with prolonged use.

4.9 Overdose

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see side effects).

In the event of accidental ingestion, the patient should be observed and treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Triamcinolone acetonide is a potent fluorinated corticosteroid with rapid anti-inflammatory, antipruritic and anti-allergic actions.

The combined action of the antibiotics neomycin and gramicidin provides comprehensive antibacterial therapy against a wide range of gram-positive and gram-negative bacteria, including those micro-organisms responsible for most bacterial skin infections.

Nystatin is an antifungal antibiotic, active against a wide range of yeasts and yeast-like fungi, including *Candida albicans*.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No further data which are relevant to the prescriber of the product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Plastibase™ (liquid paraffin and polyethylene resin).

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

4 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tubes containing 10g 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

Bristol-Myers Squibb Pharmaceuticals Limited,
Swords,
Co. Dublin,
Ireland.

8 MARKETING AUTHORISATION NUMBER

PA 2/33/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5 June 1979

Date of last renewal: 5 June 2004

10 DATE OF REVISION OF THE TEXT

August 2005