IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0002/009/001
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 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**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Kenacomb Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Triamcinolone acetonide	0.1	% w/w
Neomycin (as sulphate)	0.25	% w/w (1625 units/g)
Gramicidin	0.025	% w/w
Nystatin	2.27	% w/w (100,000 units/g)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ointment
A smooth, shiny, amber-yellow coloured homogeneous ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of corticosteroid sensitive dermatoses complicated by infections due to micro-organisms sensitive to the anti-infectives.

4.2 Posology and method of administration

Infants and neonates:

In infants, long-term continuous topical steroid therapy should be avoided. Courses should be limited to 5 days and occlusion should not be used.

Adults and children:

Apply to the affected area two to four times daily.

Elderly:

Corticosteroids should be used sparingly and for short periods of time, as natural thinning of the skin occurs in the elderly.

If, after about 7 days application, little or no improvement has occurred, cultural isolation of the offending organism should be followed by appropriate local or systemic antimicrobial therapy.

4.3 Contraindications

In tuberculous treponemal and most viral lesions of the skin, particularly herpes simplex and varicella. Also in fungal lesions not susceptible to nystatin.

In patients with hypersensitivity to any of the components of Kenacomb Ointment.

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

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

The products should not be used for extensive areas because of possible risk of systemic absorption and neomycin-induced ototoxicity.

Contact with eyes or mucous membranes should be avoided.

Should not be used in children under one year of age.

4.4 Special warnings and precautions for use

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

Neomycin may be toxic if absorbed from open surfaces, leading to nephrotoxicity and ototoxicity. The product should be used with caution in patients with established hearing loss, or renal impairment.

Continuous treatment for longer than three weeks should be avoided in patients particularly those under the age of three years because of the possibility of adrenocortical and growth suppression. Courses should be limited to 5 days.

Prolonged use of topical corticosteroids may induce localised atrophy and striae.

Use with occlusive dressings should only be undertaken if the physician considers it necessary and the treatment is carried out under close supervision.

This product should be kept out of the eyes.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable

4.6 Pregnancy and lactation

This product should not be used in pregnancy and lactation unless considered essential by the physician. 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 foetal ototoxicity; therefore the product should be used with caution only when the benefit outweighs the potential risk.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Side effects include erythema, hypopigmentation, hypersensitivity reactions. Excessive dryness or peeling should be managed by reduced frequency of use.

The possibility of the systemic effects which are associated with all steroid therapy should be considered. This may include: reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycaemia, and glycosuria in some patients.

4.9 Overdose

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic 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 relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Plastibase ^{TM} (Polyethylene resin, Liquid paraffin).

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

4 years.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Aluminium tubes with HDPE screw caps, containing 15g 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 Ltd.
Swords
County Dublin

8 MARKETING AUTHORISATION NUMBER

PA 2/9/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1 April 1977
Date of last renewal: 1 April 2007

10 DATE OF REVISION OF THE TEXT

August 2008