

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0002/008/002

Case No: 2054993

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

Graneodin 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 **25/09/2008**.

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

Graneodin Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Neomycin (as sulphate) 0.25% w/w (1625 I. Units/g) and gramicidin 0.025% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.

Soft, slightly opaque, colourless ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the local treatment of superficial infections due to micro-organisms sensitive to these anti-infectives.

4.2 Posology and method of administration

Adults and Children over 12 years:

To be applied two to four times a day. Any crusts should be removed and the ointment rubbed well in.

Elderly:

No specific dosage recommendations or precautions.

If a satisfactory response has not been achieved after 7 days, treatment should be stopped and the organism identified.

In cases of sycosis barbae a longer period of therapy may be necessary to treat the deep infection in the follicle.

4.3 Contraindications

Use in patients hypersensitive to any of the ingredients.

Use in patients with fungal or viral infections without appropriate specific therapy.

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

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

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.

All the anti-infectives present may be toxic if absorbed from open surfaces. Occlusion should be avoided.

Prolonged or excessive use may lead to systemic absorption with nephrotoxic or ototoxicity.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

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

None stated.

4.8 Undesirable effects

Local hypersensitivity or irritation may occur especially with prolonged use. Ototoxicity and nephrotoxicity have been reported.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Neomycin is active against a wide range of Gram-positive and Gram-negative bacteria, including many of the organisms responsible for bacterial skin infections.

Gramicidin is active against Gram-positive bacteria and supplements the action of neomycin against the many common skin pathogens found in this group.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No further relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
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 with polyethylene caps containing 25g.

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

Dilution of the ointment is not recommended.

7 MARKETING AUTHORISATION HOLDER

Bristol-Myers Squibb Pharmaceuticals Ltd.
Swords
County Dublin

8 MARKETING AUTHORISATION NUMBER

PA 2/8/2

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

October 2007