IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0540/032/006
Case No: 2064842

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

sanofi-aventis Ireland Limited

Citywest Business Campus, **Dublin 24**, **Ireland**

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

Batrafen 1% w/v Cutaneous Solution

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 **10/07/2009** until **17/12/2010**.

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

Batrafen 1% w/v Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 10 mg ciclopiroxolamine in an alcoholic aqueous base.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution
Colourless to faintly yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

All fungal infections of the skin where rapid drying is an advantage.

4.2 Posology and method of administration

Batrafen solution should be gently rubbed into the infected area twice a day.

4.3 Contraindications

Batrafen solution should not be used in patients with known hypersensitivity to any component. It should not be applied to the eyes or mucosa. Batrafen is not recommended for use during pregnancy or in women who are breast feeding infants or in children less than six years old. Do not apply Batrafen to an open wound.

4.4 Special warnings and precautions for use

To avoid relapses treatment should be continued for one to two weeks after disappearance of the symptoms - usually within two weeks.

All possibly infected areas should be treated at the same time.

Additional hygienic measures e.g. sprinkling powder into socks or shoes should be recommended.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Batrafen solution should not be used during pregnancy or in women breast feeding infants.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

In rare cases transient local reactions e.g. pruritis or a slight burning sensation may occur, as may allergic contact dermatitis. If any of these reactions are severe, treatment should be discontinued.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active substance ciclopiroxolamine is a broad spectrum antimycotic for the topical treatment of infections due to superficial dermatophytes, candida species and other sensitive fungi.

5.2 Pharmacokinetic properties

For topical use.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 400
2-Propanol
Purified water

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

LDPE squeeze bottles containing 20 ml.

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

sanofi-aventis Ireland Ltd
Citywest Business Campus
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 540/32/6

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 December 1985

Date of last renewal: 18 December 2005

10 DATE OF REVISION OF THE TEXT

January 2009