IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA1410/049/001
Case No: 2068861

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

Bayer Limited

The Atrium, **Blackthorn Road**, **Dublin 18**, **Ireland**

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

Mycospor 1% w/w Gel

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 **08/10/2009** until **21/11/2010**.

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

Mycospor 1% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The gel contains 1% w/w bifonazole.

For excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Gel
A clear colourless gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of fungal skin infections due to dermatophytes, yeasts, moulds and other fungi.

4.2 Posology and method of administration

After cleansing and drying the affected area, the preparation should be thinly applied and rubbed in once daily, preferably at night before retiring.

Duration of treatment need not usually exceed four weeks.

4.3 Contraindications

Use in patients with hypersensitivity to imidazoles.

4.4 Special warnings and precautions for use

Local irritation or increased inflammation may occur particularly after application to broken skin. If these effects persist, use should be stopped and the doctor consulted.

Absorption of imidazole antimycotics may lead to systemic toxicity. Studies with Mycospor, however, suggest a low level of absorption after topical application. The preparation should only be used with care on areas of denuded skin or in association with occlusive dressings including that afforded by nappies.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

After oral administration to animals at high doses, bifonazole was not teratogenic, but embryotoxic and foetotoxic effects were observed. Mycospor Gel for topical administration should not normally be used in pregnancy. As no information is available on the effect of bifonazole on lactation, it should not be used in nursing mothers.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Rarely patients may experience local, mild burning or irritation immediately after application of the gel. This is transient and usually disappears with continued treatment.

4.9 Overdose

In the event of accidental oral ingestion, routine measures such as gastric lavage should be performed as soon as possible after ingestion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Bifonazole is a broad spectrum imidazole antifungal agent. It is effective against dermatophytes, yeasts, moulds and other fungi.

5.2 Pharmacokinetic properties

After a single application (topical) of 15.2mg [14C] bifonazole cream, and subsequent occlusion for six hours, 0.6±0.3% of the dose was absorbed. The absorption rate was approximately 0.008mg/100cm2 per hour. In inflamed skin these values were higher by a factor of four. Similar results were obtained after the application of bifonazole as a 1% solution.

Plasma levels up to 16ng/ml were obtained in babies with nappy rash after a single 5g application of the cream.

After intravenous administration of 0.016mg/kg [14C] bifonazole, tissue uptake was rapid. Bifonazole is, however, rapidly metabolised with only 30% of an intravenous dose remaining unaltered 30 minutes post-dose.

Elimination of the metabolites is biphasic (T½ of eight and 50 hours). Within five days of administration 45% of the administered dose has been excreted renally, with 40% being eliminated via the liver and bile (faeces).

5.3 Preclinical safety data

Toxicological studies showed good local tolerability. However, for Mycospor Cream and Solution slight skin irritant effects were observed which could be attributed to the additives 2-octyldodecanol (cream) and isopropyl myristate (solution), respectively. There were no indications of changes caused specifically by the active substance, and no signs of any systemic effects were observed. Studies on reproductive toxicity showed no evidence of teratogenic activity. However, embryotoxic effects were seen in rabbits at high oral doses (30mg/kg bodyweight). Bifonazole had no influence on fertility and showed no mutagenic properties.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyoxyethylene-30-cetylstearyl alcohol
Macrogol 7 glycerol cocoate
Isopropyl isostearate
Lactic acid
Ethanol
Benzyl alcohol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

42 months.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Collapsible aluminium tubes containing 15g, 20g and 50g of gel.

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

Avoid contact with eyes.

7 MARKETING AUTHORISATION HOLDER

Bayer Ltd
The Atrium
Blackthorn Road
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 1410/49/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 22 November 1985

Date of last renewal: 22 November 2005

10 DATE OF REVISION OF THE TEXT

October 2009