IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0046/005/003
Case No: 2049660

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

Leo Laboratories Limited

Cashel Road, **Dublin 12**, **Ireland**

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

Fucidin H 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 **13/05/2008** until **28/03/2010**.

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

Fucidin H Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains sodium fusidate 2% w/w and hydrocortisone acetate 1% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Ointment
Off-white viscous ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Use in inflammatory dermatoses where bacterial infection is present or likely to occur.

4.2 Posology and method of administration

Apply a small quantity to the affected area twice daily until a satisfactory response is obtained. A single treatment course should not normally exceed 2 weeks.

4.3 Contraindications

Use in patients hypersensitive to the active ingredients.
Use in the presence of infections due to non-sensitive organisms.

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.
Continuous treatment for longer than three weeks should be avoided in patients under the age of three years because of the risk of adrenocortical suppression. Prolonged use with occlusive dressings may result in suppression of adrenocortical function.
Due to the presence of wool fat (lanolin) and cetyl alcohol this product may cause local allergic skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

The product should not be used in pregnancy unless considered essential by the physician.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. There may, therefore be a small risk of such effects in the human foetus.

Animal studies and many years of clinical experience have suggested that fusidic acid is devoid of teratogenic effects. There is evidence to suggest that when given systemically, fusidic acid can penetrate the placental barrier.

Safety in nursing mothers has not been established.

When fusidic acid (as sodium salt) has been given systemically, levels have been detected in breast milk, but with topical use the possible amount of drug present is unlikely to affect the infant.

4.7 Effects on ability to drive and use machines

Presumed to be safe or unlikely to produce an effect.

4.8 Undesirable effects

Hypersensitivity has rarely been encountered with the use of topical Fucidin.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Fucidin H Ointment combines the potent topical antibacterial action of sodium fusidate with the anti-inflammatory and anti-pruritic effects of hydrocortisone. Fusidic acid and its salts exhibit fat and water solubility properties with strong surface activity, and show unusual ability to penetrate intact skin. However, they are poorly systemically absorbed after topical administration.

Concentrations of 0.03 - 0.12 µg/ml inhibit nearly all strains of *Staphylococcus aureus*. Topical Fucidin is also active against Streptococci, Corynebacteria, Neisseria and certain Clostridia.

5.2 Pharmacokinetic properties

There are no data which define the pharmacokinetics of Fucidin H Ointment, following topical administration in man.

However, *in vitro* studies show that fusidic acid and its salts can penetrate intact human skin in concentrations well above the MIC-values of susceptible organisms. The degree of penetration depends on factors such as the duration of exposure to fusidic acid (or its salts) and the condition of the skin. Fusidic acid and its salts are excreted mainly in the bile with little excreted in the urine.

Hydrocortisone is absorbed following topical administration. The degree of absorption is dependant on factors including skin condition and site of application. Absorbed hydrocortisone is extensively metabolised and rapidly eliminated in the urine.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wool fat (Lanolin)
Cetyl alcohol
Liquid paraffin
White soft paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Aluminium tube in carton containing 15g or 30g 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

LEO Laboratories Ltd.
Cashel Road
Dublin 12

8 MARKETING AUTHORISATION NUMBER

PA 46/5/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1977

Date of last renewal: 29 March 2005

10 DATE OF REVISION OF THE TEXT

November 2006