IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0144/044/001
Case No: 2029075

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

Stiefel Labs (U.K.) Ltd.

Holtspur Lane, **Wooburn Green**, **High Wycombe**, **Bucks HP10 0AU**, **England**

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

Stiefel Emollient Soap

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 **25/02/2007**.

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

Stiefel Emollient Soap

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains liquid paraffin 7.5 % w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Medicated Soap

A salmon pink, oval soap bar.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Stiefel Emollient Soap is indicated as a gentle cleanser for dry sensitive skin. It is suitable for the treatment of diseases where ordinary soaps have an adverse effect, such as pruritus, eczema and atopic dermatitis. The use of Stiefel Emollient Soap in these conditions will cleanse, soothe and hydrate the skin.

4.2 Posology and method of administration

Stiefel Emollient Soap is for topical use only.

Stiefel Emollient Soap should be applied to wet skin. A rich lather should be worked up and massaged into the affected areas. The lather should be removed with very little water and the area patted dry.

4.3 Contraindications

Stiefel Emollient Soap should not be used on patients who have acne or other greasy skin conditions

4.4 Special warnings and precautions for use

FOR EXTERNAL USE ONLY.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There are no restrictions on the use of Stiefel Emollient Soap in pregnancy and lactation

-

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None known.

4.9 Overdose

No specific symptoms may be expected from excessive topical use of the product.

Ingestion may result in nausea, vomiting and diarrhoea. Following ingestion, administer copious quantities of water.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The effect of Stiefel Emollient Soap on dry skin is to leave a thin oily film on the surface, thus keeping it lubricated. One of the principle factors in the successful management of eczema and dry skin conditions is the prevention of excessive moisture loss and the restoration of normal skin humidity levels. This is achieved by the use of the well-established emollient - Liquid paraffin. Emolliency can be equated with occlusive activity and with corresponding reduction in trans-epidermal water loss, and therefore the deposition of oil on the skin following the use of Stiefel Emollient Soap results in emollient action.

Stiefel Emollient Soap contains a high specification cosmetic soap base containing high molecular weight fatty acid salts to minimise irritancy.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soap Pellets
N-hydroxyethyl ethylene diamine triacetate solution
Sunset Yellow (E110), 1% aqueous solution
Carmoisine (E122), 1% aqueous solution
Perfume No. 58

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

3 years

6.4 Special precautions for storage

Do not store above 30°C

6.5 Nature and contents of container

Stiefel Emollient Soap is presented as a 100 gram solid bar. It is wrapped in a polyethylene film sealed with gold foil paper packed in a printed cardboard carton.

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

Stiefel Laboratories (UK) Ltd
Holtspur Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0AU
England

8 MARKETING AUTHORISATION NUMBER

PA 144/44/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th February 1992

Date of last renewal: 25th February 2007

10 DATE OF REVISION OF THE TEXT

March 2007