

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0144/043/001

Case No: 2044218

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 Sunblock Lotion Padimate O 8.0% w/w Avobenzone 2.0% w/w Octyl Methoxycinnamate 10.0% w/w

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 **06/12/2007**.

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 Sunblock Lotion
Padimate O 8.0% w/w
Avobenzone 2.0% w/w
Octyl Methoxycinnamate 10.0% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Padimate O USP	8.0% w/w
Avobenzone (Butyl Methoxy Dibenzoyl Methane)	2.0% w/w
Octyl Methoxycinnamate	10.0% w/w

Excipients: Also contains Sorbic acid 0.3% w/w and Miglyol 840 Gel B 4% w/w.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous emulsion

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

STIEFEL SUNBLOCK LOTION is indicated as a protective Sunblock in patients with photodermatoses, including those caused by radiotherapy.

It is effective in protecting against UVA and UVB rays in most types of photosensitisation, solar urticaria, acute solar dermatitis, drug-induced photosensitivity, acute lupus erythematosus, herpes simplex and polymorphic light eruption.

STIEFEL SUNBLOCK LOTION can also be used in cases of cutaneous albinism and vitiligo and to protect normal skin types in intense sunlight, especially sun-sensitive subjects in phototypes O, I and II.

4.2 Posology and method of administration

Apply STIEFEL SUNBLOCK LOTION carefully and evenly to areas to be exposed or protected only by light clothing. Allow 45 minutes before swimming or sweat producing exercise. A single application may give day long protection, but the product should be reapplied during prolonged periods of sunning, swimming or excessive sweating.

4.3 Contraindications

STIEFEL SUNBLOCK LOTION should not be used by patients with known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Do not apply to broken skin. Avoid contact with the eyes, mouth and other mucous membranes.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

There is no evidence to confirm the safety of STIEFEL SUNBLOCK LOTION in human pregnancy and lactation. The sunscreen agents contained in the product have, however, been in widespread use for many years without apparent ill effects.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Sunscreen agents occasionally produce a sensitivity reaction and can cause contact dermatitis.

Treatment should be discontinued if a skin rash or irritation develops.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

STIEFEL SUNBLOCK LOTION is a water resistant protective Sunblock lotion which absorbs ultra violet light in both the UVA wavelength range (320 to 400nm), which causes tanning in normal subjects and which is implicated in skin cancer and skin ageing, and in the UVB wavelength range (290 to 320 nm) which is responsible for sunburn.

STIEFEL SUNBLOCK LOTION offers a high degree of protection with SPF 30.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Titanium Dioxide
Light Liquid Paraffin
White Soft Paraffin
Polyoxyethylene Fatty Acid Ester
Glyceryl Sorbitan Oleostearate
Miglyol 840 Gel B (Propylene Glycol Dicaprylate/Dicaprate, Stearalkonium Hectorite and Propylene Carbonate)
Di-n-butyl Adipate

Phenyl trimethicone
Glycerol
Dried Magnesium Sulphate DAB7
Disodium Edetate
Sorbic Acid
Benzyl Alcohol
Perfume – Tropics 52341
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

There are no special storage conditions.

6.5 Nature and contents of container

High density polyethylene bottles containing 150ml, fitted with screw caps.

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 Labs (UK) Ltd
Holtspur Lane
Wooburn Green
High Wycombe
Bucks HP10 0AU
England

8 MARKETING AUTHORISATION NUMBER

PA 144/43/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th December 2002
Date of last authorisation: 6th December 2007

10 DATE OF REVISION OF THE TEXT

May 2009