

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solaban A + B

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Padimate O	8.0% w/w
Avobenzone	2.0% w/w
Oxybenzone	3.0% w/w

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Cutaneous solution.

A smooth cream coloured solution with the odour of perfume.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

SOLABAN A + B 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.

SOLABAN A + B 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 SOLABAN A + B 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

SOLABAN A + B should not be used by patients with known hypersensitivity to any of the ingredients.

4.4 Special warnings and special 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 SOLABAN A + B 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

SOLABAN A + B is a water resistant protective sunblock lotion which absorbs ultra violet light in both the UVA wavelength range (320 to 400 nm), 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.

SOLABAN A + B offers a high degree of protection with SPF 28.

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 and stearylalkonium hectorite and propylene carbonate)
Din- butyl adipate
Phenyl trimethicone
Glycerol
Dried magnesium sulphate
Disodium edetate

Sorbic acid
Benzyl alcohol
Perfume - Tropics 52341
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 3 years.
Opened: Do not use after the expiry date on the label.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

High density polyethylene bottles fitted with screw caps.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Stiefel Laboratories (UK) Ltd
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8 MARKETING AUTHORISATION NUMBER

PA 144/32/1

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Date of last renewal: 4th January 2004

10 DATE OF REVISION OF THE TEXT

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