

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Spectraban 4

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Padimate O 3.2% w/w.

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Cutaneous solution

A clear blue slightly viscous liquid with a slight odour of alcohol.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

SpectraBAN 4 is a protective sunscreen lotion indicated in patients at risk from exposure to UV light in the UVB wavelength range (290 - 320nm). Use of the product should allow four times normal exposure to sunlight before burning.

SpectraBAN 4 is indicated in sun sensitive conditions such as polymorphic light eruptions and solar urticaria, and any condition made worse by UVB light such as lupus erythematosus.

##### 4.2 Posology and method of administration

Apply carefully and evenly to areas to be exposed or protected only by light clothing. Allow to dry before dressing. 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 sunning or after swimming or excessive sweating.

##### 4.3 Contraindications

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 are no restrictions on the use of SpectraBAN 4 in pregnancy and lactation.

## 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

Padimate O is a sunscreen agent which acts through absorption of UV light in the UVB wavelength range, 290 - 320nm. This is the range which is principally responsible for producing erythema and sunburn.

## 5.2 Pharmacokinetic properties

Not applicable.

## 5.3 Preclinical safety data

Not applicable.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Denatured alcohol  
Oleyl alcohol  
Carbomer 941  
Polyoxyethylene 15 cocoamine  
Patent blue V (E131)  
Essence A-3012  
Purified water

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf Life

3 years.

## 6.4 Special precautions for storage

Store below 25°C.

## **6.5 Nature and contents of container**

High density polyethylene bottles of 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**

Do not apply to broken skin.

Avoid contact with the eyes, mouth and other mucous membranes.

Avoid flame.

## **7 MARKETING AUTHORISATION HOLDER**

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

## **8 MARKETING AUTHORISATION NUMBER**

PA 144/21/1

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 01 October 1984

Date of last renewal: 01 October 2004

## **10 DATE OF REVISION OF THE TEXT**

June 2006