

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

SpectraBan 15

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Padimate O	3.2	% w/w
Para-Aminobenzoic Acid	5.0	% w/w

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution

A pink transparent liquid having a faint odour of alcohol.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

SpectraBAN 15 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 fifteen times normal exposure to sunlight before burning.

SpectraBAN 15 is indicated in 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.

SpectraBAN 15 can stain clothing and other items permanently.

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 15 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.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Padimate O and Para aminobenzoic acid are sunscreen agents which act 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

Carbomer 941
Ethanol 96%
Polyoxyethylene 15 cocoamine
Carmoisine red (E122)
Oleyl Alcohol
Essence A-3012
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Avoid flame. Store below 25°C.

6.5 Nature and contents of container

High density polyethylene bottle fitted with a screw cap containing 150ml.

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

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8 MARKETING AUTHORISATION NUMBER

PA 144/7/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 11 July 2003

10 DATE OF REVISION OF THE TEXT

February 2006