Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sarnol Lotion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Camphor	0.50	% w/w
Menthol	0.50	% w/w
Benzyl Alcohol	1.00	% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution
Off-white coloured solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of chronic dry itching dermatoses, including senile pruritus, nodular prurigo and neurodermatoses.

4.2 Posology and method of administration

Apply liberally to the affected area of skin, rubbing in gently. Repeat as necessary or as directed by a doctor.

4.3 Contraindications

Sarnol Lotion should not be used on patients with a known hypersensitivity to the product or any of its components.

4.4 Special warnings and precautions for use

For external use only.

Avoid contact with the eyes, nostrils and mucous membranes.

If irritation increases after application of Sarnol Lotion, discontinue use.

The product should not be used on children under 2 years of age except under medical supervision.

Do not use under compresses or bandages.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

No precautions for the use of Sarnol Lotion in pregnancy are proposed. Sarnol Lotion should not be applied to the nipples or surrounding skin during lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

In rare cases sensitivity, discontinue use.

4.9 Overdose

In the unlikely event of adverse effects resulting from excessive use, discontinue treatment, rinse the skin thoroughly and apply emollients as necessary.

Accidental ingestion of small quantities of Sarnol Lotion should not cause an adverse effect. Should more than 50ml have been consumed, empty stomach by gastric lavage and aspiration. Administer a saline purgative, such as sodium sulphate, 30g in 250ml of water. Convulsions may be controlled with a short-acting barbiturate such as thiopentone sodium or by diazepam.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sarnol Lotion contains long-standing antipruritics whose efficacy and safety has been documented extensively. The active ingredients act directly to depress the cutaneous sensory receptors for pain and itch and thus relieve the symptoms.

Camphor, at concentrations of 0.1%-3% acts to depress the cutaneous sensor receptors and has a mild local anaesthetic action.

Menthol when present in concentrations of 0.1%-1% stimulates the receptors for cold while depressing those for pain. It is normally used in combination with other antipruritics, commonly with camphor.

Benzyl alcohol is an aromatic alcohol and, as such, exerts a topical anaesthetic action. At the concentration used it is also bacteriostatic.

The FDA have approved combinations of camphor, menthol and benzyl alcohol for use in over-the-counter products.

The lotion base has been formulated for its soothing emollient properties to augment the antipruritic effects of the active ingredients.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sonojel No. 9 (White soft paraffin)
Cetyl Alcohol
Stearic Acid
Polyethylene Glycol 400 Monostearate (PEG 400 MS)
Glyceryl PEG 100 Stearate
Isopropyl Myristate
Carbomer 940
Sodium Hydroxide
Perfume Bouquet MR564
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

High density polyethylene tubes containing 150 ml.

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 144/14/1

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Date of last renewal: 3 February 2004

10 DATE OF REVISION OF THE TEXT

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