Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Anthranol 2.0%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dithranol 2.0% w/w.

3 PHARMACEUTICAL FORM

Ointment
A waxy yellow ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Anthranol 2.0 Ointment is indicated for the topical treatment of psoriasis.

4.2 Posology and method of administration

Anthranol 2.0 Ointment is one of a range of dithranol products which include 0.4 and 1.0 ointments.

Treatment should begin with Anthranol 0.4. Clinical response and tolerance will determine the necessity for progression to Anthranol 1.0 and subsequently Anthranol 2.0.

Apply the ointment once daily, sparingly to the psoriatic plaque. Surrounding normal skin should be protected with white soft paraffin. Leave the ointment on for the required time then remove excess ointment with a paper tissue and wash off the remainder thoroughly.

If Anthranol has been applied to the scalp, the ointment should be removed by shampooing.

The initial daily treatment time with each strength should not exceed 10 minutes. The time may be increased gradually over a period of 7 days to a maximum of 30 minutes. The daily treatment time should not normally exceed 30 minutes. In the event of undue irritation, stop treatment for 2 days and resume on alternate days.

Treatment should be continued at the optimum tolerated strength and leave-on time, depending on patient response.

4.3 Contraindications

Anthranol 2.0 Ointment is contra-indicated in pustular psoriasis and is not suitable for the treatment of acute psoriasis. It should not be used by patients with known hypersensitivity to the ingredients.

Anthranol 2.0 Ointment should not be applied to the face, the inside of the thighs, the genital region or skinfold areas.

4.4 Special warnings and precautions for use

Dithranol is a strong irritant, the hands should always be washed after use and the product kept away from the eyes. Should contact with the eyes occur, bathe immediately with water and seek medical advice.

The product will cause staining and discolouration of the skin. It will also stain or discolour clothing and may stain bathroom ware. Stains on clothing should be assumed to be permanent; stains on bathroom ware may be removed by bleach.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

Although there is no evidence to support the safety of Anthranol in pregnancy and lactation, no adverse effects have been reported.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Dithranol preparations can cause irritation; if this develops, or redness is observed on adjacent normal skin, the frequency of application should be reduced.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The use of dithranol in the treatment of psoriasis is well established. It has been suggested that the mode of action involves combination with deoxyribonucleic acid and other nucleic acids, inhibiting the synthesis of nucleic protein and thus decreasing the cellular proliferation which is increased in the psoriatic epidermis.

5.2 Pharmacokinetic properties

The product is a topical preparation which acts locally at the site of application. Pharmacokinetic data are not applicable.

5.3 Preclinical safety data

Not applicable. Dithranol has been in wide-spread use for many years. The relevant information is given in section 4 of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Cetyl alcohol
Sodium Laurilsulfate
Salicylic acid
Light liquid paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

Internally lacquered aluminium tubes of 50g.

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 144/17/2

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Date of last renewal: 23 March 2005

10 DATE OF REVISION OF THE TEXT

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