Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dithrocream 0.1%w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dithranol 0.1% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream
Pale yellow cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of subacute and chronic psoriasis, including psoriasis of the scalp.

Dithrocream 0.5%w/w, Dithrocream 1.0%w/w and Dithrocream 2.0%w/w should only be used for those patients who have failed to respond to lower strengths of dithranol (see section 4.2 below). Dithrocream 1.0%w/w and 2.0%w/w should normally only be applied for 'short contact' periods.

Dithrocream has been developed as a cream formulation of dithranol for particular convenience for home treatment, and is especially suitable for the exposed surfaces and hairy regions of the body.

4.2 Posology and method of administration

Dithranol therapy customarily involves titrating the concentration applied to skin to suit individual patient’s circumstances. Dithrocream is, therefore, available in five strengths. The different strengths are colour coded as follow:

0.1% w/w	pale blue
0.25% w/w	red
0.5% w/w	purple
1.0% w/w	brown
2.0% w/w	yellow

For adults and the elderly
It is important to determine each patient's optimal treatment strength, as too high a strength may induce a burning sensation. Where the response to Dithrocream has not previously been established, always commence with Dithrocream 0.1%w/w, continuing for at least one week and then, if necessary, increase to the 0.25%w/w followed by the 0.5%w/w, the 1.0%w/w and finally the 2.0%w/w strength. The aim should be to build up gradually over approximately 4 weeks to the highest tolerated strength to produce the optimum therapeutic effect. This optimum concentration will depend upon such factors as the thickness and location of the psoriatic plaques, as well as the variation between individual patients in their reaction to dithranol. Dithrocream 0.5%w/w, Dithrocream 1.0%w/w and Dithrocream 2.0%w/w should always be used under medical supervision.

Dithrocream should be applied once every 24 hours, at any convenient time of the day or evening, and then removed by washing off, usually no more than one hour after application. Alternatively, it may be applied at night before retiring and washed off in the morning.

Dithrocream should be applied sparingly, only to the affected areas. Rub the cream gently and carefully into the skin until completely absorbed. It is most important to avoid applying an excessive amount of the cream, which may cause unnecessary soiling and staining of the clothing and/or bed linen. After each period of treatment, a bath/shower should be taken to remove any residual cream. To prevent the possibility of discolouration, particularly where Dithrocream 1.0%w/w or 2.0%w/w has been used, always rinse the bath/shower with hot water immediately after washing/showering and then use a suitable cleanser to remove any deposit on the surface of the bath/shower.

For use on the scalp, first comb the hair to remove scalar debris and, after suitably parting, rub the cream well into the affected areas.

Treatment should be continued until the skin is entirely clear, i.e. when there is nothing to feel with the fingers and the texture is normal.

By gradually increasing the strength of the cream applied, it should be possible to clear psoriasis patches within 4 to 6 weeks.

For children
No evidence of any adverse effects. However, use cautiously as described above for adults and the elderly, with regular supervision.

4.3 Contraindications

Not to be used for acute or pustular psoriasis, or on the face.
Not to be used in cases of sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

After use on the scalp, a shampoo may be used to remove the Dithrocream residue. Great care must be taken when washing out the shampoo (which may contain some Dithrocream residue), to ensure that it does not get into the eyes or on the face. This is particularly important when the higher strengths of Dithrocream have been used.

Although a feeling of warmth at the application site is normal, if this amounts to a burning sensation, or if the lesions spread, treatment should be stopped at once, and the dosage re−evaluated by a doctor.

Dithrocream is not normally recommended for use on areas of folded skin such as the groin and beneath the breasts. Do not use high strengths on these sites. Keep away from the eyes and mucous membranes. Always wash the hands after use.

As long term use of topical corticosteroids is known to destabilise psoriasis, and withdrawal may give rise to a rebound phenomenon, an interval of at least one week should be allowed between the discontinuance of such steroids and the commencement of Dithrocream therapy. A suitably bland emollient may usefully be applied in the intervening period.

The excipients, chlorocresol and cetostearyl alcohol may on rare occasions give rise to allergic or local skin reactions (e.g. contact dermatitis) in sensitive people.

Contact with fabrics, plastics and other materials may cause permanent staining and should be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Although there is no experimental evidence to support the safety of the drug in pregnancy or during lactation, no adverse effects have been reported.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Some skin irritation and/or a feeling or warmth at the site of application is normally associated with dithranol therapy. Dithrocream applied at too high a strength, or left in contact with the skin for too long, may induce a burning sensation. Dithrocream may also cause temporary staining of the skin and/or hair.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal products is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel +353 1 6764971; Fax +353 1 6762517. Website: http://www.hpra.ie/, Email: medsafety@hpra.ie

4.9 Overdose

There are no known side effects from an overdose, other than irritation of the skin.
Dithranol is a cathartic (laxative). If accidentally swallowed, it should be removed by gastric lavage and supportive treatment given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dithranol has been used in the treatment of sub-acute and chronic psoriasis for over 70 years and, during that time it has become established as a safe and effective form of therapy.

Its precise mode of action is still to be confirmed, although it has been shown to inhibit DNA replication, cellular respiration and key cellular enzymes e.g. glucose-6-phosphate dehydrogenase.
Because dithranol causes staining and irritation, it is now widely used in short contact therapy where the preparation is washed off the skin after periods of one hour or less. For this purpose, Dithrocream is particularly suitable, as it is convenient to apply and washes off easily in a bath or shower.

5.2 Pharmacokinetic properties

The traditional formulations of dithranol are based on soft paraffin from which it is effectively released into the skin. In Dithrocream, during manufacture, the oily paraffin phase of the cream is heated until the dithranol entirely dissolves so that, on cooling, it is retained solely within the paraffin phase and does not spread into the aqueous phase. After application of Dithrocream to the skin, the water is lost through absorption and evaporation, leaving the oily phase which then acts in the same way as a dithranol ointment.

However, since the cream may be rubbed into the skin more effectively than the ointment, it is convenient to apply and, owing to the presence of the emulsifying components, is easier to wash off. The availability of the dithranol has now been confirmed in numerous publications detailing the results of clinical trials.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Cetostearyl alcohol
Salicylic acid
Ascorbic acid
Sodium Laurilsulfate
Chlorocresol
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

Do not store above 25°C. Replace cap tightly after use.

6.5 Nature and contents of container

Membrane-sealed, epoxy resin-coated aluminium collapsible tube with high density polyethylene white spiked screw cap, containing 50 g of cream.

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 278/1/1

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