Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mycortin Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fluprednidene acetate	0.1 % w/w
Miconazole nitrate	2.0 % w/w

3 PHARMACEUTICAL FORM

Cream
A white to off white pliant cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of the acute inflammatory phase of mycotic skin infections.

4.2 Posology and method of administration

For topical application in adults.

The cream should be thinly applied to the affected area once or twice daily, as directed by the physician.

4.3 Contraindications

Use in infants under 2 years old. Use in infants in conjunction with occlusion. Use in the presence of infections of viral, tuberculous or treponemal origin, or of bacterial infections due to gram-negative organisms.

4.4 Special warnings and precautions for use

Mycortin Cream should not usually be used for longer than one week.

If there is no clinical improvement after 1 week of treatment, you should contact your doctor to review the treatment.

Consult your doctor before use if you have facial rosacea, acne or perioral dermatitis.

In the elderly, corticosteroid containing preparations should be used sparingly and for short periods.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

The product should not be used during pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Excessive use may result in local atrophy of the skin, striae and superficial vascular dilatation. Prolonged use of topical corticosteroids may result in suppression of pituitary adrenal function. In rare cases, allergic or irritate skin reactions may occur requiring discontinuation of treatment.

4.9 Overdose

Prolonged or excessive use of this product may lead to adrenal insufficiency; symptoms are usually reversible on cessation of treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Fluprednidene 21-acetate is a synthetic fluorinate corticosteroid specifically developed for topical use. At a concentration of 0.1% w/w it is classified as a “strong” corticosteroid and demonstrated marked anti-inflammatory and antiproliferative effects and the suppression of immunological responses.

Miconazole has a broad spectrum of antifungal activity and is also effective against gram-positive bacteria, sensitive fungi including Candida and dermatophytes Epidermophyton, Microsporum and Trichophyton species (spp). Sensitive bacteria include Staphylococci and Streptococci spp.

5.2 Pharmacokinetic properties

The Pharmacokinetics of the combination preparation have been investigated in animal experiments with female pigs. After topical administration of Mycortin cream the degree of absorption exhibited by fluprednidene acetate (measured from area under the curve -AUC values) was 2.4% and the absorption rate of miconazole was 0.8%.

After administration of Mycortin cream to humans for 21 days, no reduction in hydrocortisone levels was observed and there was no effect on the ACTH stimulation capacity of the adrenal cortex. A possible systemic effect of fluprednidene can therefore be almost excluded.

After topical application of the cream, fluprednidene acetate rapidly penetrates the skin and accumulates in the topmost layer of the epidermis in the form of a depot.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimeticone (silicone oil)
Medium chain triglycerides
White petrolatum
Glycerol monostearate
Arlacel 165
Stearyl alcohol

Propylene glycol
Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

4 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Container: Aluminium tube with polypropylene or polyethylene cap.
Contents: Each tube contains one of the following amounts:-20g, 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

Crookes Healthcare Limited
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8 MARKETING AUTHORISATION NUMBER

PA 43/35/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7 September 1992

Date of last renewal: 7 September 2002

10 DATE OF REVISION OF THE TEXT

September 2004