Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tinaderm Plus Cutaneous Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tolnaftate 1.0% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous powder

A white to off-white powder and herbal odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Tinaderm Plus Powder is recommended for use as a fungicide in the topical treatment and prophylaxis of infections due to dermatophytes sensitive to this agent including Microspora, Epidermophyta and Trichophyta.

4.2 Posology and method of adminstration

Sprinkle a sufficient quantity of powder over the affected areas twice daily, after thoroughly washing and drying the areas concerned.

Dosage is similar in all age groups.

4.3 Contraindications

Use in patients hypersensitive to the ingredients.

4.4 Special warnings and precautions for use

Tinaderm Plus Powder is for external use only.

In mixed infections supplementary anti-infective therapy is indicated. If there is no response after 4 weeks, reassessment of diagnosis should be made.

4.5 Interaction with other medicinal products and other forms of interaction

None Known.

4.6 Pregnancy and lactation

There is no evidence of safety of the drug in human pregnancy or during lactation, but it has been in wide use for many years without apparent ill consequence. If drug therapy is needed during pregnancy, this drug can be used if

there is no safer alternative.

Compared with control groups no significant teratogenic effects were seen in rabbits, guinea-pigs, mice and rats following oral, topical or subcutaneous administration of tolnaftate.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Skin reactions occur rarely with tolnaftate and include irritation and contact dermatitis. If this occurs treatment should be stopped and referral made to GP.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Tolnaftate is a highly effective fungicidal agent against cutaneous fungal infections. The powder base contains a drying agent which aids the treatment of moist and/or macerated skin conditions.

5.2 Pharmacokinetic properties

Not applicable due to topical application.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Talc, purified;
Powdered cellulose;
Deo Herbal Green Fragrance;
Starch-graft-poly (sodium acrylate-co-acrylamide) polymer (A-120)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Bottle-high density polyethylene.
Two piece cap - low density polyethylene.
Pack sizes: 50 g

6.6 Instructions for use and handling

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Schering-Plough Ltd
Shire Park
Welwyn Garden City
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AL7 1TW
UK

8 MARKETING AUTHORISATION NUMBER

PA 277/62/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd April 1992

Date of last renewal: 22nd April 2002

10 DATE OF REVISION OF THE TEXT

November 2004