Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tinaderm Plus Powder Aerosol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tolnaftate 0.09% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray suspension.

A white to pale yellow suspension with a faint herbal odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Tinaderm Plus Powder Aerosol 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

Tinaderm Plus Powder Aerosol should be sprayed to cover the affected areas twice daily after thoroughly washing and drying the areas concerned. Spray into shoes and socks or stockings which may act as reservoirs of infection. Dosage is similar in all groups.

4.3 Contraindications

Use in patients hypersensitive to the ingredients.

4.4 Special warnings and precautions for use

Tinaderm Plus Powder Aerosol 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

As tolnaftate is applied topically, these data are not applicable.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene-Polypropylene glycol monobutyl ether
Butylated hydroxytoluene
Denatured ethanol
Fragrance ; 837-AL
Starch-graft-poly (sodium acrylate co-acrylamide) polymer (A-180)
Talc WC&D 1623
Aerosol Propellant 30 (butane/propane propellant)

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

2 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Pressurised container: Lacquered aluminium can with internal epoxy-phenolic lacquer. Pack size: 75g

6.6 Instructions for use and handling

Not applicable

7 MARKETING AUTHORISATION HOLDER

Schering-Plough Ltd
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AL7 1TW
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8 MARKETING AUTHORISATION NUMBER

PA 277/62/2

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