Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tinaderm Cream 1% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tolnaftate 1.0% w/w

Excipients: Also includes Chlorocresol 0.1%w/w, cetostearyl alcohol 7.2% w/w and Butylated hydroxytoluene (E321) 0.002% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A smooth homogeneous white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Tinaderm is recommended in the topical treatment of Tinea pedia, Tinea crurus, Tinea corporis, tinea manuum, due to infection with *Trichophyton rubrum, Trichophyton mentagrophytes, Trichophyton tonsurans, Microsporum audouinii, Epidermophyton fluccusum,* and for Tinea versicolor due to *Malassezia furfur.*

4.2 Posology and method of administration

The cream should be applied topically to the affected area twice a day. When treating Athlete's Foot, the feet should be thoroughly washed and dried before applying the cream.

Symptomatic relief is usually rapid, often within 2-3 days and lesions generally clear within two or three weeks but may take longer when palmar or plantar sites are involved. Removal of hardened skin for calluses from these areas if helpful.

4.3 Contraindications

Use in patients hypersensitive to the ingredients.

4.4 Special warnings and precautions for use

Tinaderm Cream 1% is for external use only.

This product should be kept away from the eyes and mucous membranes.

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 Fertility, 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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product 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: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D01AE18

Tolnaftate is an effective fungicidal agent against cutaneous fungal infections.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Sodium Dihydrogen Phosphate Dihydrate
White Soft Paraffin
Macrogol cetostearyl Ether
Cetostearyl Alcohol
Paraffin Liquid
Butylhydroxytoluene (E321)
Phosphoric acid
Sodium Hydroxide
Purified Water

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

Epoxy lined aluminium tubes with polyethylene caps containing 15 g.

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

Bayer Limited
The Atrium
Blackthorn Road
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1410/080/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 July 1983

Date of last renewal: 21 April 2007

10 DATE OF REVISION OF THE TEXT

April 2015