

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mycil Cutaneous Powder
1% w/w Tolnaftate
0.25% w/w Chlorhexidine Hydrochloride.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tolnaftate 1.0 % w/w (10mg/g)
Chlorhexidine Hydrochloride 0.25 % w/w (2.5mg/g)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous powder.
Fine, free-flowing, white or off-white homogenous powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the adjunctive treatment and prevention of infection due to superficial dermatophytes in particular Tinea Pedis and Tinea Cruris, and in the presence of Miliariasis with excessive perspiration.

4.2 Posology and method of administration

Routine use of powder can help prevent infection.

For topical application to the skin.

Wash and thoroughly dry the affected area before applying the powder liberally morning and night. Continue the treatment for at least a week after the infection has cleared up.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

The labelling will state:

If the condition does not improve or is aggravated, suspend treatment and consult the doctor.
Keep all medicines out of the reach of children.
For external use only.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

No special precautions necessary.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None known.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D01A E20

Tolnaftate is a well established drug substance having potent antifungal properties.

Chlorhexidine hydrochloride is a well established drug substance having potent antimicrobial properties.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no preclinical safety data of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal Silicone Dioxide
Purified Talc
Maize Starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Tins with polythene closures or printed white or blue plastic bottles with plastic plug and screw cap containing 55 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

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 0979/048/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 August 1991

Date of last renewal: 26 August 2006

10 DATE OF REVISION OF THE TEXT

July 2012