

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mycil Ointment (1% w/w Tolnaftate, 0.1% Benzalkonium Chloride)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tolnaftate Ph. Eur. 1.0 % w/w (10mg/g)

Benzalkonium Chloride Solution Ph. Eur. 0.2 % v/w equivalent to Benzalkonium Chloride 0.1 % w/w (1mg/g).

Also contains Cetostearyl Alcohol 6.0% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

Smooth, odourless, homogeneous white oil-in-water cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the adjunctive treatment and prevention of infections 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

For topical application to the skin.

Wash and thoroughly dry the affected area before applying the ointment 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 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.

Benzalkonium chloride 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

Self Emulsifying Glyceryl Monostearate
Cetostearyl Alcohol
Dimeticone 20
Liquid Paraffin
Glycerol
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

Collapsible, internally lacquered metal tube with blind end nozzle, containing 25 g.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA 0979/046/001

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

November 2008