Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mycil Athlete's Foot Spray 1% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tolnaftate 1% w/w.
1% w/w refers to the active content relative to the talc content of the formulation, which is the main non-volatile component of the formulation. The concentration of active in the total content is 0.12% w/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, powder.
A white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the adjunctive treatment and prevention of athlete's foot (Tinea Pedis). It is also effective in other conditions, such as dhobie itch (Tinea Cruris) and prickly heat (Miliaria).

4.2 Posology and method of administration

For topical application to the skin.

Wash and thoroughly dry the infected skin before use. Hold the can 15cm from the skin, then spray liberally morning and night. Continue the treatment for at lest a week after the infection has cleared up. Routine use of the spray can help prevent infection.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

If symptoms persist or sensitivity occurs, discontinue use and consult your doctor.
Keep all medicines out of the reach of children.
Keep away from eyes.
For external use only.
Patients may experience thermal burns if Mycil Athlete's Foot Spray is applied at a distance of less than 15cm from the skin of the area affected.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant drug interactions known.

4.6 Fertility, pregnancy and lactation

No special requirements.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Skin reactions including irritation and pruritus may occur; contact dermatitis has been reported.

4.9 Overdose

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Tolnaftate is a well established drug substance having potent antifungal 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

Talc
Denatured ethanol
Bentone 38
Dimethyl ether

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 25°C. The canister contains pressurized liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister.

6.5 Nature and contents of container

Internally lacquered aluminium can fitted with a continuous spray valve and an actuator. 150 ml.

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

Keep away from eyes.
Caution flammable. Do not use near fire or flame. Pressurised container. Do not pierce or burn, even after use. Do not spray on a naked flame. Do not use near, or place container on polished or painted surfaces. CFC-free – does not contain CFCs which damage ozone.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 979/47/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 January 1993
Date of last renewal: 05 January 2008

10 DATE OF REVISION OF THE TEXT

October 2011