

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Boots Athlete's Foot Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredient</u>	<u>Quantity</u>
Tolnaftate BP	1.0% w/w
Benzalkonium chloride solution BP	0.2% v/w
Excipients of known effect	Quantity
Cetostearyl alcohol	6.0% w/w

See section 4.4 for further information.

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Boots Dual Action Athlete's Foot Cream is indicated for the treatment and prevention of Athlete's Foot (Tinea Pedis). It is also effective in other conditions, such as Dhobie Itch (Tinea Cruris).

For cutaneous use.

4.2 Posology and method of administration

Adults, children and the elderly: The affected area should be treated morning and night. Treatment should continue for at least a week after the infection has cleared.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and special precautions for use

Keep all medicines out of the reach of children.
For external use only.
If symptoms persist consult your doctor.

Excipient

Contains Cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis)

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant drug interactions known.

4.6 Pregnancy and lactation

No special requirements.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Occasionally may cause skin irritation, hypersensitivity and contact dermatitis.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App store.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Benzalkonium chloride is a well established drug substance having potent anti-microbial properties.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Arlatone 983S
Cetostearyl alcohol
Dimethicone 20
Liquid paraffin
Glycerol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months

6.4 Special precautions for storage

Store in a cool place below 25°C.

6.5 Nature and contents of container

An internally lacquered metal tube with blind end nozzle. Tube to contain 25gm or 35gm.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham NG2 3AA

8 MARKETING AUTHORISATION NUMBER(S)

PL 00014/0457

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 April 1994

10 DATE OF REVISION OF THE TEXT

30/09/2022