

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Boots Antiseptic Cream

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

<u>Active ingredients</u>		<u>% w/w</u>
2, 4 Dichlorobenzyl alcohol	HSE	0.5%
Cetrimide	EP	0.5%
Allantoin BPC' 34	BPC	0.2%

#### Excipient(s) with known effect

Cetostearyl alcohol 10% w/w

Fragrance containing allergen (in Perfume Compound AG 8053 CPL)

For the full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Cream

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

For abrasions, minor burns and scalds, small areas of sunburn, dry chapped skin, nappy rash, insect bites, spots and pimples.

#### **4.2 Posology and method of administration**

Adults, Children and Elderly:

Apply the cream gently to the affected area two or three times a day.

For topical application.

#### **4.3 Contraindications**

Hypersensitivity to any of the ingredients.

#### **4.4 Special warnings and precautions for use**

Prolonged and repeated applications are inadvisable as hypersensitivity may occur.

If symptoms persist, consult your doctor.

For external use only.

Keep all medicines out of the reach of children.

##### Information about some of the ingredients

This medicine contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

This medicine contains fragrance with liliac which may cause allergic reactions.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

No clinically significant interactions known.

#### **4.6 Fertility, pregnancy and lactation**

The safety of antiseptic cream during pregnancy and lactation has not been established, but use during these periods is not considered to constitute a hazard.

#### **4.7 Effects on ability to drive and use machines**

Not applicable

#### **4.8 Undesirable effects**

Hypersensitivity reactions may occasionally occur in certain individuals following repeated application.

##### **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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **4.9 Overdose**

Where excessive application has been made to the skin, excess cream should be removed and the area washed with soap and water. Otherwise no further treatment is necessary.

In case of ingestion, the product may cause burns and irritation in the mouth and oesophagus. If any treatment is required at all, milk should be given to drink, otherwise symptomatic/supportive therapy should be given.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Dichlorobenzyl alcohol has antiseptic properties. Cetrimide is a quarternary ammonium antiseptic which has bactericidal activity against both gram-positive and gram negative organisms. Allantoin is claimed to stimulate tissue formation and hasten wound healing.

## **5.2 Pharmacokinetic properties**

Not available.

## **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**

Hyetellose (Hydroxyethyl Cellulose)  
Cetostearyl Alcohol  
Ceresin  
Light Liquid Paraffin  
Cetomacrogol 1000  
Dimethicone 20  
Polyethylene Glycol 300  
Perfume Compound AG 8053 CPL (containing lialial)  
Sodium Citrate Granular  
Anhydrous Citric Acid Granular  
Purified Water

## **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

24 months

### **6.4 Special precautions for storage**

Do not store above 30°C.

### **6.5 Nature and contents of container**

Internally lacquered collapsible aluminium tube having a membrane seal and cap, in a cardboard carton.

Pack sizes: 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 120g.

Laminate tube with polypropylene cap in a cardboard carton.

Pack sizes: 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 120g.

Laminate tube with polypropylene cap and polythene/aluminium membrane seal in a cardboard carton.

Pack sizes: 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 120g.

### **6.6 Special precautions for disposal**

Not applicable

## **7 MARKETING AUTHORISATION HOLDER**

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

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 00014/5138R

**9      DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

Date of First Authorisation:    7 November 1984  
Last Renewal:                      15 June 1995

**10     DATE OF REVISION OF THE TEXT**

08/07/2024