

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Boots Bite and Sting Relief Hydrocortisone Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone Acetate BP 1.0% w/w

3 PHARMACEUTICAL FORM

A smooth, white cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Insect bite and sting reactions

4.2 Posology and method of administration

For topical administration

Apply sparingly to a small area, once or twice a day, for a maximum of 2-3 days. Do not use in pregnancy without medical advice or in children under 10.

4.3 Contra-indications

Hypersensitivity to hydrocortisone acetate or to any other excipients listed in

section 6.1

The product should not be used on the eyes or face, the ano-genital area or on broken or infected skin including impetigo, cold sores, acne, athlete's foot, scabies or infected bites or stings.

In the presence of untreated infections of bacterial, viral, tuberculous or fungal origin.

Not for use with an occlusive dressing or on large areas of the body.

4.4 Special Warnings and Precautions for Use

The product should not be used during pregnancy or breast-feeding unless recommended by a health care professional (see section 4.6).

The product labelling shall include the following statements:

If the condition does not improve consult your doctor. Do not use on the eyes or face, anal or genital areas or on broken skin or infected skin, e.g. impetigo, cold sores, acne, athlete's foot, scabies or infected bites or stings. Do not use for other bites or stings or for other skin conditions.

Visual impairment:

Visual impairment may be reported with systemic and topical use of corticosteroids. If patients develop symptoms such as blurred vision or other visual disturbances, consideration should be given to referring the patient to an ophthalmologist to establish the possible cause which may include cataract, glaucoma or rare conditions such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and Lactation

Pregnancy

This product should not be used in pregnancy without medical advice. There is no information about effects on lactation.

Breast-feeding

This product should not be used whilst breast-feeding unless recommended by a health care professional. Corticosteroids are excreted in human milk. There

is no information about effects on lactation. A risk to new-borns/infants cannot be excluded.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable Effects

Treatment with hydrocortisone is usually well tolerated but treatment should be

stopped if symptoms of hypersensitivity occur, including allergic contact dermatitis or worsening of the original condition.

Eye disorders:

Frequency not known: blurred vision (see also section 4.4)

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

No special precautions or antidotes are likely to be needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hydrocortisone is a corticosteroid which has anti-inflammatory activity.

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

White soft paraffin
Liquid paraffin
Phenoxyethanol
Purified water
Cetomacragol emulsifying wax

6.2 Incompatibilities

None known.

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

Internally lacquered collapsible aluminium membrane-sealed tube with a polypropylene cap. Pack size is 10g.

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 00014/0658

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/11/2024

10 DATE OF REVISION OF THE TEXT

07/11/2024