

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Bite and Sting Relief Antihistamine Cream
Boots Bite & Sting Relief 2 Years Plus Antihistamine Cream (GSL only)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Ingredient</u>	<u>% quantity</u>
Mepyramine maleate, Ph Eur.	2.0% w/w

<u>Excipients of Known Effect</u>	<u>% quantity</u>
Cetostearyl alcohol	8 % w/w
Lanolin anhydrous	1 % w/w

For more information see section 6.1

3. PHARMACEUTICAL FORM

Cream.

4.1 Therapeutic indications

P: For the symptomatic relief of insect bites and stings and nettle rash.

GSL: For the symptomatic relief of insect bites and stings and nettle stings.

For topical application to the skin.

4.2 Posology and method of administration

P: For adults, children and the elderly: Rub gently on to the affected area sparingly two or three times each day for up to three days. Early application is essential to obtain the optimum response.

GSL: For adults, elderly and children 2 years of age and over: Rub gently on to the affected area sparingly two or three times each day for up to three days. Early application is essential to obtain the optimum response.

4.3 Contraindications

Hypersensitivity to any of the ingredients or other antihistamines.
Should not be applied to acute vesicular and exudative dermatoses or eczema.

4.4 Special warning and precautions for use

P & GSL:

Do not apply to broken skin or eczema.

Not to be applied to large areas of skin.

If a rash develops, gets worse or if skin sensitisation occurs, stop using the product.

Do not use for longer than a few days. If skin sensitisation occurs, stop using the product immediately. If symptoms do not go away, talk to your doctor.

This medicine contains Lanolin and Cetostearyl alcohol which may cause local skin reactions (e.g., contact dermatitis)

For external use only.

Keep all medicines out of the reach of children.

In addition, GSL:

Do not apply to sunburnt skin.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant drug interactions expected.

4.6 Pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established. In view of the potential for systemic absorption through the skin, the product should not be used during these periods unless under medical supervision.

4.7 Effects on ability to drive and to use machines

May theoretically be extensively absorbed through the skin when applied over large areas and cause somnolence and mild disorientation.

4.8 Undesirable effects

Skin sensitisation has been reported on rare occasions.

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

If accidentally ingested, the amount of mepyramine in a whole tube this dose would constitute a dangerous overdose in young children.

The chief symptom of overdosage is unconsciousness and there may be convulsions in the intervening periods. The stomach should be washed out. Stimuli liable to provoke convulsions should be avoided, but if this complication should occur, parenteral Diazepam should be given; sedatives which are liable to increase respiratory depression should be avoided. Other measures such as artificial respiration and oxygen may also be required, and an antibiotic can be given as a prophylactic against pneumonia.

5.1 Pharmacodynamic Properties

Mepyramine maleate is an H₁ receptor antagonist (antihistamine) of the ethylene diamine type. It diminishes or abolishes the effects of histamine in the body by competitive reversible blockade of histamine receptor sites on tissues.

5.2 Pharmacokinetic Properties

Mepyramine maleate is readily absorbed through the skin, metabolised in the liver and excreted, mainly as metabolites in the urine.

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

White soft paraffin BP
Liquid paraffin Ph Eur
Anhydrous lanolin EP
Arlacel 83 HSE
Cetomacrogol 1000 BP
Cetostearyl alcohol Ph Eur
Citric acid monohydrate Ph Eur
Sodium citrate Ph Eur
Purified water Ph Eur

6.2 Incompatibilities

None known.

6.3 Shelf Life

24 months.

6.4 Special Precautions for Storage

Do not store above 25°C.

6.5 Nature and Contents of Container

A collapsible internally lacquered aluminium tube with membrane seal fitted with a high density polyethylene cap.

Pack size:

P: 25gm, 30gm.

GSL: 20 gm

6.6 Instruction for Use, Handling and Disposal

Not applicable.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PL 00014/0440

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

Date of first authorisation:	28 th September 1993
Date of last renewal:	13 th November 1998

10 DATE OF REVISION OF THE TEXT

18/06/2024