

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Boots Pharmaceuticals Bite and Sting Relief Antihistamine 2% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 20mg mepyramine maleate (2% w/w)

Excipients: contains cetostearyl alcohol 8% w/w and anhydrous lanolin 1% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

Smooth white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

For topical application to the skin.

For Adults, Children 2 years and over and the Elderly: Rub gently on to the affected area sparingly two or three times each day for up to three days.

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 warnings and precautions for use

Do not apply to broken skin or eczema.

Not to be applied to large areas of skin.

If rash develops or gets worse stop using the product.

For external use only.

Keep all medicines out of the reach of children.

If symptoms do not go away, talk to your doctor.

Do not apply to sunburnt skin.

Excipient warnings: Cetostearyl alcohol and anhydrous lanolin may cause local skin reactions (eg. contact dermatitis)

4.5 Interaction with other medicinal products and other forms of interactions

No clinically significant drug interactions expected.

4.6 Fertility, 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 use machines

No adverse effects known.

4.8 Undesirable effects

Occasional local hypersensitivity reactions.

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 website: <http://www.hpra.ie/>.

4.9 Overdose

In cases of excessive application to the skin, sufficient absorption may occur to give rise to systemic adverse effects. Treatment should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

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
Liquid paraffin
Anhydrous lanolin
Sorbitan sesquioleate
Cetomacrogol 1000
Cetostearyl alcohol
Citric acid monohydrate
Sodium citrate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

An aluminium tube internally lacquered with a membrane seal and an unwadded plastic cap.
Pack size 20, 25 or 30 grams.

Not all pack size may be marketed.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Taw Pharma (Ireland) Ltd
104 Lower Baggot Street
Dublin 2
Dublin
D02 Y940
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23081/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9 December 2005

Date of last renewal: 9 December 2010

10 DATE OF REVISION OF THE TEXT

December 2020