

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Anthisan Bite and Sting 2% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mepyramine Maleate 2% w/w

Also contains:

Castor oil	23,60% w/w
Ceto-stearyl alcohol	13,80% w/w
Propylene glycol 600 monostearate	4,90% w/w
Methyl hydroxybenzoate	0,20% w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

A smooth off-white cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic relief of skin irritation caused by insect stings, insect bites and nettle stings.

Route of Administration: Topical

4.2 Posology and method of administration

Adults, elderly and children over 2 years of age and older. Anthisan Bite and Sting Cream should be applied directly to the affected parts two or three times a day for up to three days. Early application is essential to obtain the optimum response.

4.3 Contraindications

Anthisan Bite and Sting Cream should not be used in eczematous conditions or on extensively broken skin surfaces, or if the skin is cut or grazed. Do not use on large areas of skin or on areas of sunburnt skin.

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Repeated application of Anthisan Bite and Sting Cream to the same area for longer than three days is not recommended and treatment should be discontinued immediately if skin sensitisation occurs.

4.5 Interaction with other medicinal products and other forms of interaction

No significant interactions described.

4.6 Fertility, Pregnancy and lactation

There is no evidence of the safety of mepyramine maleate in human pregnancy, but it has been widely used for many years without apparent ill consequence. Absorption of a significant amount after topical application is unlikely in the prescribed method of use, nevertheless, Anthisan Bite and Sting Cream should not be used during pregnancy or lactation, unless considered essential.

4.7 Effects on ability to drive and use machines

Anthisan Bite and Sting Cream has minor or moderate influence on the ability to drive and 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 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

A 20g tube of Anthisan Bite and Sting Cream contains 400mg mepyramine maleate. If the product is ingested in significant amounts, this could be life-threatening in young children.

The chief symptoms 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 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mepyramine maleate is an antihistamine with anti-pruritic and local analgesic actions.

ATC code: Antihistamines for Topical Use R06AC01

5.2 Pharmacokinetic properties

No pharmacokinetic data available by any route of administration.

5.3 Preclinical safety data

There are no findings of relevance to the prescriber, additional to those already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ceto-stearyl alcohol

Polyethylene glycol 600 monostearate

Castor oil

Methyl hydroxybenzoate

Foin coupe (fragrance)

Silicone antifoam

Purified water

6.2 Incompatibilities

Not applicable.

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

Collapsible aluminium tube with extended nozzle and polyethylene screw cap containing 20g cream.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Phoenix Labs Unlimited Company,
Suite 12, Bunkilla Plaza,
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Clonee,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 35104/0038

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7 June 2000

Date of latest renewal: 2 September 2005

10 DATE OF REVISION OF THE TEXT

04/01/2024