

SUMMARY OF PRODUCT CHARACTERISTICS.

1. Name of the medicinal product

Antihist Cream.

2. Qualitative and quantitative composition

Mepyramine maleate BP 2.0% w/w.

3. Pharmaceutical form

Cream.

4. Clinical particulars

4.1 Therapeutic indications

Effective relief from itching, irritation of the skin in insect bites, stings and other pruritic conditions caused by hypersensitivity.

Route of Administration: Topical.

4.2 Posology and method of administration

Adults, elderly and children. Antihist 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

Antihist Cream should not be used in eczematous conditions or on extensively broken skin surfaces.

4.4 Special warnings and precautions for use

Repeated application of Antihist Cream for periods longer than a few 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 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, Antihist Cream should not be used during pregnancy or lactation, unless considered essential.

4.7 Effects on 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 Antihist Cream contains 400mg Mepyramine maleate. If the product is ingested in significant amounts, this could be life-threatening 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. Pharmacological properties

5.1 Pharmacodynamic properties

Mepyramine maleate is an antihistamine with antipruritic and local analgesic actions.

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 elsewhere in the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Liquid paraffin

Petroleum jelly

Cetostearyl alcohol

Cetomacrogol 1000

Propylene glycol

Benzyl alcohol

Sodium acid phosphate

Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in a dry place, below 30°C. Protected from light.

6.5 Nature and contents of container

Collapsible aluminium tube with extended nozzle and polythene cap containing 20gm cream.

6.6 Special precautions for disposal and other handling

None stated.

7. Marketing authorisation holder

Dawa Limited

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