Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Anthisan Cream 2% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mepyramine maleate 2% w/w

Also contains Methyl Parahydroxybenzoate (E 218) and Cetostearyl Alcohol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

Smooth homogeneous cream of fairly firm consistency, off-white to pale in colour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Anthisan has analgesic, anti-histaminic and anti-pruritic properties.
Symptomatic relief in insect bites, stings and nettle rash.

4.2 Posology and method of administration

The route of administration is topical.

Recommended Dosage

Apply to affected area 2 to 3 times daily for up to 3 days or as directed by the physician.

4.3 Contraindications

Acute vesicular and exudative dermatoses.
Use in eczematous conditions or on broken skin.
Use with occlusive dressings.
Use in patients hypersensitive to mepyramine maleate or any of the excipients of Anthisan Cream.
Use in premature infants and neonates.
Pregnancy and lactation.

4.4 Special warnings and precautions for use

Repeated application for periods longer than a few days is not recommended and treatment should be discontinued immediately if skin sensitization occurs.

If symptoms persist, consult a doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

There is no evidence of the safety of Mepyramine Maleate in human pregnancy. Absorption of a significant amount after topical application is unlikely in the prescribed method of use, nevertheless Anthisan Cream should not be used during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Anthisan cream may be absorbed when applied over large areas of skin. This could cause somnolence and mild disorientation. If this happens, do not drive or use any tools or machines.

4.8 Undesirable effects

Topical therapy may produce hypersensitivity reactions, particularly of the skin, and cross sensitivity to related drugs may occur.

Skin sensitisation, eczematous reactions and photosensitivity may develop after topical application.

Systemic side-effects have been reported after topical application of antihistamines to large areas of the skin.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

4.9 Overdose

A 25 gram tube of Anthisan Cream contains 500mg Mepyramine Maleate. If accidentally ingested this dose would constitute a dangerous overdose in young children.

Overdosage may be fatal especially in infants and children. Overdosage is associated with antimuscarinic, extrapyramidal, gastrointestinal and central nervous system effects. In infants and children, central nervous system stimulation predominates over central nervous system depression. This can cause ataxia, excitement, tremors, psychoses, hallucinations, convulsions and hyperpyrexia. Deepening coma and cardiorespiratory collapse may follow. In adults, central nervous system depression is more common with drowsiness, coma and convulsions, progressing to respiratory failure or possibly cardiovascular collapse.

The stomach should be washed out. Stimuli liable to provoke convulsions should be avoided but if this complication should occur, parential diazepam should be given. Sedatives which are liable to increase respiratory depression should be avoided. Other measeures 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

ATC: D04 AA02

A topical preparation with analgesic, antihistamine and anti-pruritic properties.

5.2 Pharmacokinetic properties

No pharmacokinetic data available by any route of administration.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Macrogol 600 monostearate
Castor oil
Methyl parahydroxybenzoate (E218)
Foin coupe (36% benzyl benzoate, 21% oil of cedarwood, other aromatics and essential oils)
Silicone MS antifoam A (a mixture of liquid dimethicones containing finely divided silicone dioxide)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Collapsible internally lacquered aluminium tube with extended nozzle and Polypropylene cap, packed in outer carton.

Pack size: 25 g

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

Phoenix Labs
Suite 12, Bunkilla Plaza
Bracetown Business Park
Clonee
Co. Meath.
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1113/024/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1979

Date of last renewal: 1st April 2009

10 DATE OF REVISION OF THE TEXT

January 2024