

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Anthisan 2% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mepyramine maleate 2% w/w

Excipients: includes methyl parahydroxybenzoate (E218), cetostearyl alcohol and benzyl benzoate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from the UK

Smooth homogenous 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 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

If symptoms persist, consult a doctor.

Contains methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

Contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

Contains benzyl benzoate : mildly irritant to the skin, eyes and mucous membrane

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.

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, parental 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

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
Polyethylene glycol 600 monostearate
Castor oil
Methyl parahydroxybenzoate (E218)
Foin coupe (fragrance which contains benzyl benzoate)
Silicon antifoam
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the outer carton and aluminum tube of the product as marketed in the country of origin

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Overlabelled collapsible aluminium tube with extended nozzle and polyethylene cap, packed in an overlabelled carton
Pack size: 25g

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 PARALLEL PRODUCT AUTHORISATION HOLDER

G & A Licensing Ltd
Ballymurray
Co. Roscommon

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1447/70/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th of October 2010

10 DATE OF REVISION OF THE TEXT