

DATA SHEET

1 ANTHISAN™ (CREAM)

Anthisan™ 2.0% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mepyramine maleate 2.0% w/w

Excipient(s) with known effect:

Castor oil - may cause skin reactions

Cetostearyl alcohol – may cause local skin reactions (e.g. contact dermatitis)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream: Smooth, homogenous, white to off-white cream in colour.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

This medicine is indicated in adults and children for the symptomatic relief in insect stings and bites and nettle rash.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults, Elderly and Children

Anthisan cream should be applied directly to the affected areas two or three times a day for up to three days.

Early application is essential to obtain the optimum response.

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

Anthisan 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 Anthisan 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 MEDICINES AND OTHER FORMS OF INTERACTION

No significant interactions described.

4.6 FERTILITY, PREGNANCY AND LACTATION

Pregnancy

Safety during pregnancy has not been established. Medical advice is required for use in pregnancy.

Breast-feeding

Safety during lactation has not been established. Use during lactation only with medical advice.

Fertility

Anthisan Cream has not been evaluated for the effects on fertility.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

This product 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 tool or machines.

4.8 UNDESIRABLE EFFECTS

The following CIOMS frequency rating is used:

Very common $\geq 10\%$; Common ≥ 1 and $< 10\%$; Uncommon ≥ 0.1 and $< 1\%$;
Rare ≥ 0.01 and $< 0.1\%$; Very rare $< 0.01\%$; Not known (cannot be estimated from available data).

- Skin and subcutaneous tissue disorders

Not Known: Skin sensitisation

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>.

4.9 OVERDOSE

A 25 g tube of Anthisan Cream contains 500 mg mepyramine maleate. If the product is ingested in significant amounts, this could be life-threatening or fatal in young children.

The chief symptom of overdose is unconsciousness and there may be convulsions in the intervening periods.

Symptomatic and supporting treatment is recommended.

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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Antihistamines for topical use, ATC code: D04AA02

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

5.2 PHARMACOKINETIC PROPERTIES

No pharmacokinetic data are 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 data sheet.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

The medicine also contains the following excipients:

Castor oil
Methyl hydroxybenzoate
Cetostearyl alcohol
Macrogol 600
Foin coupe
Simethicone
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

One collapsible aluminium tube with extended nozzle and polythene cap containing 25g cream.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No Special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE

General sale medicine.

8 SPONSOR

sanofi-aventis new zealand limited
Level 8,
56 Cawley Street
Ellerslie
Auckland
New Zealand

Tel: (09) 580 1810

9 DATE OF FIRST APPROVAL

31/12/1969

10 DATE OF REVISION OF THE TEXT

25 May 2017

SUMMARY OF CHANGES

Section	Summary of Change
All	Format change to align with new data sheet format
1	Editorial changes
2	Addition of excipients with known effect
3	Expanded visual description
4.1, 4.2, 4.4, 4.7	Editorial changes
4.3	Addition of contraindication; Editorial changes
4.6	Pregnancy and Breast-Feeding information updated; Fertility section added.
4.8	Update of adverse event frequency; Addition of reporting suspected adverse reactions
4.9	Overdose information revised.
5.1	Addition of ATC code
5.3	Section added
6.1	Excipients names revised to align with INN
6.2, 6.3	Editorial change
6.6	Section expanded

Section	Summary of Change
8	Editorial change to address
9	Section added