

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Anthisan Plus Sting Relief Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mepyramine Maleate 2% w/w.

Benzocaine 2% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, solution

A clear, colourless to slightly yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Symptomatic relief in insect bites and stings, and nettle stings.

4.2 Posology and method of administration

Each metered dose delivers 2 mg mepyramine maleate and 2 mg benzocaine.

Adults, elderly and children over 12 years:

Pressing the nozzle head once delivers a single metered dose.

Two to three metered doses to be sprayed on to the site of the bite or sting two or three times a day for up to three days.

Early application is essential to obtain optimum response.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

Anthisan Plus Sting Relief Spray should not be used in eczematous conditions or on extensively broken skin surfaces.

Do not use on large areas of skin or on areas of sunburnt skin.

Do not use near the eyes or mouth.

4.4 Special warnings and precautions for use

Repeated applications of Anthisan Plus Sting Relief Spray for longer than a few days are not recommended and treatment should be discontinued immediately if skin sensitisation occurs. The spray should not be applied near a naked flame.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions following topical use are known.

4.6 Pregnancy and lactation

There is inadequate evidence for the safety of Anthisan Plus Sting Relief Spray in pregnancy or lactation. Anthisan Plus Sting Relief Spray should not be used in pregnancy or lactation unless considered essential by a physician.

4.7 Effects on ability to drive and use machines

None when used as recommended. However following inappropriate use with application to large areas absorption may theoretically occur which could result in somnolence or mild disorientation.

4.8 Undesirable effects

Hypersensitivity reactions.

4.9 Overdose

Unlikely following topical administration.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mepyramine maleate is an antihistamine with anti-pruritic properties and local analgesic actions.
Benzocaine is surface anaesthetic of the ester type with low systemic toxicity, which provides effective relief of pain.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

No animal data is available relating to Anthisan Plus Sting Relief Spray. The active agents mepyramine maleate and benzocaine have been used in human medicine for over 40 years.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Propylene Glycol

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Store below 25°C. Keep away from naked flames.

6.5 Nature and contents of container

Aluminium internally lacquered can with 100 microlitre pump/actuator and containing either 60 or 180 metered doses. Not all pack sizes may be marketed.

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

Sanofi-Aventis Ireland Ltd.
Citywest Business Campus
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 540/13/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 January 2000

Date of last renewal: 07 January 2005

10 DATE OF REVISION OF THE TEXT

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