

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

Anthisan™ Cream

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Mepyramine maleate BP 2.0% w/w.

## **3 PHARMACEUTICAL FORM**

Cream

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Symptomatic relief in insect stings and bites and nettle rash.

Route of Administration: Topical.

### **4.2 Posology and method of administration**

Adults, elderly and children. Anthisan 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**

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 medicinal products and other forms of interaction**

No significant interactions described.

### **4.6 Fertility, 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, Anthisan 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](http://www.mhra.gov.uk/yellowcard)

#### **4.9 Overdose**

A 25g tube of Anthisan Cream contains 500mg mepyramine maleate. If accidentally ingested this dose would constitute a dangerous overdose 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**

Ceto-stearyl alcohol BP, Polyethylene glycol 600 monostearate, Castor oil BP, Methyl hydroxybenzoate BP, Foin coupe, Silicone antifoam, Purified water BP.

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

36 months.

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

Collapsible aluminium tube with extended nozzle and polypropylene cap containing 25g cream.

### **6.6 Special precautions for disposal**

None stated.

## **7 MARKETING AUTHORISATION HOLDER**

Phoenix Labs Unlimited Company,

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

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 35104/0039

**9      DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

4<sup>th</sup> April 2002

**10     DATE OF REVISION OF THE TEXT**

04/01/2024