

## SUMMARY OF PRODUCT CHARACTERISTICS

### INTAMINE CREAM

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<b>1. Name of the medicinal product</b>
<b>a) Proprietary name of a medicine</b>
Intamine Cream
<b>b) Approved generic name(s)</b>
Mepyramine Maleate BP
<b>2 Qualitative and quantitative composition</b>
Mepyramine Maleate 2.0% w/w For Excipients 6.1
<b>3 Pharmaceutical form Dosage form</b>
Cream
<b>4 Clinical particulars</b>
<b>4.1 Therapeutic indication(s)</b>
Intamine cream is a topically applied antihistamine and antipruritic used for the relief of irritation associated with urticaria, allergic skin conditions, to alleviate the discomforts of sunburn, prickly heat, insect bites and nettle stings.
<b>4.2 Posology and method of administration</b>
Topical
Adults, elderly and children. Intamine 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
<b>4.3 Contra-indications</b>
Intamine Cream should not be used in eczematous conditions or on extensively broken skin surfaces.
<b>4.4 Special warnings and precautions for use</b>
Repeated application of Intamine Cream for periods longer than a few days is not recommended and treatment should be discontinued immediately if skin sensitization occurs.
<b>4.5 Interactions</b>
No significant interactions described
<b>4.6 Pregnancy and lactation</b>
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

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application is unlikely in the prescribed method of use, nevertheless, Anthisan Cream should not be used during pregnancy or lactation, unless considered essential.

### **Effects on the ability to drive and operate machinery**

May theoretically be extensively absorbed through the skin when applied over large areas and cause somnolence and mild disorientation

### **4.6 Undesirable effects:**

Skin sensitization has been reported on rare occasions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important.

### **4.7 Overdose**

A 25g tube of Intamine 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.

### **5.4 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**

Emulsifying wax  
White Soft Paraffin  
Liquid Paraffin  
Cetomacrogol  
Disodium Hydrogen Phosphate

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Citric acid anhydrous  
Polysorbate 80  
Propylene Glycol  
Chlorocresol  
Chlorocresol

**6.2 Incompatibilities** - None known.

**6.3 Shelf-life** -

- In the original unopened container; 36 months
- After reconstitution (where appropriate) NA
- Shelf-life after first opening: Not applicable

**Special precautions for storage:**

Intamine should be stored below 25°C, in a dry and dark place.  
Keep out of the reach of children

**6.4 Nature and composition of containers**

Pack Size: 25g. Intamine cream, aluminum Tubes, Intamine Cream Leaflets, Intamine Cream unit cartons,

**Instruction for use/handling**

For external use only  
Wash hands before and after use.

**Restriction on sale / distribution:**

Prescription only medicine (POM)

## **7 Administrative data**

**i. Name and address of holder of a registration.**

**Regal Pharmaceuticals Limited**

**Phone: 8564211/2/3/4**

**Fax: 8560946/8564093**

**Email: info@regalpharmaceuticals.com**

**Plot No.: 7879/18, Off Baba Dogo Road, Ruaraka,**

**P.O. Box 44421-00100, Nairobi, Kenya**

**8.i Registration number. – H92/245**

**ii. Date of first registration- 23/09/1997**

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### **DECLARATION BY AN APPLICANT**

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I further confirm that the information referred to in my application dossier is available for verification during GMP inspection.

I also agree that I shall carry out pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to the National Medicines Regulatory Authority of the EAC Partner States.

I further agree that I am obliged to follow the requirements of the Partner States Legislations and Regulations, which are applicable to medicinal products.

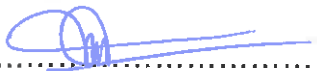
I also consent to the processing of information provided by the EAC Partner States.

It is hereby confirmed that fees will be paid/have been paid according to the National/Community rules\*

Name: DR. MANDERE ATEBE JAMES

Position in the company: COMPANY PHARMACIST

Signature: .....



Date: .....

20<sup>th</sup> May 2019

Official stamp: .....

\* Note: If fees have been paid, attach proof of payment