

PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS**S2****1. NAME OF MEDICINE****ALLERGEX MEPYRAMINE CREAM****Strength**

Mepyramine maleate 2 g

Pharmaceutical form:

Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g contains:

Mepyramine maleate 2 g

Preservative:

Methyl hydroxybenzoate 0,123 % m/m

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A smooth, white cream with a characteristic odour.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

ALLERGEX MEPYRAMINE CREAM is indicated for the treatment of allergic and pruritic conditions such as, urticaria, allergic dermatoses, itching pruritis, atopic dermatitis, contact dermatitis and insect bites.

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4.2 Posology and method of administration

Apply to the affected area two or three times daily for up to three days.

For external use only.

Method of administration:

Topical

4.3 Contraindications:

Hypersensitivity to the active substances or to any of the excipients.

Should not be used for acute vesicular and exudative dermatoses

Mepyramine is contra-indicated in premature infants or neonates.

Use with occlusive dressings.

Use on broken skin and in patients hypersensitive to mepyramine.

4.4 Special warnings and precautions for use

Repeated application of **ALLERGEX MEPYRAMINE CREAM** for periods longer than a few days is not recommended and treatment should be discontinued immediately if skin sensitization occurs.

4.5 Interaction with other medicinal products and other forms of interaction

No significant interactions described.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

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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 SIDE effects and special precautions**b. Tabulated list of adverse reactions presented in system organ class**

System organ class	Undesirable effects
Skin and subcutaneous tissue disorders	Local application of antihistamines causes a risk of skin sensitisation with eczematous eruptions.
General disorders and administrative site conditions	Systemic side effects have been reported after topical application of antihistamines to large areas of the skin.
Nervous system disorders	Somnolence and mild disorientation

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/publications/Index/8>

May also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

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4.9 Overdose

If accidentally ingested, the stomach should be emptied by aspiration. Emetics should not be used. Other treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

A 13.4.2 Dermatological preparations. Other

Mechanism of action:

ALLERGEX MEPYRAMINE CREAM exhibits the action of mepyramine maleate, an H₁ blocker as a topical application for allergic states.

5.2 Pharmacokinetic properties

No pharmacokinetic data available by route of administration.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Emulsifying wax, liquid paraffin and purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Two years

6.4 Special precautions for storage

Store at or below 25 °C. Protect from light. Keep tightly closed.

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KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Tubes containing 25 gram and jars containing 500 gram.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER

G 1540 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27 April 1991

10. DATE OF REVISION OF THE TEXT

10 March 2022