SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PHENERGAN 2 PERCENT, cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Promethazine .... 2.00 g
For 100 g of cream.
Excipients with known effect: wool grease (lanolin), methylparaben.
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Local symptomatic treatment of pruritus, particularly insect bites.

4.2. Posology and method of administration

Thin layer application, 2-3 times per day. Wash hands after use.
Do not use for more than 3 or 4 days without consulting your doctor.

4.3. Contraindications

· Hypersensitivity to any component (promethazine, parabens, lanolin or wool grease, ...) mentioned in Section 6.1.

· Oozing dermatitis,

· Infected dermatoses

· Eczema.

4.4. Special warnings and precautions for use

Special warnings

Itching is a symptom. It requires in all cases the research and treatment of its etiology.
Given the allergenic potential of the components of this drug, the risks must be weighed against the expected benefit.
Given the presence of promethazine, there is a risk of skin sensitization and photosensitivity. If skin sensitization proven to promethazine contained in the cream, cross-sensitization may occur after administration of phenothiazines systemically.

Precautions

Avoid sun exposure to UVA and during treatment.
This medicine contains lanolin (wool fat) and can cause local skin reactions (eg eczema).
This medicine contains cetostearyl alcohol may cause local skin reactions (eg contact dermatitis).
This medication contains methylparaben and may cause allergic reactions (possibly delayed).

4.5. Interaction with other medicinal products and other forms of interaction

At recommended doses, promethazine for topical use is not likely to cause significant drug interactions from a medical point of view.

4.6. Fertility, pregnancy and lactation

Use cautiously in pregnant or breastfeeding women due to atropine and sedative promethazine. Do not apply to the breasts during breastfeeding.

4.7. Effects on ability to drive and use machines

By analogy with the oral, attention is drawn, especially for drivers and machine operators, on the risks of drowsiness attached to the use of this medication, especially early in treatment. This is accentuated by the consumption of alcoholic beverages or medicines containing alcohol. It is best to start the treatment of allergic manifestations evening.

4.8. Undesirable effects

Risk of skin allergy and sensitization.

Reporting suspected adverse reactions
Reporting suspected adverse reactions is important. It allows continuous monitoring of the benefit/risk ratio of the medicinal product. Healthcare professionals must report any suspected adverse reaction in accordance with the procedures defined in the Protocol for Therapeutic Use and Data Collection (see PUT RD).

4.9. Overdose

· Signs of promethazine overdose: convulsions (especially in infants and children), impaired consciousness, coma;

· Symptomatic treatment should be instituted in a specialized

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group:
ANTIHISTAMINE H1
Antipruriginous
Code ATC : D04AA10
(D. Dermatology)

5.2. Pharmacokinetic properties

Not specified.

5.3. Preclinical safety data

Not specified

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

stearic acid, cetostearyl alcohol mixture and sodium cetearyl sulfate (CS Kolliphore A), cholesterol, wool wax, trolamine, glycerol, methylparaben, coumarin, lavender essential oil, purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years

6.4. Special precautions for storage

Store at a temperature below 30 ° C.

6.5. Nature and contents of container

Aluminum tube capped varnish 30 g closed by a polyethylene cap.

6.6. Special precautions for disposal and handling

No special requirements.
Any unused product or waste material should be disposed in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

OWNER AND OPERATOR TO INTERNATIONAL:
FRILAB SA
17, rue des Pierres du Niton
1207 Genève SWITZERLAND

Production site :
Laboratórios Vitória, Rua Elias Garcia, 28, 2700-327 Amadora, Portugal

8. DATE OF REVISION OF THE TEXT

October 2019

9. DOSIMETRY

Not applicable.

10. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERY

Medicinal product not subject to medical prescription.