SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PHENERGAN 2 PERCENT, cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Promethazine .....2.00 g
Per 100g of cream.
Excipients with known effect: wool fat (lanolin), methyl parahydroxybenzoate, cetostearyl alcohol .
For the 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

Posology
Apply a thin layer 2 to 3 times a day. Wash your hands after application.
Do not use for more than 3 to 4 days without medical advice.

Method of administration
Cutaneous route.

4.3. Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

- Weeping dermatoses,
- Infected dermatoses,
- Eczema.

4.4. Special warnings and precautions for use

Special warnings

Itching is only a symptom. In all cases, it requires the investigation and treatment of its underlying cause.
Given the allergenic potential of the components of this medication, the risks involved must be weighed against the expected benefit.
Given the presence of promethazine, there is a risk of skin sensitization and photosensitivity. In cases of proven skin sensitization to the promethazine contained in the cream, cross-sensitization may occur after systemic administration of phenothiazines.

Precaution for use

Avoid sun and UVA exposure during treatment.
This medicine contains lanolin (wool fat) and may cause local skin reactions (e.g. , eczema).
cetostearyl alcohol and may cause local skin reactions (e.g., eczema).
This medicine contains methyl parahydroxybenzoate and may cause allergic reactions (possibly delayed).

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

At recommended doses, promethazine for topical use is not likely to cause clinically significant drug interactions.

4.6. Pregnancy and breastfeeding

Use with caution in pregnant or breastfeeding women due to promethazine's atropine-like and sedative properties. Do not apply to the breasts while breastfeeding.

4.7. Effects on the ability to drive vehicles and use machinery

By analogy with oral administration, particular attention should be paid, especially by drivers and machine operators, to the risk of drowsiness associated with the use of this medication, particularly at the beginning of treatment. This effect is exacerbated by the consumption of alcoholic beverages or medications containing alcohol. It is preferable to begin treatment for allergic reactions in the evening.

4.8. Undesirable effects

Risk of skin allergy and photosensitivity.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions is important. It allows for continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals must report any suspected adverse reactions according to the procedures defined in the Therapeutic Use and Data Collection Protocol (PUT RD).

4.9. Overdose

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

Symptomatic treatment will be initiated in a specialized setting

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class : H1 antihistamine and **antipruritic, ATC code: D04AA 10** (**D. Dermatology**)

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Stearic acid, mixture of cetostearyl alcohol and sodium cetostearyl sulfate (Kolliphore CS A), cholesterol, wool fat, trolamine , glycerol, methyl parahydroxybenzoate, coumarin, lavender essential oil, purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years

6.4. Special storage precautions

Store at a temperature below 30°C.

6.5. Nature and contents of container

30g varnished aluminium tube with a capped polyethylene stopper.

6.6. Special precautions for disposal and handling

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

7. OPERATORS AND MANUFACTURERS

Operator of the export marketing authorization
FRILAB SA
17, rue des Pierres du Niton
1207 Geneva SWITZERLAND

Manufacturers
Faes Farma , Rua Elias Garcia, n°28, Amadora, 2700 – 327, Portugal

8. DATE OF REVISION OF THE TEXT

29 July 2022.

9. DOSIMETRY

Not applicable.

CONDITIONS FOR PRESCRIPTION AND DISPENSING

This medication is not subject to medical prescription.