

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF DRUG

**PHENERGAN 2 PERCENT, cream**

### 2. Qualitative and quantitative composition

Promethazine ..... 2.00  
g

100 g of cream.

Excipients with known effect: wool grease (lanolin), methylparaben, cetostearyl alcohol.

For a full list of excipients, [see section 6.1](#).

### 3. PHARMACEUTICAL FORM

Cream.

### 4. CLINICAL DATA

#### 4.1. Therapeutic indications

Local symptomatic treatment of pruritus, particularly insect bites.

#### 4.2. Dosage and administration

Thin layer application, 2-3 times per day.

#### 4.3. Cons-indications

- Hypersensitivity to any component (promethazine, parabens, lanolin or wool grease, ...)
- Oozing dermatitis,
- Infected dermatoses
- Eczema.

#### 4.4. Special warnings and precautions

##### **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.

##### **Job Caution**

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. Interactions with other drugs 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. Pregnancy and breast feeding**

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. Side effects**

Risk of sensitization to various components of the preparation: promethazine, lanolin or wool grease, parabens ....

#### **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:**  
**ANTI-HISTAMINE H1**  
**Antipruriginous**  
(D. Dermatology)

#### **5.2. pharmacokinetic properties**

Not specified.

#### **5.3. Preclinical safety data**

Not specified

### **6. PHARMACEUTICAL DATA**

#### **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. incompatibility**

Not applicable.

### **6.3. The duration of the conversation**

3 years

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

Store at a temperature below 25 ° 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.

## **7. Farmers and Manufacturers**

### **OWNER AND OPERATOR TO INTERNATIONAL:**

FRILAB SA

17, rue des Pierres du Niton

1207 Genève SWITZERLAND

### Production sites :

Laboratórios Vitória / Grupo Faes Farma, Rua Elias Garcia, 28, 2700-327 Amadora, Portugal  
(Vamfarma, Officina di Comazzo 26833 (LO)5 Via Kennedy - Italy)

## **8. DOSIMETRY**

Not applicable.

## **9. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS**

Not applicable.

## **CONDITIONS OF PRESCRIPTION AND DELIVERY**

Medicinal product not subject to medical prescription.