SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF DRUG

PHENERGAN 0.1 PERCENT syrup

2. Qualitative and quantitative composition

Promethazine hydrochloride .... 0.113 g
corresponding amount promethazine base .... 0.100 g
For 100 ml syrup.
A measuring cup of 5 ml mark (1 c.à.c) contains 5 mg of promethazine base.
A measuring cup of 10 ml mark (2 c.à.c) contains 10 mg of promethazine base.
excipients:· A measuring cup of 5 ml mark(1 c.à.c)contains 37 mg of alcohol and 4.2 g of sucrose. · A measuring cup of 10 ml mark(2 c.à.c)contains 73 mg of alcohol and 8.3 g of sucrose.
Alcohol content: 0.9% (V / V).
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

4. CLINICAL DATA

4.1. Therapeutic indications

Symptomatic treatment of various allergic manifestations:

· Rhinitis (seasonal and perennial)

· Conjunctivitis,

· Hives.

4.2. Dosage and administration

RESERVED FOR ADULTS AND CHILDREN OVER 2 YEARS.
orally.
Use the measuring cup graduated at 5 and 10 ml or a teaspoon:
For children 2 to 6 years: it is imperative to seek medical attention and respect his prescription.
In children 6 to 12 years: 1-2 graduations of 5 ml of the measuring cup per dose, 2-3 times a day, not to exceed 5 graduations of 5 ml per day.
In children over 12 years: 1-2 graduations 10 ml of the measuring cup per dose, 4 times a day, not to exceed 5 graduations of 10 ml per day.
In adults2 graduations 10 ml of the measuring cup per dose, 4-5 times daily.
Given the pronounced sedative effect of promethazine, the highest decision will be reserved for evening.

4.3. Cons-indications

This drug is CONTRAINDICATED in the following cases:

- Children under 2 years

· Hypersensitivity to antihistamines,

· History of agranulocytosis,

· Risk of urinary retention related to urethroprostatic disorders

· Risk of glaucoma angle closure.

This medicine is GENERALLY NOT RECOMMENDED:

· In association with sultopride (see section 4.5)

· During lactation

4.4. Special warnings and precautions

Special warnings

If persistent or worsening symptoms (respiratory distress, swelling, skin lesions ...) or signs associated with viral infection, the course of action should be reassessed.

CAUTION THIS MEDICINE CONTAINS ALCOHOL:
The alcohol content of the solution is 0.9% is:

· 37 mg of alcohol in 5 ml mark of the measuring cup,

· 73 mg of alcohol in 10 ml mark of the measuring cup.

This product contains 0.9% v / v of ethanol (alcohol), that is to say up to 73 mg of alcohol in 10 ml mark. The use of this drug is dangerous for alcoholics and must be taken into account in pregnant or nursing women, children and high risk groups such as hepatic impairment or epilepsy.
This medicine contains sucrose. Its use is not recommended in patients with intolerance to sucrose.

Precautions

Insofar as phenothiazines such as promethazine were considered as hypothetical risk factors in the occurrence of sudden infant death syndrome, this medicine is against-indicated in children younger than 2 years.
Monitoring (clinical and possibly electric) must be strengthened in epileptics because of the possibility of lowering the seizure threshold.
Promethazine should be used with caution:

· Elderly patients presenting:

o greater sensitivity to orthostatic hypotension, vertigo and sedation,

o chronic constipation (risk of paralytic ileus)

o a possible prostatic hypertrophy;

· In subjects with certain cardiovascular conditions, due tachycardisants hypotensive effects of phenothiazines,

· In hepatic and / or severe renal impairment (due to the risk of accumulation).

Consumption of alcoholic beverages or other medication containing alcohol (see section 4.5) Is strongly recommended during the treatment period.
Given the photosensitizing effect of phenothiazines, it is better not to sunbathe during treatment.
This medication contains 4.2 g sucrose per 5 ml measuring cup graduation and 8.3 g of sucrose per graduation of measuring cup 10 ml to be taken into account in the daily ration in the case of diet low in sugars or diabetes.

4.5. Interactions with other drugs and other forms of interaction

combinations not recommended

+ Alcohol
Increase by alcohol of the sedative effect of H1 antihistamines. The alteration of vigilance can make it dangerous to drive vehicles and use machines.
Avoid the intake of alcoholic beverages and medications containing alcohol.
+ Sultopride
Increased risk of ventricular arrhythmias, including torsade de pointes, by adding electrophysiological effects.

To be taken into account

+ Other central nervous system depressants (Sedative antidepressants, barbiturates, clonidine and related substances, hypnotics, morphine derivatives (analgesics and: antitussives), methadone, neuroleptics, anxiolytics)
Enhancement of the central depression. Impaired vigilance may make it dangerous to drive vehicles and use machines.
+ Atropine and other atropine-like substances (Tricyclic antidepressants, antiparkinson anticholinergics, antispasmodics atropine, disopyramide, phenothiazine neuroleptics)
Addition of atropine side effects such as urinary retention, constipation, dry mouth.

4.6. Pregnancy and breast feeding

Pregnancy

· Appearance malformation (1st quarter):

o There is no reliable data on teratogenesis in animals for promethazine.

o Clinically, the use of promethazine in a limited number of pregnancies was apparently revealed no malformative or fetotoxic particular date. However, additional studies are needed to assess the consequences of exposure during pregnancy.

· Fœtotoxic Aspect (2nd and 3rd quarters): In newborns of mothers treated chronically with high doses of an anticholinergic antihistamine were rarely described digestive signs associated with antimuscarinic properties phenothiazines (abdominal distension, meconium ileus, delay the emission of meconium, difficulty starting up the power supply, tachycardia, neurological disorders ...).

Given these data The use of this drug is to be avoided, as a precaution, during the first trimester of pregnancy. It should only be prescribed if necessary thereafter, limiting the 3rd quarter, a one-time use.
If the administration of the drug was in late pregnancy, it seems appropriate to observe a period of monitoring of neurological and digestive functions of the newborn.

feeding

The passage of promethazine in breast milk is not known. Given the possibilities of sedation or paradoxical excitation of the newborn, and more risk of sleep apnea discussed with phenothiazines, this drug is not recommended during lactation.

4.7. Effects on ability to drive and use machines

Attention is drawn, especially for machine users about the risks of drowsiness attached to the use of this medication, especially early in treatment.
This is accentuated by taking alcohol or other drug containing alcohol.
It is best to start treatment one evening.

4.8. Side effects

The pharmacological characteristics of promethazine are responsible of side effects of varying intensity and whether or not related to the dose (see section 5.1):

· Autonomic effects:

o sedation or drowsiness, more marked the beginning of treatment;

o anticholinergic effects such as dry mucous membranes, constipation, blurred vision, mydriasis, heart palpitations, risk of urinary retention;

o orthostatic hypotension;

o problems with balance, dizziness, decreased memory or concentration;

o incoordination, tremors (more common in the elderly);

o confusion, hallucinations;

o more rarely, type of excitation effects: restlessness, nervousness, insomnia;

· Sensitization reactions:

o rash, eczema, pruritus, purpura, possibly giant hives,

o edema, rarely angioedema,

o anaphylactic shock,

o photosensitivity;

· Hematologic:

o leukopenia, neutropenia, agranulocytosis exceptional;

o thrombocytopenia,

o hemolytic anemia.

4.9. Overdose

· Signs of an overdose of Promethazine:

o convulsions (especially in infants and children)

o disorders of consciousness, coma.

· Symptomatic treatment should be instituted in a specialized environment.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ANTIHISTAMINE SYSTEMIC USE
(D: Dermatology)
(R: Respiratory system)
promethazine
H1 antihistamine, phenothiazine aliphatic side chain, which is characterized by:

· A sedative effect marked with the usual doses of histaminergic origin and central adrenergic blocking agent,

· Anticholinergic effect causing peripheral adverse effects.

· An adrenergic blocking effect device, which can resound in hemodynamically (risk of orthostatic hypotension).

Antihistamines have in common ownership to object, competitive antagonism by more or less reversible, effects of histamine including vessels, skin and conjunctival mucosa, bronchial and intestinal.

5.2. pharmacokinetic properties

promethazine
The bioavailability of promethazine is between 13 and 40%.
The time to reach maximum plasma concentration is 1.5 to 3 hours.
The volume of distribution is high due to lipid solubility of the molecule, approximately 15 l / kg.
The binding to plasma proteins is equal to 75-80%.
The half-life is between 10 and 15 hours.
Metabolism is a sulfoxidation followed by demethylation.
Renal clearance is less than 1% of total clearance and about 1% of the administered amount of promethazine is recovered unchanged in the urine. The metabolites in the urine, including sulfoxide, about 20% of the dose.
phvsiopathologique Change: Risk of accumulation of antihistamines in patients with renal or hepatic impairment.

5.3. Preclinical safety data

Unspecified.

6. PHARMACEUTICAL DATA

6.1. List of excipients

citric acid monohydrate, sodium gentisate, alcohol, sweet orange essential oil terpeneless essential oil of orange blossom, caramel (E150), purified water, sucrose solution.

6.2. incompatibility

Not applicable.

6.3. The duration of the conversation

5 years.

6.4. Special precautions for storage

Store at a temperature below 25 ° C and away from light.

6.5. Nature and contents of container

150 ml flask of brown glass type III, closed by a cap made of aluminum provided with a seal made of polyethylene (+ polypropylene graduated measuring cup to 5 ml and 10 ml)

6.6. Special precautions for disposal and handling

No special requirements.

7. OPERATING AND MANUFACTURER

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

MANUFACTURERS:

TERIAK, ZI or ZI El Jebel West Fejja - 1153 El Mornaguia -Tunisia

(POLYMEDIC Rue Amyot Inville, District Arsalan - Casablanca MOROCCO)

8. DOSIMETRY

Not applicable.

9. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERY

Medicinal product not subject to medical prescription.