SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF DRUG

PHENERGAN 2.5 percent solution for injection

2. Qualitative and quantitative composition

Promethazine hydrochloride .... 2.820 g
corresponding amount promethazine base .... 2.500 g
For 100 ml solution for injection.
excipients: potassium disulphite (E224), anhydrous sodium sulfite (E221).
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Injection.

4. CLINICAL DATA

4.1. Therapeutic indications

Symptomatic treatment of acute urticaria.

4.2. Dosage and administration

RESERVED FOR ADULTS AND CHILDREN OVER 15 YEARS.
deep intramuscular injection or intravenous infusion.
1 bulb renew if necessary once.

4.3. Cons-indications

This drug is CONTRAINDICATED in the following cases:

· Hyper-sensitivity to one of the compounds,

· Children under 15 years

· Due to the presence of promethazine:

o history of agranulocytosis with other phenothiazines,

o risk of urinary retention related to urethroprostatic disorders

o risk of glaucoma by 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

The use of this drug should not delay, if necessary, the administration of adrenaline.
This medicine contains "sulfite" and can cause severe allergic reactions and bronchospasm.

Precautions

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).

The consumption of alcoholic beverages and medications 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.

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 taking alcoholic drinks and medicines 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, benzodiazepines, 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 to 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, such as promethazine were rarely described digestive signs associated with antimuscarinic properties phenothiazines (distension abdominal, 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 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.

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

· A traitementsymptomatique be established in a specialized environment.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ANTIHISTAMINE SYSTEMIC USE
(D: Dermatology)
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 side 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 the skin, vessels and conjunctival mucosa, nasal, bronchial and intestinal.

5.2. pharmacokinetic properties

promethazine
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.
pathophysiological 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

potassium disulphite (E 224), sodium sulfite anhydrous (E 221), sodium gentisate, water for injections.

6.2. incompatibility

In the absence of compatibility studies, this medicinal product must not be mixed with other drugs.

6.3. The duration of the conversation

5 years.
After opening / dilution: the product must be used immediately.

6.4. Special precautions for storage

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

6.5. Nature and contents of container

colorless glass bulb (type I) of 2 ml. Box 5

6.6. Special precautions for disposal and handling

No special requirements.

7. OPERATORS AND MANUFACTURERS

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

Maker :
FAMAR MADRID - SPAIN

9. DOSIMETRY

Not applicable.

10. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.