

Summary of Product Characteristics (SmPC)

1.3.1.1 Name of the product: Promethazine Injection 50mg/2ml

1.3.1.2 Qualitative and quantitative composition

Each 2ml ampoule contains promethazine BP equivalent to 50mg of the anhydrous substance.

RAW MATERIAL	LABEL CLAIM PER VIAL	QUANTITY PER BATCH
Promethazine Hydrochloride	50mg	250g
NaCl	6mg	60g
sodium sulfite, anhydrous	1mg	10g
sodium bisulfite	1mg	10g
Vitamin C	2mg	20g
Water for injection	2ml	10000ml

1.3.1.3 Pharmaceutical form

A colourless or almost colourless solution.

1.3.1.4 Clinical particulars

Therapeutic indications

Allergies to skin and mucosa: Suitable for long-term and seasonal allergic rhinitis, coryza vasomotorica, allergic conjunctivitis, nettle-rash, acute circumscribed edema, allergic reactions to blood or plasma products, dermography.

Motion sickness: prevention and treatment of car sickness, seasickness, halo aircraft.

Used in anaesthesia and pre-operative adjuvant treatment, including sedation, hypnosis, analgesia, and anaesthesia.

Used to prevent and treat radiation sickness or drug-induced nausea and vomiting.

Usage and dosage

Intramuscular injection

Adult dosage: (1) Anti-allergies, 25mg once, repeat after 2 hours if necessary;

In severe hypersensitivity, 25-50 mg should be injected intramuscularly, and the maximum dose should not exceed 100mg. (2) In special emergencies, can use sterilized water for injection to dilute to 0.25% and have a slowly intravenous injection (; 3) To stop vomiting , 12.5 ~ 25mg, repeat every 4 hours if necessary;

(4) Sedation hypnosis, once 25~50mg. Infantile dosage : (1) Anti-allergic, 0.125mg/kg or surface area 3.75 mg / m², once every 6 hours; (2) Anti-vertigo, can be given as needed before bedtime, according to body weight 0.25~0.5mg/kg or surface area 7.5~15mg/m². Or once 6.25~12.5mg, three times a day; (3) Stop vomiting, 0.25~0.5mg/kg by

body weight or 15 mg / m² by body surface area, repeat every 4-6 hours if necessary;

(4) Sedative hypnosis, if necessary by weight of 0.5~1mg/kg or every time 12.5 to 25 mg.

Pharmacological toxicology

Promethazine is a phenothiazine antihistamines, it can also be used for vomiting, anti dizziness and sedative hypnosis.

(1) Antihistamine action:competition for H1 receptor with histamine released by tissue antagonistic effect of histamine on contraction or contracture of gastrointestinal tract, trachea, bronchus or bronchiolus smooth muscle, relieving the spasmodic and hyperemia effects of histamine on bronchial smooth muscle.

(2) Antiemetic effect: It may be related to the inhibition of the chemosensory region of emesis in the medulla oblongata.

(3) Anti-motion sickness:It may act on vestibular and vomiting centers and midbrain medullary receptors through central anticholine activity.The stimulation of blocking cholinergic synaptic labyrinth in the vestibular nucleus.

(4) Sedative and hypnotic effect: It may be that it indirectly reduces the stress of the brain-stem network uplink activation system.

Pharmacokinetics

After injection, the absorption was fast and complete, and the plasma protein binding rate was high.The effective time was 20 minutes after intramuscular injection and 3 minutes after intravenous injection.The duration of antihistamine action was 6 ~ 12 hours, and the sedative action lasted 2 ~ 8 hours.It is mainly metabolized in the liver. The inactive metabolites are excreted by urine, and the excretion by feces is less.

Untoward effect

Promethazine is a phenothiazine derivative. There are no obvious side effects at low dose, but the common side effects of phenothiazine can be found in large amount and long time application.

(1) The more common side effects were somnolence;Rare adverse reactions include blurred vision or color blindness (mild), dizziness, dry oropharynx, tinnitus, rash, stomachache or stomach discomfort, slow response (common in children), fainting (hypotension), nausea or vomiting, and even jaundice.

(2) Increase skin sensitivity to light, nightmares, irritability, agitation, hallucinations, toxic delirium.Extrapyramidal response in children.The incidence of these reactions was not high.

(3) Adverse cardiovascular reactions are rare, with elevated blood pressure and occasionally a slight decrease in blood pressure.Leukopenia, granulocytopenia and dysplastic anaemia are rare.

Attention

(1) People who are known to be highly allergic to phenothiazines are also allergic to this product.

(2)The following situations should be used with caution:Acute asthma, bladder neck obstruction, myelosuppression, cardiovascular disease, coma, angle closure glaucoma, liver dysfunction, hypertension, gastric ulcers, prostatic hypertrophy, pyloric or duodenal obstruction, respiratory diseases (especially children, sticky sputum, expectoration, cough reflex), and coughing reflex, and coughing reflex (coughing

reflex) Injection can increase the severity of convulsions, jaundice, various liver diseases and renal failure, Reye syndrome. It should be paid special attention to the presence or absence of intestinal obstruction , or the amount of drugs , poisoning , etc .

Drug interaction

(1) Interference with diagnosis:The glucose tolerance test showed an increase in glucose tolerance. can interfere with urine pregnancy immunity test , and the result is false positive or false negative .

(2) Alcohol or other central nervous depressants, especially anesthetics, barbiturates, monoamine oxidase inhibitors or tricyclic antidepressants, can be used to increase the effects of promethazine or (and) drugs, and the dosage should be adjusted separately.

(3) When anticholine drugs, especially atropine and promethazine, were used together, the anti-muscarinoid effect of the latter increased.

(4) The hypotensive effect of benzyl bromide, guanidine and promethazine was enhanced when combined with promethazine.The α effect of epinephrine can be blocked when the adrenaline is used with promethazine, which makes the β effect dominant.

(5) The ototoxicity symptoms can be masked by the use of ototoxic drugs such as cisplatin , baulvin , and other aminoglycosides antibiotics , salicylic acid preparations ,vancomycin , etc .

(6) Not suitable for mixed injection with aminophylline.

Medication for pregnant and lactating women.

(1) Pregnant women can induce jaundice and extrapyramidal symptoms. Therefore, pregnant women should stop using this medicine in 1-2 weeks before labor.

(2) Breast-feeding women should weigh the advantages and disadvantages of this product .

Medication for Children.

General antihistamines have greater risk to infants, especially newborns and preterm infants.Infants with less than 3 months old are deficient in drug metabolizing enzymes and should not be used.There is also the possibility of renal insufficiency.Neonatal or preterm infants, children with acute disease or dehydration, and children with acute infection are prone to dystonia after injection of promethazine .

Medication for elderly patients.

The elderly are prone to dizziness, stupor, insanity and hypotension.Extrapyramidal symptoms, especially Parkinson's disease, akathisia and persistent dyskinesia, were also susceptible to extrapyramidal symptoms.It is also prone to extrapyramidal symptoms, especially Parkinson's disease, akathisia, and persistent dyskinesia.High dosage or gastrointestinal administration is more likely to occur.

1.3.1.5 Pharmacological properties

1.3.1.5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Histamine H1 receptor antagonist; antihistamine.

ATC code: R06AD02

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1.3.1.5.2 Pharmacokinetic properties

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1.3.1.5.3 Preclinical safety data

The Promethazine injection belong to the generic drug. So it is not necessary.

1.3.1.6 Pharmaceutical particulars

1.3.1.6.1 List of excipients

NaCl
sodium sulfite, anhydrous
sodium bisulfite
Vitamin C
Water for injection

1.3.1.6.2 Incompatibilities

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cisplatin , baulvin , and other aminoglycosides antibiotics , salicylic acid preparations , vancomycin , etc .

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1.3.1.6.3 Shelf life

36 months

1.3.1.6.4 Special precautions for storage

Promethazine Injection should be protected from light. Do not store above 30°C.

1.3.1.6.5 Nature and contents of container

2ml low borosilicate glass ampoule.

1.3.1.6.6 Special precautions for disposal and other handling

Protect from light

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

1.3.2 Labelling (out & inner labels)

Not available yet.

1.3.3 Package Insert (also known as patient information PIL)

Not available yet.

1.4 Regional Summaries

1.4.1 Bioequivalence Trial Information Form (BTIF)

Not applicable

1.4.2 Quality Information Summary (QIS)

Description : A colourless or almost colourless solution for intramuscular or intravenous administration.

Dosage form : Injection

Strength : 50mg/2ml

Category : Antihistamines

Shelf Life : 3 Years

Storage Conditions: Stored below 30°C in cool and dry place. Protect from heat and light. Keep out of reach of children.

Composition: Each 2ml ampoule contains promethazine BP equivalent to 50mg of the anhydrous substance.

In summary, the Finished Product Specifications are considered to comprise sufficient tests and appropriate limits to ensure the batch-to-batch quality of the products.

1.5 Electronic Review Documents

If you need electronic editions, we'll available.

1.6 Samples

Not applicable

SUNZONEM