1 NAME OF THE MEDICINAL PRODUCT

Avomine 25mg Tablets

Numark Travel Sickness Relief 25mg Tablets

Promethazine Teoclate 25mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Promethazine teoclate 25 mg.

3 PHARMACEUTICAL FORM

Tablet.
White to pale cream, plain, circular biconvex tablets of 8.5 mm marked “PT” on one side with a score line on the reverse.
The tablet can be divided into equal halves.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Avomine is a long acting anti-emetic, indicated for:

- prevention and treatment of nausea and vomiting, including motion sickness and post operative vomiting;

- vertigo due to Meniere's syndrome, labyrinitis and other causes.

4.2. Posology and method of administration

Motion sickness

Adults

For the prevention on long journeys: one 25 mg tablet each evening at bedtime, starting the day before setting out. The duration of action is such that a second dose in 24 hours is not often necessary.

For the prevention of motion sickness on short journeys: one 25 mg tablet one or two hours before travelling or as soon after as possible.

Treatment of motion sickness: One 25 mg tablet as soon as possible and repeated the same

evening followed by a third tablet the following evening.

Nausea and vomiting due to other causes

Adults

One 25 mg tablet at night is often sufficient, but two or three tablets are sometimes necessary. Alternatively, more frequent administration such as 25 mg two or three times a day may be required for some patients. It is often not necessary to give more than four of the 25 mg Avomine tablets in 24 hours.

Children

In the above indications children over 10 years of age may be given the lower adult doses described above. Children between 5 and 10 years may be given half the adult dose. Tablets are not suitable for administration to children aged between 2 and 5 years. An oral liquid preparation is recommended in this age group. Not for use in children under 2 years of age (see section 4.3).

Elderly

No specific dosage recommendations.

Administration: Oral.

4.3 Contraindications

Avomine should not be given to patients with a known hypersensitivity to promethazine, other phenothiazines, or to any of the excipients listed in section 6.1. Avomine should not be used in patients in coma or suffering from CNS depression of any cause.

Avomine should not be used in children less than two years of age because of the potential for fatal respiratory depression.

Avomine should not be administered to patients who have been taking monoamine oxidase inhibitors within the previous 14 days.

4.4 Special warnings and precautions for use

Hypersensitivity reactions including anaphylaxis, urticaria and angioedema have been reported with promethazine use. In case of allergic reaction, treatment with Promethazine must be discontinued and appropriate symptomatic treatment initiated (see Section 4.8).

Avomine should be avoided in patients with liver or renal dysfunction, Parkinson's disease, hypothyroidism, cardiac failure, pheochromocytoma, myasthenia gravis, or prostate hypertrophy, or in patients with a history of narrow angle glaucoma or agranulocytosis.

Caution must be exercised when using H1-antihistamines such as avomine due to the risk of sedation. Combined use with other sedative medicinal products is not recommended (see section 4.5).

Avomine may thicken or dry lung secretions and impair expectoration, it should therefore be used with caution in patients with asthma, bronchitis or bronchiectesis.

Use with care in patients with severe coronary artery disease, narrow angle glaucoma, epilepsy or hepatic and renal insufficiency.

Caution should be exercised in patients with bladder neck or pyloro-duodenal obstruction.

Avomine should not be used for longer than seven days without seeking medical advice.

Ototoxicity

Promethazine may mask the warning signs of ototoxicity caused by ototoxic drugs eg. salicylates.

Promethazine may also delay the early diagnosis of intestinal obstruction or raised intracranial pressure through suppression of vomiting.

QT interval

As phenothiazines can prolong the QT interval, caution is advised in treated patients with pronounced bradycardia, cardiovascular disease, with a hereditary form of prolongation of the QT interval and concomitant use with other products leading to QT prolongation.

Photosensitivity reactions

Due to the risk of photosensitivity, exposure to strong sunlight or ultraviolet light should be avoided during or shortly after treatment (see section 4.8).

Paediatric population

The use of promethazine should be avoided in children and adolescents with signs and symptoms suggestive of Reye's syndrome.

Alcohol and alcohol-containing medicines should be avoided while on this medicine (see section 4.5).

Phenothiazines may be additive with, or may potentiate the action of, other CNS depressants such as opiates or other analgesics, barbiturates or other sedatives, general anesthetics, or alcohol.

The occurrence of unexplained infections or fever may be evidence of blood dyscrasia (see section 4.8) and requires immediate hematological investigation.

All patients should be advised that, if they experience fever, sore throat or any other infection, they should inform their physician immediately and undergo a complete blood count. Treatment should be discontinued if any marked changes (hyperleucocytosis, granulocytopenia) are observed in the blood count.

Excipient(s) with known effect

Contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interactions with other medicinal products and other forms of interaction

Avomine will enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative or hypnotic.

Alcohol should be avoided during treatment. Combination with alcohol enhances the sedative effects of H1 antihistamines.

Avomine may interfere with immunologic urine pregnancy tests to produce false - positive and false-negative results.

Avomine should be discontinued at least 72 hours before any skin tests using allergen extracts as it may inhibit the cutaneous histamine response thus producing false-negative results.

Special caution is required when promethazine is used concurrently with other products leading to QT prolongation, including medicinal products such as antipsychotics, i.e., some phenothiazines (chlorpromazine, levomepromazine), benzamides (sulpiride, amisulpride, tiapride), pimozide, haloperidol, droperidol, citalopram, halofantrin, methadone, pentamidine, and moxifloxacine.
Cytochrome P450 2D6 Metabolism: Some phenothiazines are moderate inhibitors of CYP2D6. There is a possible pharmacokinetic interaction between inhibitors of CYP2D6, such as phenothiazines, and CYP2D6 substrates. Co administration of promethazine with amitriptyline/amitriptylinoxide, a CYP2D6 substrate, may lead to an increase in the plasma levels of amitriptyline/amitriptylinoxide. Monitor patients for dose-dependent adverse reactions associated with amitriptyline/amitriptylinoxide.

Avomine should be avoided in patients taking monamine oxidase inhibitors within the previous 14 days, and monamine oxidase inhibitors should be avoided while using Avomine.

Seizure threshold-lowering drugs: Concomitant use of seizure-inducing drugs or seizure threshold-lowering drugs should be carefully considered due to the severity of the risk for the patient (see section 4.4).

Gastro-intestinal agents that are not absorbed (magnesium, aluminium and calcium salts, oxides and hydroxides): Reduced gastro-intestinal absorption of phenothiazines may occur. Such gastro-intestinal agents should not be taken at the same time as phenothiazines (at least 2 hours apart, if possible).

Drugs with anticholinergic properties: Concomitant use of Avomine with drugs with anticholinergic properties enhances the anticholinergic effect.

4.6 Fertility, pregnancy and lactation

Pregnancy

The use of Avomine is not recommended during pregnancy and in women of childbearing potential not using contraception, unless the potential benefits outweigh the potential risks. When promethazine has been given in high doses during late pregnancy, promethazine has caused prolonged neurological disturbances in the infant.

Advise patients to inform their healthcare provider of a known or suspected pregnancy. Advise patients to avoid becoming pregnant while receiving this medicine. Advise female patients of reproductive potential to use effective contraception.

There are no available animal studies regarding reproductive toxicity

Breast-feeding

Available evidence suggests that the amount excreted in milk is insignificant. However, there are risks of neonate irritability and excitement. Avomine is not recommended for use in breast-feeding.

Fertility

There are no relevant fertility data in animals.

4.7. Effects on ability to drive and use machines

Ambulant patients receiving Avomine for the first time should not be in control of vehicles or machinery for the first few days until it is established that they are not hypersensitive to the central nervous effects of the drug and do not suffer from disorientation, confusion or dizziness.

Because the duration of action may be up to 12 hours, patients should be advised that if they feel drowsy, dizzy and have blurred vision, they should not drive or operate heavy machinery.

4.8 Undesirable effects

The following CIOMS frequency rating is used: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10 00 to <1/1000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Immune system disorders
Frequency not known: Allergic reactions, including anaphylactic reaction, urticaria, angioedema.

Skin and subcutaneous tissue disorders
Frequency not known: Rash, photosensitivity reaction.

Nervous system disorders
Very common: Sedation or somnolence
Frequency not known: Dizziness, headaches, extrapyramidal effects including restless legs syndrome, muscle spasms and tic-like movements of the head and face, neuroleptic malignant syndrome, psychomotor hyperactivity.

Frequency not known: Dystonia, including oculogyric crisis, usually transitory are commoner in children and young adults, and usually occur within the first 4 days of treatment or after dosage increases.
Frequency not known: Anticholinergic effects such as ileus paralytic, risk of urinary retention, dry mouth, constipation, accommodation disorder.

The elderly are particularly susceptible to the anticholinergic effects and confusion due to promethazine.

Frequency not known: children less than 6 years of age also experienced psychomotor Hyperactivity.

Psychiatric disorders
Frequency not known: Agitation, confusional state, anxiety, hallucinations, aggression.
Frequency not known: Infants, newborns and premature are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability, restlessness, nightmares, disorientation
Frequency not known: children less than 6 years of age also experienced aggression and hallucination.

Eye disorders
Frequency not known: Blurred vision

Gastrointestinal disorders
Frequency not known: Epigastric irritation/discomfort, dry mouth

Renal and urinary disorders
Frequency not known: Urinary retention

Metabolism and nutrition disorders
Frequency not known: Decreased appetite

Cardiac disorders
Frequency not known: Palpitations, arrhythmias, QT prolongation, Torsade de pointes

Vascular disorders

Frequency not known: Hypotension

Respiratory, thoracic and mediastinal disorders
Frequency not known: Respiratory depression (see Section 4.4), nasal congestion

Hepatobiliary disorders
Frequency not known: Jaundice cholestatic

Blood and lymphatic system disorders
Frequency not known: Blood dyscrasias including haemolytic anaemia, agranulocytosis, leukopenia, eosinophilia, thrombocytopenia (including thrombocytopenic purpura).

General disorders and administration site conditions
Frequency not known: Tiredness

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

Common features may include nausea, vomiting, flushing, dilated pupils, dry mouth and tongue, hot dry skin, fever, drowsiness and delirium. Symptoms of severe overdosage are variable. They are characterised in children by various combinations of excitement, ataxia, incoordination, athetosis and hallucinations, while adults may become drowsy and lapse into coma. Convulsions may occur in both adults and children; coma or excitement may precede their occurrence. Cardiac conduction abnormalities and dysrhythmias may occur; cardiorespiratory depression is uncommon. Tachycardia may develop. Patients who have been unconscious may be hypothermic.

Prolonged QT interval and cases of severe arrhythmias with fatal outcome have been described in overdose of phenothiazines.

Management

Consider use of activated charcoal only if the patient presents within one hour of ingestion. If the patient is seen soon enough after ingestion, it should be possible to induce vomiting with ipecacuanha despite the antiemetic effect of promethazine; alternatively, gastric lavage may be used. Treatment is otherwise supportive with attention to maintenance of adequate respiratory and circulatory status. Convulsions should be treated with intravenous diazepam and delirium treated with oral diazepam or other suitable anticonvulsant. Arrhythmias may be treated by

correction of hypoxia, acidosis and other biochemical abnormalities. The use of antiarrhythmic drugs to treat dysrhythmias should be avoided. Procyclidine injection may be effective in the treatment of dystonic reactions.

In the event of overdose of promethazine, take all appropriate measures immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use; Phenothiazine derivatives, ATC Code: R06AD02
Promethazine teoclate is a potent, long acting antihistamine with anti-emetic, central sedative and anticholinergic properties.

Promethazine is metabolised in the liver (the major metabolite being the sulphoxide) and slowly excreted in the urine. The drug is highly bound to plasma proteins.

5.2. Pharmacokinetic properties

Promethazine is well absorbed after oral administration, peak plasma concentrations occurring in 2-3 hours. It is widely distributed in the body. It enters the brain and crosses the placenta. Phenothiazines pass into the milk at low concentrations.

5.3. Pre-clinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Sodium metabisulphite (E223)
Potato starch
Dextrin
Microcrystalline cellulose
Stearic acid
Magnesium stearate

6.2. Incompatibilities

None.

6.3. Shelf-life

Five (5) years.

6.4. Special precautions for storage

Store in the original container.

6.5 Nature and contents of container

Blister pack of 10 x 25 mg tablets.

Blister pack of 28 x 25 mg tablets.

Blister pack of 30 x 25 mg tablets.

Securitainer of 60 x 25 mg tablets.

Securitainer or bottle of 250 x 25 mg tablets.

The blister comprises PVDC coated aluminium foil, 20 micron thick and PVDC coated UPVC.

The bottle and securitainer are comprised of high density polyethylene or polypropylene with low density polyethylene caps.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Manx Pharma Limited
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Warwick
CV34 6UQ
UK

8. MARKETING AUTHORISATION NUMBER

PL: 15833/0003.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

September 1997.

10 DATE OF REVISION OF THE TEXT

11/06/2025