1. NAME OF THE MEDICINAL PRODUCT

Avomine 25mg Tablets
Lloydspharmacy Travel Sickness and Nausea 25mg Tablets
Careway Travel Sickness and Nausea 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 “AVOMINE” 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 used in patients with:

- Hypersensitivity to promethazine or any of the excipients
- Hypersensitivity to other phenothiazines
- Coma or 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

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.

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.

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

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

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 may enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative or hypnotic. Alcohol should be avoided during treatment.

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.

4.6. Pregnancy and lactation

Use in pregnancy: It should not be used in pregnancy unless the physician considers it essential. The use of Avomine tablets is not recommended in the two weeks prior to delivery in view of the risk of irritability and excitement in the neonate.

Use in lactation: Available evidence suggests that the amount excreted in milk is insignificant. However, there are risks of neonate irritability and excitement.

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.

4.8. Undesirable effects

Side-effects may be seen in a few patients: drowsiness, dizziness, restlessness, headaches, nightmares, tiredness and disorientation. Anticholinergic side-effects such as blurred vision, dry mouth and urinary retention occur occasionally. Newborn and premature infants are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability. The elderly are particularly susceptible to the anticholinergic effects and confusion may occur.

Other side-effects include anorexia, gastric irritation, palpitations, hypotension, arrhythmias, extrapyramidal effects, muscle spasms and tic-like movements of the head and face. Anaphylaxis, jaundice and blood dyscrasias including haemolytic anaemia rarely occur. Photosensitive skin reactions have been reported; strong sunlight should be avoided during treatment.

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

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, inco-ordination, 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. Patients who have been unconscious may be hypothermic.

Treatment
Consider use of activated charcoal only if the patient presents within one hour of ingestion. 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: R06AD02
Promethazine teoclate is a 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 polyethylene 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 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
Taylor Group House
Wedgnock Lane
Warwick
CV34 5YA
United Kingdom

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

22/02/2018