

**DATA SHEET**  
**AVOMINE**  
**25 mg tablets**

**COMPOSITION**

Promethazine theoclate (25 mg)

**ACTIONS**

Antihistamine, antinauseant

**INDICATIONS**

Prevention and treatment of motion sickness.

**CONTRAINDICATIONS**

Avomine should not be used in patients who are in a coma or suffering from CNS depression of any cause. It must not be given to patients hypersensitive to phenothiazines. Avomine should be avoided in patients who have been taking monoamine oxidase inhibitors within the previous 14 days.

Use in children: Avomine should not be used in children less than ten years of age.

**PRECAUTIONS**

Care is necessary with patients who take alcohol, anticholinergic agents, tricyclic antidepressants, sedatives or hypnotics, as such agents are enhanced by Avomine. It may cause mild and temporary confusion or disorientation in certain individuals. It should, therefore, be used with caution in persons in charge of vehicles until their reaction to the drug is known.

Avomine may thicken or dry lung secretions and impair expectoration, it should therefore be used with caution in patients with asthma, bronchitis or bronchiectasis. 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; e.g. salicylates.

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

Avomine may interfere with immunologic urine pregnancy tests to produce false-positive or false-negative results. Avomine should be discontinued at least 72 hours before the start of skin tests using allergen extracts as it may inhibit the cutaneous histamine response thus producing false-negative results.

In nausea and vomiting of unknown origin, it is essential to establish the diagnosis before giving an antiemetic, to ensure that a serious underlying condition is not masked.

**Use in Pregnancy (Category C)**

When given in high doses during late pregnancy, phenothiazines have caused prolonged extrapyramidal disturbances in the child. There is inadequate evidence of safety of the drug in human pregnancy, but it has been in wide use for many years without apparent ill consequence; animal studies having shown no hazard.

**Warnings and Precautions – Children**

Post-marketing cases of respiratory depression, including fatalities, have been reported with use of promethazine in paediatric patients less than two years of age. Excessive dosages of antihistamines in children may cause hallucinations, convulsions and sudden death. The use

of Avomine should be avoided in children and adolescents with signs and symptoms suggestive of Reye's Syndrome.

## **ADVERSE REACTIONS**

### **More common reactions**

Gastrointestinal. Dry mouth, epigastric distress, loss of appetite, nausea, vomiting, diarrhoea, constipation.

Nervous system. Sedation, restlessness, dizziness, lassitude, incoordination, fatigue.

Ocular. Blurred vision.

### **Less common reactions**

Cardiovascular. Tachycardia, bradycardia, faintness, palpitations, hypotension, arrhythmias.

Dermatological. Contact dermatitis (topical), photosensitisation, urticaria, angioneurotic oedema.

Haematological. Leucopenia, agranulocytosis, aplastic anaemia, thrombocytopenic purpura.

Hepatic. Jaundice.

Musculoskeletal. Extrapyrmidal symptoms.

Nervous system. Tinnitus, euphoria, nervousness, insomnia, convulsive seizures, oculogyric crises, excitation, catatonic-like states, hysteria, extrapyramidal symptoms, tardive dyskinesia.

Respiratory. Marked irregular respiration.

Other. Anaphylaxis, headaches, nightmares, urinary retention.

### **Serious or life-threatening reactions**

Agranulocytosis. Care is needed in the intramuscular administration of promethazine to children. A severe neurological reaction resulting in coma is possible.

### **Overdosage - Symptoms**

The chief symptom of acute poisoning from the ingestion of promethazine is unconsciousness which is, however, commonly delayed. In addition, convulsions have occurred, with unconsciousness in the intervening periods.

### **Overdosage - Treatment**

An immediate first aid measure is to induce vomiting mechanically or to give an emetic, the value of which, however, is limited by the antiemetic activity of Avomine once absorbed. The most important step in treatment must be, therefore, to remove as much as possible of the unabsorbed material by means of gastric lavage with warm sodium bicarbonate solution. Some sodium bicarbonate solution should be left in the stomach to precipitate insoluble promethazine base, thus delaying its absorption. Should convulsions occur, special care must be taken of the use of sedatives which may increase the depression of respiration. Intravenous amphetamine or intramuscular ephedrine should be given for CNS stimulation, if indicated. Oxygen under pressure should be given if respiration is depressed. The administration of an antibiotic as a prophylactic against pneumonia should be considered.

## **DOSAGE AND ADMINISTRATION**

### **Adults - Travel sickness**

#### **Prevention**

Long journeys: 1 tablet each night at bedtime commencing on the night before travelling.

Short journeys: 1 tablet to be taken 1 to 2 hours before the journey commences.

#### **Treatment**

1 tablet followed by a second tablet the same evening and a third tablet on the following evening. Prompt treatment is important. Additional tablets may safely be taken as a preventive or when they appear to be needed but it will seldom be necessary to give more than 4 tablets in 24 hours or to repeat a dose in less than 8 hours.

**PRESENTATION**

Tablets, 25 mg (white, scored):10's

**STORAGE**

Store below 30°C. Protect from light.

**MEDICINE CLASSIFICATION**

Pharmacy only medicine

**NAME AND ADDRESS****Distributed by:**

sanofi-aventis new zealand pty ltd  
Level 8, James & Wells Tower  
56 Cawley Street  
Ellerslie  
Auckland  
New Zealand  
Ph: (09) 580 1810

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