NEW ZEALAND DATA SHEET

1 AVOMINE 25 MG TABLETS

Avomine Tablets 25 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Promethazine theoclate

Avomine tablets contain 25 mg of promethazine theoclate.

Excipients with known effect: lactose monohydrate and wheat starch.

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Tablets, 25 mg (white, scored).

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Prevention and treatment of motion sickness.

4.2 DOSE AND METHOD OF 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.

4.3 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 promethazine, phenothiazines or to any of the excipients listed in section 6.1. 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.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Avomine may cause mild and temporary confusion or disorientation in certain individuals.

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 or epilepsy. 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.

There have been case reports of drug abuse with promethazine. The risk of abuse is greater in patients with a history of drug abuse,

As with neuroleptics, Neuroleptic Malignant Syndrome (NMS) characterised by hyperthermia, extrapyramidal disorders, muscle rigidity, altered mental status, autonomic nervous instability and elevated CPK, may occur. As this syndrome is potentially fatal, promethazine must be discontinued immediately and intensive clinical monitoring and symptomatic treatment should be initiated.

Due to the risk of photosensitivity, exposure to the sun or ultraviolet light should be avoided during or shortly after treatment.

Use in hepatic impairment

Use with care in patients with hepatic insufficiency.

Use in renal impairment

Use with care in patients with renal insufficiency.

Use in the Elderly

See Section 4.8 Adverse Effects (Undesirable effects).

Paediatric Use

This product must not be used in children under 2 years of age, due to the potential for fatal respiratory depression (see Section 4.3.). 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.

Effects on laboratory tests

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

4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

Care is necessary with patients who take anticholinergic agents, tricyclic antidepressants, sedatives or hypnotics, as such agents are enhanced by Avomine.

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

4.6 FERTILITY, PREGNANCY AND LACTATION

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.

Promethazine should be used in pregnancy only if the potential benefits to the patient are weighed against the possible risk to the foetus.

Breast-feeding

Avomine is excreted in breastmilk. There are risks of neonatal irritability and excitement. Avomine is not recommended for use in breastfeeding.

Fertility

No data available.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Avomine considerably affects the ability to drive a vehicle and operate machines.

4.8 UNDESIRABLE EFFECTS

More common reactions

Gastrointestinal disorders: Dry mouth, epigastric distress, loss of appetite, nausea, vomiting, diarrhoea, constipation.
Nervous system disorders: Sedation, restlessness, dizziness, lassitude, incoordination, fatigue.
Eye disorders: Blurred vision.

Less common reactions

Cardiovascular: Tachycardia, bradycardia, faintness.
Skin and subcutaneous tissue disorders: Contact dermatitis (topical), urticaria, angioneurotic oedema.
Haematological: Leucopenia, agranulocytosis, aplastic anaemia, thrombocytopenic purpura.
Nervous system disorders: Tinnitus, euphoria, nervousness, insomnia, convulsive seizures, oculogyric crises, excitation, catatonic-like states, hysteria, tardive dyskinesia.
Respiratory: Marked irregular respiration.
Other: nightmares.

Reactions with frequency unknown

Skin and subcutaneous tissue disorders: Photosensitivity reaction
Hepatobiliary disorders: Jaundice
Renal and Urinary Disorders: Urinary retention
Nervous system disorders: Neuroleptic Malignant Syndrome, somnolence, headaches, tic-like movements of the head and face, extrapyramidal symptoms including

muscle spasm, the elderly are particularly susceptible to the anticholinergic effects and confusion due to promethazine

Immune system disorders: Allergic reactions, including urticaria, rash, pruritus, and anaphylactic reaction have been reported

Metabolism and Nutrition Disorders: Anorexia

Blood and lymphatic system disorders: Blood dyscrasias including haemolytic anaemia, agranulocytosis

Psychiatric disorders: Infants, newborns and premature are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability, restlessness, nightmares, disorientation

Cardiac disorders: Palpitations, arrhythmias

Vascular disorders: Hypotension.

General disorders and administration site conditions: Tiredness

Severe 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions at https://nzphvc.otago.ac.nz/reporting/ .

4.9 OVERDOSE

Overdose - Symptoms

Symptoms of severe overdosage are variable. The chief symptom of acute poisoning from the ingestion of promethazine is unconsciousness which is, however, commonly delayed. Symptoms are characterised in children by various combinations of excitation, 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. Tachycardia may develop. Cardiorespiratory depression is uncommon.

Overdose - 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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Antihistamines for systemic use; ATC code: R06AD02

Mechanism of Action

Antihistamine, antinauseant.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICAL SAFETY DATA

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Dextrin

Lactose monohydrate

Magnesium stearate

Purified talc

Starch.

6.2 INCOMPATIBILITIES

Not applicable.

6.3 SHELF LIFE

36 months from date of manufacture

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C. Protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

Blister packs containing 10 tablets.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements for disposal.

7 MEDICINE SCHEDULE

Pharmacy Only Medicine

8 SPONSOR

sanofi-aventis new zealand limited
Level 8, James and Wells Tower
56 Cawley Street
Ellerslie
Auckland

Telephone: (09) 580 1810

9 DATE OF FIRST APPROVAL

31 December 1969

10 DATE OF REVISION OF THE TEXT

05 October 2018

Summary table of changes

Section changed	Summary of new information
All	Text moved and added, and headings updated to align with the revised DS format
4.4	Editorial changes; add photosensitivity precaution; strengthen paediatric warning
4.5	Strengthen alcohol warning
4.6	Strengthen pregnancy warning; add lactation warning
4.7	Strengthen warning
4.8	Change frequency and add new adverse effects; modify terminology
4.9	Add overdose symptoms; editorial changes