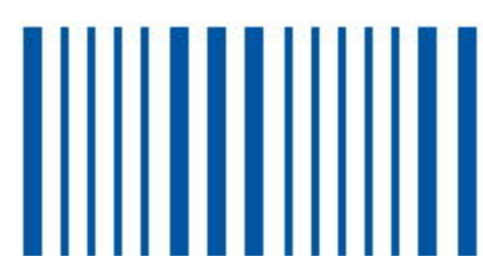


# Avomine®

Promethazine Theoclate BP



50050

SANOFI 

## Presentation

Avomine tablet: white, circular tablets, each containing Promethazine Theoclate BP 25 mg, indented 'AVOMINE' on one face and with a break line on the reverse.

## Uses

Long-acting anti-emetic, indicated for prevention and treatment of nausea and vomiting arising from various causes including motion sickness and postoperative vomiting. Vertigo due to Meniere's syndrome labyrinthitis and other causes. Promethazine Theoclate has central sedative, antihistamine and anticholinergic properties.

## Dosage and administration

*Motion sickness : Adults : For 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 prevention of motion sickness on short journeys:* One 25 mg tablet one or two hours before traveling or as soon after as possible.

*Treatment of motion sickness:* One 25mg tablet as soon as possible and repeated the same evening followed by a third tablet on the following evening.

*Nausea and vomiting due to other causes: Adults:* One 25mg tablet at night is often sufficient, but two or three tablets are sometimes necessary. Alternatively, more frequent administration such as 25mg two or three times a day may be required for some patients. It is not often necessary to give more than four of the 25mg 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 adults dose.

*Elderly:* No specific dosage recommendations.

## Kinetics

Promethazine is well absorbed after oral administration, peak plasma concentrations occurring in 2-3 hours. It is distributed widely in the body, metabolised in the liver and slowly excreted in the urine. The drug is highly plasma protein bound. It enters the brain and crosses the placenta, phenothiazines pass into the milk in low concentrations.

## Contra-Indications, Warnings, etc.

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 neonates, premature infants or patients hypersensitive to promethazines. Avomine should be avoided in patients who have been taking monoamine oxidase inhibitors within the previous 14 days.

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. This product should not be used in children under 2 years of age because safety of such use has not been established.

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

## Use in pregnancy

There is epidemiological evidence for the safety of promethazine in pregnancy and animal studies have shown on hazard, nevertheless 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 neonatal irritability and excitement.

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.

## Interactions

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 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 anti-emetic, to ensure that serious underlying condition is not masked.

## Side-effects

Side-effects may be seen in a few patients: drowsiness, dizziness, restlessness, headaches, night mares, tiredness and disorientation, Anticholinergic side-effects such as blurred vision, dry mouth and urinary retention occur occasionally. The elderly are particularly susceptible to the anticholinergic effects and confusion due to promethazine. 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.

## Treatments of overdose

Symptoms of severe overdose are variable. They are characterised in children by various combinations of excitation, ataxia, inco-ordination, athetosis and hallucinations, while adults may become drowsy and lapse into coma. Convulsion may occur in both adults and children; coma or excitement may precede their occurrence. Cardiorespiratory depression is uncommon. If the patient is seen soon enough after ingestion, it should be possible to induce vomiting with ipecacuanha despite the anti-emetic 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 diazepam or other suitable anticonvulsant.

## Pharmaceutical precautions

Protect from light.

## Package quantities

Avomine tablet : Box of 50 x 10 x 25 mg in blister pack

Do not use later than the date of expiry

Keep all medicines out of the reach of children

To be dispensed only on the prescription of a registered physician.

Manufactured by :

**Sanofi Bangladesh Limited**

Tongi, Gazipur, Bangladesh.