

**Avil**<sup>®</sup>

Pheniramine Maleate BP

SANOFI **PRESENTATION**

Preparation	Unit	Pheniramine Maleate
Avil Tablets	1 Tablet	22.7 mg
Avil Syrup	1 Measuring Spoonful (5ml)	15 mg
Avil Injection Solution	1 Ampoule (2ml)	45.5 mg
Avil Retard Dragees	1 Coated Tablet	75 mg

**INDICATIONS**

Avil is indicated for-

- Allergic conditions including hay fever, drug rashes, angioneurotic oedema, serum sickness, allergic conjunctivitis, food allergy etc.
- Conditions of the respiratory tract that are accompanied by increased secretion, including vasomotor rhinitis and acute rhinitis.
- All itching skin conditions, including neurodermatitis, eczema of any origin, lichen planus, acute and chronic urticaria, pruritis of the anus or genitals, pruritis in icterus and diabetes, radiation sickness etc.
- Prevention and treatment of motion sickness.
- Prevention and treatment of nausea, vomiting and vertigo due to Menière's disease and other labyrinthine disturbances.

**DOSAGE & ADMINISTRATION**

Doses must be individually determined in all cases and should be taken with or soon after food. Treatment should be commenced at the lowest possible dose because experience has shown that antihistamines are often effective at low doses. The maximum dose of 3mg/kg per day should not be exceeded. Elderly patients should use the adult dose with caution.

To prevent travel sickness, it is recommended that the first dose be taken at least 30 minutes before travelling. Due to the risk of drowsiness, the patient should not drive a motor vehicle or operate machinery after taking a dose.

**Avil tablets:** In adults and children over 10 years of age, treatment is commenced with half a tablet taken up to three times daily. This dose may be increased to one tablet taken up to three times daily if required. Children 5-10 years of age: half a tablet up to three times daily. Avil tablets are not recommended in children under 5 years of age.

**CONTRAINDICATIONS**

- Patients with hypersensitivity to pheniramine or any other ingredient (eg. Methyl hydroxybenzoate or propyl hydroxybenzoate in the syrup).
- Patients with symptomatic prostatic hypertrophy.
- Patients receiving MAO-inhibitor therapy.
- Newborn and premature infants.

**PRECAUTIONS**

Avil may cause drowsiness. Both the dosage and the time of administration should be carefully considered in patients whose activities (e.g. driving a car or operating machinery) demand special concentration.

Patients should be cautioned against the simultaneous ingestion of alcohol and other central nervous system depressants. Avil may possibly be hallucinogenic in toxic doses. **Due to the possible CNS stimulating effects of antihistamines, pheniramine has the potential for abuse.**

Due to the anticholinergic effect of pheniramine, caution and close monitoring are required if it is used in patients with conditions such as prostatic hypertrophy, narrow angle glaucoma, asthma or **severe cardiovascular disease.**

The anti-emetic effect of pheniramine may mask the signs of other conditions.

Products containing pheniramine should not be taken on an empty stomach.

**Use in pregnancy:** Category A. Use only if strictly indicated.

**Use in lactation:** Use only if strictly indicated.

**INTERACTIONS**

- MAO-inhibitors may prolong and intensify the anticholinergic effect of pheniramine (see Contraindications).
- Adverse CNS effects of pheniramine may be enhanced when it is taken with alcohol or other CNS depressants (eg. hypnotics, sedatives, tranquilizers).
- Atropine and related drugs may enhance the anticholinergic activity of pheniramine.

**ADVERSE REACTIONS**

The most common adverse reaction is sedation, which often disappears after a few days if tolerance is acquired. Hypersensitivity reactions have been reported.

**Central Nervous System:** Lassitude, dizziness, tinnitus, inability to concentrate, incoordination, irritability, insomnia and tremors. Agitation and convulsions, especially in children and restlessness, disorientation and hallucinations in adults, are common symptoms following overdose.

**Gastrointestinal:** Nausea, vomiting, diarrhoea, colic, epigastric pain, anorexia, dryness of mouth and constipation.

Genitourinary: Urinary retention.

**Cardiovascular:** Palpitations, headache.

Ocular: Blurred vision, increased intraocular pressure.

**Musculoskeletal:** Muscular weakness.

**Haematological:** Rare cases of blood dyscrasias including agranulocytosis and haemolytic anaemia have been reported.

**OVERDOSAGE**

**Symptoms:** Antihistamine drugs in toxic doses produce a complex of CNS excitatory and depressant effects. Accidental ingestion in small children has resulted in convulsions and sometimes death.

**Management:** As there is no specific antidote, treatment should be symptomatic and supportive. Induction of vomiting should only be used immediately after ingestion as the sedative action of any absorbed antihistamine can lead to life-threatening pulmonary aspiration during emesis. Gastric lavage with a cuffed endotracheal tube in situ may be useful for some time after ingestion of antihistamines as their anticholinergic action slows down gastric emptying.

Stimulants should not be used as they may precipitate convulsions. Diazepam or short-acting barbiturates may be used to control convulsions. Vasopressors may be used to treat hypotension. Mechanical support of respiration may be required if respiration is seriously depressed. Continuous ECG monitoring is recommended if cardiac toxicity develops, which can be treated with centrally-acting

anticholinesterases such as physostigmine.

**PHARMACEUTICAL PRECAUTIONS**

- Store in a cool and dry place, protected from light
- 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

**PACKAGE QUANTITY**

Avil Tablet: Box of 20 X 15 X 22.7mg in strip packs.

Avil Syrup: Bottle of 75ml.

Avil Injection: Box of 25 X 2ml ampoules.

Avil Retard Dragees: Box of 10 X 10 X 75mg in strip packs.

Manufactured by:

**Sanofi Bangladesh Limited**  
Station Road, Tongi, Gazipur.

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