For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

This package insert is continually updated: Please read carefully before using a new pack.

Pheniramine Maleate Tablets I.P.

Avil® 25
Avil®50

Pheniramine Maleate Injection I.P.

Avil® Injection

COMPOSITION

Avil® 25 – Each uncoated tablet contains:
Pheniramine Maleate I.P. ……. 25mg
Excipients ……..q.s.

Avil® 50 – Each uncoated tablet contains:
Pheniramine Maleate I.P. ……. 50mg
Excipients …….q.s.

Avil® Injection (in 2ml ampoule) – Each ml contains:
Pheniramine Maleate I.P. …… 22.75mg
Water for Injections I.P. …… q.s

Avil® Injection (in 10ml vial) – Each ml contains:
Pheniramine Maleate I.P. …… 22.75mg
Methyl-Parahydroxybenzoate I.P. (as preservative) ……0.135%w/v
Propyl-Parahydroxybenzoate I.P. (as preservative) ……0.015%w/v
Water for Injections I.P. …… q.s

INDICATIONS

- 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, pruritus 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 AND ADMINISTRATION

Tablets:

Adults & Children (above 10 years): Initially 1 tablet of Avil 25 two to three times a day. The dose may be increased to two tablets of Avil 25 or one tablet of Avil 50, administered two to three times a day if needed.

Children 5-10 years of age: 1 tablet of Avil 25 up to two times a day. Avil® tablets are not recommended in children under 5 years of age.

Avil® should be swallowed with plenty of water. Do not chew them.

Avil® should be taken with or soon after food. Do not take the medicine on an empty stomach.

If taken to prevent travel sickness, the dose should be taken at least 30 minutes before travelling.

Injection: 1-2ml twice a day intramuscular or slow intravenous injection

Avil® injection is administered to adults and young people aged 12 years or over either slowly by intravenous route (1ml per minute) or intramuscularly. To infants and children upto 12 years old the injection must be given intramuscularly. The recommended dose may be repeated at 12 hourly intervals until acute symptoms have subsided.

Pheniramine is metabolized in the liver and dose adjustments should be considered in patients with severe hepatic disease.

CONTRAINDICATIONS

- Patients with hypersensitivity to pheniramine or any other ingredient in the formulation
- Patients with symptomatic prostatic hypertrophy.
- Patients receiving MAO-inhibitor therapy.
- Newborn and premature infants.

WARNINGS/PRECAUTIONS

Avil® may cause drowsiness. Both the dosage and the time of administration should be carefully considered in patients whose activities (eg. driving a car or operating machinery) demand special concentration. Patients who cannot tolerate the sedative effects should consult their Physicians for swapping to a non-sedating antihistamine such as Allegra® (fexofenadine).

Patients should be cautioned against the simultaneous ingestion of alcohol and other central nervous system depressants. Pheniramine 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.

PREGNANCY AND LACTATION

PREGNANCY

There are no available data on Avil® use in pregnant women. No conclusions can be drawn regarding whether or not Avil® is safe for use during pregnancy. Avil® should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the fetus.

LACTATION

There are no available data on the presence of Avil® in human milk, milk production, or the effects on the breastfed infant. No conclusions can be drawn regarding whether or not Avil® is safe for use during breastfeeding. Avil® should be used during breastfeeding only if the potential benefits to the mother outweigh the potential risks, including those to the breastfed child.

DRUG 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 EFFECTS

Preparations containing pheniramine are generally well tolerated. The most common adverse reaction is sedation, which often disappears after a few days if tolerance is acquired.

Central Nervous System Disorder: 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 Disorder: Nausea, vomiting, diarrhoea, colic, epigastric pain, anorexia, dryness of mouth and constipation.

Genitourinary: Urinary retention.

Cardiovascular Disorder: 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.

Immune system disorder:
Hypersensitivity reactions.

DRIVING AND/OR OPERATING HEAVY MACHINARY OR PERFORMING OTHER HAZARDOUS TASKS

Drowsiness is a major problem with the sedating antihistamines and those affected should not drive or operate machinery.

OVERDOSE AND MANAGEMENT:

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:

In the event of overdose of Avil®, take all appropriate measure immediately.

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.

Manufactured by:

Regd Office: Sanofi India Limited, Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai - 400072

Tablets: Sanofi India Limited, Plot No. 3501, 3503-15, 6310 B-14, G.I.D.C. Estate, Ankleshwar – 393 002.

Injection: Sanofi India Limited, at Unit III, Rampurghat road, Paonta sahib, District Sirmour, H.P. – 173025

Sanofi India Limited, at Plot No. 1175, AT & POST: Dabhasa, Tal – Padra, Dist – Vodadara, Gujarat – 391 440.

Created: March 2017

Updated: Feb. 2019

Sources:

1. Product Information – Avil, sanofi-aventis Australia pty ltd, Australia, Updated – 11 July 2012 (http://www.medicines.org.au/files/swpavilt.pdf) accessed on 03 Mar 2017

2. Avil leaflet (http://www.news-medical.net/drugs/Avil.aspx) accessed on 03 Mar 2017

3. CCDS –Pheniramine Maleate V.1 10 –Jan-2019

Date: Feb.2019