

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

**AVIL®  
Pheniramine Maleate Tablets & Injection**

**THERAPEUTIC CATEGORY**

Antihistaminic

**COMPOSITION**

**AVIL® 25**

Each uncoated tablet contains: Pheniramine Maleate IP...25mg

**AVIL® 50**

Each uncoated tablet contains: Pheniramine Maleate IP...50mg

**AVIL® Injection (in 2ml ampoule)**

Each ml contains: Pheniramine Maleate IP ...22.75mg

**AVIL® Injection (in 10ml vial)**

Each ml contains:

Pheniramine Maleate IP ..... 22.75mg

Methyl-Parahydroxybenzoate IP .....0.135%w/v

Propyl-Parahydroxybenzoate IP .....0.015%w/v

Water for Injection ..... q.s

**THERAPEUTIC INDICATIONS**

Allergic conditions (Hay fever, drug rashes, angioneurotic oedema, serum sickness, allergic conjunctivitis, food allergy etc.), Conditions of the respiratory tract that are accompanied by increased secretion, All itching skin conditions, Prevention and treatment of motion sickness, nausea, vomiting and vertigo due to Menière's disease and other labyrinthine disturbances.

**DOSAGE AND ADMINISTRATION**

The dosage should be adjusted individually.

When immediate or rapid response is desired, intravenous or intramuscular Avil injection should be used.

**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. The maximum dose of 3mg/kg/day should not be exceeded.

**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.

Do not take the medicine on an empty stomach. For travel sickness, the dose should be taken atleast 30 mins before travelling.

**Injection:** 1-2ml twice a day by intramuscular or slow intravenous injection (from the ampoules). Multidose vial is not recommended for intravenous use.

**SAFETY-RELATED INFORMATION**

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

**Precautions & Warnings:** Pheniramine may cause drowsiness. Use with caution in patients whose activities demand special concentration like driving a car or operating machinery. Caution against simultaneous ingestion of alcohol and other CNS depressants. Pheniramine may be hallucinogenic in toxic doses. Due to possible CNS stimulating effects of anti-histamines, pheniramine has potential for abuse. Use with caution and monitoring in patients with prostatic hypertrophy, narrow angle glaucoma, asthma or severe cardiovascular disease. Anti-emetic effect of pheniramine may mask signs of other conditions. Not to be taken on empty stomach.

**Pregnancy & Lactation:** Use only if strictly indicated.

**Adverse Reactions:** Most common adverse reaction is sedation. Hypersensitivity has been reported.

For full prescribing information, please contact: Sanofi India Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Created: March 2017

Updated: Feb 2021

Sources: 1. Product Information – Avil, sanofi-aventis Australia Pty Ltd, Australia, Updated – 13<sup>th</sup> Feb 2020

(<http://www.medicines.org.au/files/swpavilt.pdf>) accessed on 03rd Feb 2021

2. Avil leaflet (<http://www.news-medical.net/drugs/Avil.aspx>) accessed on 03rd Feb 2021

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