PACKAGE INSERT

DIMENHYDRINATE TABLET 50MG/ SYRUP 15MG/5ML

	Tablet	Syrup
Dimenhydrinate	50mg/ tab	15mg/5ml

Product Description:
Tablet: Round, yellow, convex, plain tablet with single score on one side only.
Syrup: A clear, yellow syrup with lemon flavour.

Pharmacodynamics:
Dimenhydrinate is diphenhydramine theoclate and has the general properties of diphenhydramine hydrochloride. It is basically an antihistamine with anticholinergic and sedative side effects. It appears to compete with histamine for cell receptor sites on effector cells.

Pharmacokinetics:
It is readily absorbed from the gastrointestinal tract. Following oral administration, the effects start within 15 to 30 minutes. It rapidly leaves the circulation and reaches a peak concentration in tissues in about 1 hour. The duration of action of a single dose is approximately 3 to 6 hours. The tissues are almost free of the drug in about 6 hours.
The highest concentration occurs in the lung, with progressively lower concentrations in the spleen, kidney, brain, muscle and skin. Little, if any, of the drug is excreted unchanged in the urine, most appears as degradation products that are almost completely excreted within 24 hours. The main site of metabolic transformation is the liver, but the lung and kidney can also metabolise the compound.

Indication:
Dimenhydrinate is indicated for the prevention and treatment of nausea, vomiting or vertigo and motion sickness.

Recommended Dosage:
Adult : 50mg to 100mg every 6 to 8 hours.
Children (6 to 12 years) : 25mg to 50mg every 6 to 8 hours not exceeding 150mg in 24 hours.
Children (2 to 6 years) : Up to 25mg every 6 to 8 hours not exceeding 75mg in 24 hours.
To prevent motion sickness, the first dose should be taken half to 1 hour before starting of activity.

Route of Administration: Oral

Contraindications:
This drug should not be used in newborn or premature infant and nursing mother.
It is contraindicated in patients who are found hypersensitive to it and not to be used as local anaesthetic because of the risk of local necrosis.

Warnings and Precautions:
This medicine should be used with caution when dimenhydrinate is given in conjunction with certain antibiotics which may cause ototoxicity. Dimenhydrinate may impair mental alertness required for the performance of potentially hazardous activities such as driving a vehicle or operating machinery.
Patient should also avoid alcoholic beverages while taking medication containing dimenhydrinate.
It should not be used in the presence of asthma, glaucoma, or enlargement of the prostate gland, except on advice of a physician.

Interactions with Other Medicaments:
Dimenhydrinate may enhance the sedative effects of CNS depressants. MAO inhibitors may enhance the antimuscarinic effects of dimenhydrinate. Dimenhydrinate have an additive antimuscarinic action with other antimuscarinic drugs, such as atropine and tricyclic antidepressants.

Pregnancy and Lactation:
Although clinical studies in pregnant women have not indicated that dimenhydrinate increases the risk of fetal abnormalities, like any drug, it should be used during pregnancy only if benefits outweigh the risks. As small amounts of dimenhydrinate are excreted in breast milk, benefits of therapy must be weighed against potential adverse reactions in nursing infants.

Side Effects:
Drowsiness is the most common side effect, especially on high dosage. The others are disturbed coordination, fatigue, restlessness, confusion, nervousness, blurred vision, tinnitus, tremor, irritability, epigastric distress, photosensitivity, dryness of mouth, nose and throat, excessive perspiration, drug rash and hypotension. Haemolytic anaemia, agranulocytosis, headache, difficult urination and thickening of bronchial secretions are also reported.

Symptoms and Treatment of Overdose:
Symptoms of overdosage includes hallucination, severe delirium, extrapyramidal symptoms, vomiting, vertigo, convulsions led to coma, cyanosis and death from respiratory failure. If vomiting has not occurred spontaneously, the patient should be induced to vomit. This is best done by having the patient drink a glass of water or milk, after which the patient should be made to gag. Precautions against aspiration must be taken especially in infants and children.
If vomiting is unsuccessful, gastric lavage is indicated within 3 hours after ingestion and even later if large amount of milk or cream were given beforehand. Isotonic or isotonic saline is the lavage solution of choice. Saline cathartics, such as milk of magnesia, by osmosis draw water into bowel, and therefore are valuable for their action in rapid dilution of bowel content. Vasopressors may be used to treat hypotension.

Effects on Ability to Drive and Use Machine: Not known.

Storage Conditions: Store at or below 30ºC. Protect from light.

Pack Size: Tablet: Blister pack: A box of 10 x 10 and 100 x 10 tablets per strip.
Syrup: A bottle of 60ml, 100ml and 120ml.
Pack Size (export only): Tablet: A bottle of 1000 tablets.
Syrup:A bottle of 1 litre, 3.6 litres and 3.8 litres.

Shelf-life: Tablet: 5 years.
Syrup: 3 years.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Manufacturer & Product Registration Holder:
SUNWARD PHARMACEUTICAL SDN. BHD.
No. 9, 11 & 17, Jalan Kempas 4,
Taman Perindustrian Tampoi Indah,
81200 Johor Bahru, Johor, Malaysia.

CL623B-R11
Revision Date: 26/11/2025