PACKAGE INSERT

DECONDINE TABLET/SYRUP

	Tablet	Syrup
	Each tablet contains :	Each 5ml contains :
Triprolidine HCl	2.5mg	1.25mg
Pseudoephedrine HCl	60mg	30mg

Pharmacology:
Triprolidine hydrochloride acts as an antagonists of the H1 histamine receptor. Consequently, it prevents histamine from eliciting typical immediate hypersensitivity reactions in the nose, eyes, lungs and skin.
Pseudoephedrine acts directly on alpha-adrenergic receptors in the respiratory tract mucosa producing vasoconstriction resulting in shrinkage of swollen nasal mucous membranes, reduction of tissue hyperemia, edema and nasal congestion, and an increase in nasal edema, and nasal congestion, and an increase in nasal airway potency. Drainage of sinus secretions is increased and obstructed eustachian ostia may be opened. Relaxation of bronchial smooth muscle by stimulation of beta adrenergic receptors may also occurs. Nasal decongestion usually occurs within 30 minutes and persists for 4-6 hours after oral administration of 60 mg of pseudoephedrine hydrochloride.
The pharmacokinetic properties of triprolidine were investigated by a single dose of triprolidine HCl 2mg tablets. The results are as follows: half life 3.0 ± 1.5 hours; time to maximum concentration 2.0 ± 0.9 hours; maximum plasma concentration 5.5 ± 4.8ng/ml, are under the plasma curve t2; 36.6 ± 46.1ng/ml hour. Animal distribution studies have shown localization of triprolidine in lung, spleen and kidney tissue. Liver microsome studies have revealed the presence of several metabolites with an oxidized product of the toluene methyl group predominating.
Pseudoephedrine is rapidly and almost completely absorbed from the gastrointestinal tract. After a 60 mg dose, peak plasma concentration (mean value of 274ng/ml are reached in from ½ to 2 hours. Within the normal urine pH ranges, mean plasma half-life is 6 to 7 hours. However considerable variation in half-life has been observed (from about 4 ½ to 10 hours) which is attributed to individual differences in absorption and excretion. Excretion rates also altered by urine pH, increasing with acidification and decreasing with alkalinization. As a result, mean half-life falls to about 4 hours at pH 5 and increases to 12 to 13 hours at pH 8.
After administration of a 60 mg tablet, 87 to 96% of the pseudoephedrine is cleared from the body within 24 hours. The drug is distributed to body tissues and fluids, including fetal tissues, breast milk, and the central nervous system. About 55 to 75% of an administered dose is excreted unchanged in the urine, the remainder is apparently metabolized in the liver to inactivate compounds by N-demethylation, parahydroxylation and oxidative deamination.

Indications:
It is indicated in nasal and respiratory congestion, common cold, acute sinusitis, and allergic rhinitis.

Side effects/adverse reactions:
The most frequent side effects include dryness of mouth, nose and throat, sedation, sleepiness, dizziness and disturbed coordination. Other side effects include urticaria, excessive perspiration, tachycardia, headache, hypotension, anxiety, vertigo, tinnitus, nausea, vomiting, diarrhoea, epigastric pain, irritability, anorexia, tightness of chest and wheezing.

Dosage:
Oral administration.
Tablet : Adults and children over 12 years : 1 tablet every 4-6 hours, up to 4 times a day, should not be exceeded 4 doses in 24 hours.

Syrup : Adults and children over 12 years: 10ml three times daily
Children 6 to 12 years : 5ml three times daily
Children 2 to 5 years : 2.5ml three times daily

Contraindications:
The combination of triprolidine and pseudoephedrine is contraindicated under the following conditions:
a) Hypersensitivity to pseudoephedrine or sympathomimetic amines
b) Patients taking MAO inhibitors
c) Severe hypertension
d) Severe coronary artery disease

Warnings and Precautions:
It should be used with considerable caution in patients with increased intraocular pressure, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, bladder neck obstruction, hypertension, diabetes mellitus, ischemic heart disease and hyperthyroidism.

It should be prescribed with caution for certain special risk patients, such as the elderly or debilitated and for those with severe impairment of renal or hepatic function, gallbladder disease or gallstones, respiratory impairment, cardiac arrhythmias, history of bronchial asthma, prostatic hypertrophy or urethral stricture and in patients known to be taking other antihistamines or decongestant preparations.
Patients should be cautioned about engaging in activities requiring mental alertness.
This preparation should not be used by persons intolerant to sympathomimetics used for the relief of nasal or sinus congestion.
Not recommended for children below 2 years.
Use with caution and on doctor's/pharmacist's advice in children 2 to 6 years of age.

Drug Interactions:
Concomitant use of DECONDINE with other sympathomimetic agents such as decongestants, tricyclic antidepressants and amphetamine-like psychostimulants or MAO inhibitors which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure and may diminish the antihypertensive effects of guanethidine, betanidine, methyldopa and reserpine.

Use in Pregnancy and Lactation:
As there are no adequate data on the use in pregnant women, it should be used only if clearly needed.
The components of the combination are excreted in breast milk in small amounts and because of the potential for adverse reaction in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug.

Symptoms and Treatment for Overdosage and Antidote(s):
Overdosage with triprolidine may produce reactions varying from depression to stimulation of the central nervous system; the latter is particularly likely in children. Atropine-like signs and symptoms (dry mouth, fixed dilated pupils, flushing, tachycardia, hallucination, convulsions, urinary retention, cardiac arrhythmias and coma) may occur.
Overdosage with pseudoephedrine can cause excessive CNS stimulation resulting in excitement, nervousness, anxiety, tremor, restlessness and insomnia. Other effects include tachycardia, hypertension, pallor, mydriasis, hyperglycaemia and urinary retention. Severe overdosage may cause tachypnea or hyperpnea, hallucinations, convulsions, or delirium, but in some individuals there may be CNS depression with somnolence, stupor, or respiratory depression. Arrhythmias (including ventricular fibrillation) may lead to hypotension and circulatory collapse. Severe hypokalemia can occur, probably due to a compartmental shift rather than a depletion of potassium.
Gastric emptying and/or lavage is recommended as soon as possible after ingestion even if the patient has vomited spontaneously. Either isotonic or half isotonic saline may be used for lavage. Administration of activated charcoal as a slurry is beneficial after lavage and or emesis, if less than four hours have passed since ingestion. Saline cathartics, such as milk of magnesia, help to dilute the concentration of the drugs in the bowels by drawing water into the gut, thereby hastening drug elimination.
Adrenergic receptor blocking agents are antidotes to pseudoephedrine. In practice, the most useful is the beta-blocker, propranolol, which is indicated when there are signs of cardiac toxicity. There is no specific antidote to triprolidine. Histamine should not be given.

Pack size: Syrup : A bottle of 60ml, 100ml and 120ml.
Tablet : A pack of 10x10 tablets and a bottle of 120 tablets.
Pack size (export only): Syrup : A bottle of 3.6 litres and 3.8 litres.
Tablet : A bottle of 1000 tablets.

Storage conditions:
Store at or below 30°C.Protect from light.

Shelf-life: Tablet : 3 years, Syrup : 2 years

Description:
Tablet : Round, white, convex, film-coated tablet with single score on one side only.
Syrup : Clear, yellow syrup with vanilla flavour.

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

Manufacturer & Product Registration Holder:

Malaysia:
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