LORADYNE TABLET
Description: White, oval shaped, top-scored tablet.

Content:
Loratadine 10.0 mg/tab.

Indication:
For the relief of symptoms associated with allergic rhinitis e. g. sneezing, nasal discharge and itching, as well as ocular itching and burning, chronic urticaria and other allergic dermatologic disorders.

Pharmacology:
Loratadine, derivative of azatadine, is a long acting tricyclic antihistamine with selective peripheral histamine H_1-receptor antagonistic activity. It has little central sedative or antimuscarinic activity, used for the symptomatic relief of hypersensitivity reactions (rhinitis and chronic urticaria). It diminishes or abolishes the main action of histamine by competitive, reversible blockade of histamine receptor sites on tissues. Loratadine is rapidly absorbed from the gastrointestinal tract, with peak plasma concentrations being attained in about one hour. Food increases the bioavailability of loratadine by 40% and its major active metabolite, descarboethoxyloratadine by 15%. However, the time to peak plasma concentration (Tmax) was delayed by one hour. Loratadine undergoes extensive metabolism. Its metabolite, descarboethoxyloratadine has potent histamine-H_1,blocking activity. Reported half-life of loratadine and descarboethoxyloratadine are 12 and 18 hours respectively. Loratadine is about 98% bound to plasma proteins. Descarboethoxyloratadine is less extensively bound. Approximately 80% dose administered can be found equally distributed between urine and feces in the form of metabolic products after 10 days. Loratadine and its metabolites have been detected in breast milk, but do not appear to cross the blood brain barrier to a significant extent. Loratadine and its metabolites are excreted in the urine and feces.

Contraindications:
It is contraindicated in patients hypersensitive to loratadine.

Side effects / Adverse reactions:
Most commonly reported side effects are fatigue, headache, somnolence, dry mouth, alopecia, anaphylaxis, abnormal hepatic function,gastrointestinal disorders eg. nausea, gastritis and allergic symptoms, i. e. rash.

Precautions:
Patients with impaired liver functions should be given a lower initial dose (10mg every other day is recommended) because they have reduced clearance of loratadine. As use in pregnancy has not been established, risk benefits should be considered before use. As loratadine is excreted in breast milk and increased risk of antihistamines in infants, risk benefits should be considered.

Drug Interactions:
Drugs known to inhibit hepatic metabolism should be co-administered with caution e. g. macrolide antibiotics, ketoconazole, cimetidine, ranitidine and theophyline. There does not appear to have an increase in adverse events in subjects who received oral contraceptives and loratadine compared to placebo. Although non-sedating antihistamines do not enhance the effects of alcohol, but few patients have experienced drowsiness. Therefore, caution should be exercised when administered concomitantly.

Dosage and administration:
Adult and children over 12 years: 10mg once daily. In patients with liver failure or renal insufficiency (GFR < 30ml/min): 10mg every other day should be the initial dose.

Treatment of over dosage:
Symptoms: Somnolence, tachycardia and headache has been reported with doses > 10mg (40mg - 180mg).
Treatment: General symptomatic and supportive measures should be instituted promptly and maintained for as long as necessary. Emesis with ipecac syrup, except in patients with impaired consciousness, followed by administration of activated charcoal for absorbing remaining drugs. If vomiting is unsuccessful or contraindicated, gastric lavage with normal saline should be performed. Saline cathartics may be used for rapid dilution of bowel contents. Loratadine is not cleared by hemodialysis to any appreciate extent. After emergency treatment, the patients should continue to be medically monitored.

Storage conditions : Keep container tightly closed. Store in a cool, dry place below 30°C. Protect from light.
Keep away from children.
Presentation : 10's/blister
Shelflife : 3 years.
Manufactured & Distributed by : PRIME PHARMACEUTICAL SDN. BHD.
1505, Lorong Perusahaan Utama 1, Taman Perindustrian Bukit Tengah, 14000 Bukit Mertajam, Penang, Malaysia.