For The use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

LORATADINE DISPERSIBLE TABLETS

LORIDIN RAPITAB

Composition:

Each uncoated dispersible tablet of Loridin Rapitab contains:

Loratadine 10 mg

Description:

White to off-white, smooth, round, flavoured, uncoated tablets with bevelled edges having breakline on one side and plain on the other.

Loridin Rapitab Tablets disintegrate in the mouth within seconds after placement on the tongue, allowing its contents to be subsequently swallowed with or without water, thereby greatly enhancing patient compliance.

Clinical Pharmacology:

Loratadine is a competitive blocker of peripheral histamine H1 receptors. It has a weak anticholinergic & alpha-adrenoceptor blocking action. Onset of antihistaminic action with Loratadine, as measured by wheal and flare suppression, is apparent within first hour of administration, and is sustained up to 24 hours. Loratadine 10 to 20 mg exhibits a protective effect on airways in response to inhaled histamine challenge in patient with asthma. The antiallergic activity of loratadine has been demonstrated in human using cutaneous, nasal challenge and conjunctival provocation tests.

Loratadine is well absorbed after oral administration with peak concentrations of 24.3 and 30.5 mcg/L occurring in 1 and 1.5 hours alter ingestion of 4.0 mg drug. Loratadine is 97 to 99% plasma protein bound and has a large volume of distribution (119L/kg). Loratadine is rapidly metabolised and an active metabolite descarboethoxyloratadine (DCL) is formed in vivo. Plasma elimination half-lives of loratadine and DCL range from 7.8 to 11 hours and 17 to 24 hours respectively. While loratadine is excreted into breast milk, the amount of administered drug appearing in the milk is minimal. The dosage adjustments are not required in patients with renal dysfunction and elderly.

Pharmacokinetic studies have showed that Loridin Rapitab tablets provide plasma concentrations of loratadine and descarboethoxyloratadine similar to those achieved with plain loratadine tablets.

Indications: Loridin Rapitab is indicated in the treatment of seasonal allergic rhinitis, perennial rhinitis, urticaria and allergic dermatologic disorders.

Dosage and administration:

Adults and children 12 years of age and over – 1 tablet (10mg) placed in the mouth once daily. Allow tablet to disperse in the mouth and swallow.

Contraindications:

Patients who have shown hypersensitivity or idiosyncrasy to any of the components of Loridin.

Precautions:

Patients with liver impairment or renal insufficiency (GFR <30ml/min) should be given a lower initial dose (10mg every other day). The safety and effectiveness of loratadine in pediatric patients under 2 years of age have not been established. Other drugs known to inhibit hepatic metabolism should be co-administered with caution until definitive interaction studies can be completed.

Side Effects:

Loratadine is generally well tolerated at therapeutic doses in adults, elderly patients and children. Commonly reported events are somnolence, fatigue and headache, while dry mouth and gut upset occur less frequently.

Drug Interactions:

When administered concomitantly with alcohol, loratadine has no potentiating effects as measured by psychomotor performance studies.

Drug/Laboratory Test: Loridin should be discontinued approximately 48 hours prior to skin testing procedures since antihistamines may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

Loratadine (10mg once daily) has been coadministered with therapeutic doses of erythromycin, cimetidine, and ketoconazole in controlled clinical pharmacology studies in adult volunteers. Although increased plasma concentrations (AUC 0-24 hrs) of loratadine and/or descarboethoxyloratadine were observed following coadministration of loratadine with each of these drugs in normal volunteers, there were no clinically relevant changes in the safety profile of loratadine, as assessed by electrocardiographic parameters, clinical laboratory tests, vital signs, and adverse events. There were no significant effects on QT_o intervals, and no reports of sedation or syncope. No effects on plasma concentrations of cimetidine or ketoconazole were observed. Plasma concentrations (AUC 0-24 hrs) of erythromycin decreased 15% with coadministration of loratadine relative to that observed with erythromycin alone. The clinical relevance of this difference is unknown. There does not appear to be an increase in adverse events in subjects who received oral contraceptives and loratadine.

Use in Pregnancy and Lactation:

There are no adequate and welt-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Loridin Rapitab should be used during pregnancy only if clearly needed. Loratadine and metabolite,

descarboethoxyloratadine, pass easily into breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug taking into account the importance of the drug to the mother. Caution should therefore be exercised when Loridin Rapitab is administered to a nursing woman.

Symptoms & Treatment for Overdosage & Antidote(s):

Somnolence, tachycardia and headache have been reported with overdoses greater than 10mg (40mg to 180mg). In the event of overdosage, general symptomatic and supportive measures should be instituted promptly and maintained for as long as necessary.

Treatment of overdosages would reasonably consist of emesis (ipepac syrup), except in patients with impaired consciousness, followed by administration of activated charcoal to absorb any remaining drug. If vomiting is unsuccessful or contraindicated, gastric lavage should be performed with normal saline. Saline cathartics may also be of value for rapid dilution of bowel contents. Loratadine is not eliminated by hemodialysis. It is not known if Loratadine is eliminated by peritoneal dialysis. Oral LD 50 values for Loratadine were greater than 500mg/kg in rats and mice and monkeys.

Presentation:

Loridin Rapitab is a white, flat, round, uncoated tablet with a mint flavour. It comes in a blister of 10 tablet(s); 10 such blisters in a printed box with a package insert.

Shelf life: 3 years from manufacturing date

STORE BELOW 30°C.

PROTECT FROM LIGHT & MOISTURE

KEEP OUT OF REACH OF CHILDREN

Jauhkan dari kanak-kanak
Controlled medicine/Ubat Terkawal

Product Registration Holder:

The Zyfas Medical Co., No. 7 Jalan Molek 3/10, Taman Molek, 81100 Johor Bahru.

Manufactured by

Cadila Healthcare Limited, Sarkhej-Bavla N.H. No.8 A, Moraiya, Tal: Sanand,
Dist: Ahmedabad 382210, INDIA.

Revision Date: June 2018