

# Encilor<sup>®</sup>

Loratadine 10 mg tablet

## Presentation

Encilor : Each tablet contains Loratadine INN 10 mg.

## Description

Encilor tablet is a preparation of Loratadine. Loratadine is a non-sedative histamine H<sub>1</sub>-receptor antagonist with antiallergic properties. Loratadine is a long acting tricyclic antihistamine with selective peripheral H<sub>1</sub>-receptor antagonistic activity and no central sedative or anticholinergic effect. It is rapidly effective and long-lasting, allowing once-a-day administration.

## Indication

Encilor tablet provides fast, effective relief from the symptoms of seasonal allergic rhinitis, perennial allergic rhinitis and skin allergies including chronic urticaria. It is also effective in alleviating symptoms of allergic rhinitis such as sneezing, nasal discharge, itching, ocular itching and burning. Nasal and ocular sign and symptoms are relieved rapidly after oral administration. Encilor tablet is also indicated in idiopathic urticaria. In children over 2 years Encilor tablet is indicated for the symptomatic relief of seasonal allergic rhinitis and allergic skin conditions such as urticaria, nettlerash.

## Dosage and Administration

Adults and children over 12 years of age : One Encilor tablet once daily. It is usually administered in the morning or when symptoms require treatment.

Children 2-12 years : Body weight over 30 kg one Encilor tablet once daily, below 30 kg, half Encilor tablet once daily.

Encilor tablet is not recommended for use below 2 years of age since safety and efficacy has not been established.

## Side Effects

During controlled clinical studies the incidence of adverse events, including sedation and anticholinergic effects observed with 10 mg Loratadine was comparable to that observed with placebo. Studies on the effect of loratadine on actual driving performance, and on tests of cognitive and psychomotor functioning have shown it to be comparable to placebo.

## Contraindications

Loratadine is contraindicated in patients who have shown hypersensitivity or idiosyncrasy to their components.

## Drug Interaction

There are no reports of potentially hazardous interactions with other drugs. In contrast to many other histamine H<sub>1</sub> receptor antagonists, Loratadine has no potentiating effects when administered concurrently with alcohol, as measured by psychomotor performance studies. Concomitant therapy with drugs that inhibit or are metabolized by hepatic cytochromes P450 3A4 and 2D6 may elevate plasma concentrations of either drug and this may result in adverse effects. Cimetidine inhibits both enzymes while erythromycin or ketoconazole inhibit P450 3A4. These drugs increase loratadine serum concentrations but no adverse effects are reported.

## Use in pregnancy and lactation

There is no experience of the use of Loratadine in human pregnancy. Therefore its use during pregnancy is not advisable. Loratadine is excreted in breast milk in a very small amount. So nursing mothers are advised not to take the drug.

## Overdose

In adults somnolence, tachycardia and headache have been reported with overdose greater than 10 mg. Extrapyramidal signs and palpitations have been reported in children with over doses of greater than 10 mg. In the event of overdosage, general symptomatic and supportive measures should be instituted promptly and maintained for as long as necessary. It would seem reasonable to treat patients presenting early after large overdoses with oral activated charcoal. The conscious patients may be induced to vomit or gastric lavage may be performed.

## Commercial pack

Encilor : Box containing 10 blister strips of 10 tablets.

Manufactured by



**Incepta Pharmaceuticals Ltd.**

Dhaka, Bangladesh

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