

# Lorhistina<sup>®</sup>



23000

Ref. No: B2123000/22.02

Loratadine

Antihistamine

LORHISTINA<sup>®</sup> TABLETS 10MG

LORHISTINA<sup>®</sup> SYRUP 5MG/5ML

## PRESENTATION:

**Lorhistina<sup>®</sup> Tablets 10mg:** White, circular biconvex tablet embossed 'COSMOS' on one side and a breakline on the other side. Each tablet contains Loratadine 10mg, Lactose and other excipients.

**Lorhistina<sup>®</sup> Syrup 5mg/5ml:** Straw yellow coloured syrup slightly viscous free from visible evidence of contamination with raspberry odour. Each 5ml contains: Loratadine 5mg

## CLINICAL PHARMACOLOGY:

Loratadine, a piperidine derivative related to azatadine, is a long-acting, non-sedating antihistamine with no significant antimuscarinic activity.

## Pharmacokinetics:

Loratadine is rapidly absorbed from the gastro-intestinal tract after oral administration, peak plasma concentrations being attained in about one hour. Bioavailability is increased and time to peak plasma concentrations is delayed when administered with food. Loratadine undergoes extensive metabolism. The major metabolite, descarboethoxyloratadine (desloratadine), has potent antihistaminic activity. Reported mean elimination half-lives for Loratadine and descarboethoxyloratadine are 8.4 and 28 hours respectively. Loratadine is about 98% bound to plasma proteins; descarboethoxyloratadine is less extensively bound. Loratadine and its metabolites have been detected in the breast milk, but do not appear to cross the blood-brain barrier to a significant extent. Most of a dose is excreted equally in the urine and faeces, mainly in the form of metabolites.

## USES:

Lorhistina<sup>®</sup> is a histamine H<sub>1</sub>-receptor antagonist that does not generally cause sedation or antimuscarinic effect. It is given for symptomatic relief of allergic conditions including rhinitis or chronic urticaria.

## DOSAGE AND ADMINISTRATION:

**Adults including the elderly and Children 12 years of age and over:** 10mg (one tablet) or two 5ml spoonful once daily.

**Children aged 6 to 12 years:** 10mg (one tablet) or two 5mL spoonful of syrup once daily.

**Children aged 2 to 5 years:** 5mg (one tablet) or 5mL spoonful of syrup once daily.

## CONTRA-INDICATIONS AND WARNINGS:

Drowsiness can occur and it may affect the performance of skilled tasks. Occasionally reports of convulsions in patients taking antihistamines also call for caution in patients with epilepsy. Caution is also needed in hepatic impairment. Antihistamines should not be given to neonates owing to the increased susceptibility to antimuscarinic effects.

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## **Adverse Effects:**

Occasional gastro-intestinal adverse effects of antihistamines include nausea, vomiting, diarrhoea, or epigastric pain. Administration of antihistamines may sometimes cause rashes and hypersensitivity reaction and cross-sensitivity.

Other adverse effects with antihistamines include convulsions, sweating, myalgia, paraesthesias, extrapyramidal effects, tremor, sleep disturbances, depression, tinnitus, hypotension and hair loss.

## **Interactions:**

Sedative interactions apply to non-sedating antihistamines: they do not appear to potentiate the effects of alcohol, but it should be avoided in excess. Antihistamines may suppress the cutaneous histamine response to allergen extracts and should be stopped several days before skin testing.

## **Pregnancy and Lactation:**

**Pregnancy:** A large amount of data on pregnant women (more than 1000 exposed outcomes) indicate no malformative nor fetotoxicity of loratadine. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of Loratadine 10mg tablets during pregnancy.

**Lactation:** Loratadine is excreted in breast milk, therefore the use of loratadine is not recommended in breast-feeding women.

## **PHARMACEUTICAL PRECAUTIONS:**

Store in a dry place below 25°C. Protect from light. Keep all medicines out of the reach of children.

## **LEGAL CATEGORY:**

Prescription Only Medicine (POM)

®Regd. TM



Cosmos Limited,  
Rangwe Rd; Off Lungu Lungu Rd,  
Nairobi, Kenya