Approved Professional Information for Medicines for Human Use: AUSTELL-LORATADINE 10 mg

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

AUSTELL LORATADINE 10 mg tablets.

COMPOSITION

Each tablet contains 10 mg loratadine.

Excipients

Lactose monohydrate, magnesium stearate and maize starch.

Contains sugar (lactose monohydrate 188,5 mg/tablet).

CATEGORY AND CLASS

A.5.7.1 Antihistaminics.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Loratadine is a second-generation histamine (H_1)-receptor antagonist. Loratadine exerts its action by competing with histamine for H_1-receptor sites on effector cells. It prevents, however does not reverse responses mediated by histamine. Loratadine does not cross the blood-brain barrier to any extent.

Pharmacokinetic properties

After oral administration, Loratadine is well absorbed from the gastro-intestinal tract and peak plasma concentrations are reached within within 1,5 hours. Ingestion of food may enhance the

absorption of Loratadine. Loratadine undergoes extensive first pass metabolism via the cytochrome P-450 system.

The major metabolite, desloratadine, is active. Loratadine is 97 % protein bound, while desloratadine is less extensively protein bound (73 % to 77 %). The mean elimination half-lives for loratadine and desloratadine are 8,4 and 28 hours respectively.

INDICATIONS

AUSTELL LORATADINE is indicated for the relief of symptoms associated with seasonal allergic rhinitis and chronic urticaria.

CONTRAINDICATIONS

- Hypersensitivity to loratadine or to any of the excipients of **AUSTELL LORATADINE.**
- Cross sensitivity to other antihistamines.
- Pregnancy and lactation (see HUMAN REPRODUCTION).

WARNINGS AND SPECIAL PRECAUTIONS

AUSTELL LORATADINE should be used with caution in patients with:

- Severe liver impairment, as reduced clearance of Loratadine may occur. Dosage adjustment may be needed (see DOSAGE AND DIRECTIONS FOR USE).
- The administration of **AUSTELL LORATADINE** should be discontinued at least 48 hours before skin tests since this may prevent or reduce otherwise positive reactions to dermal reactivity index.
- There is associated weight gain with the use of **AUSTELL LORATADINE** (see SIDE EFFECTS).

Safety and efficacy of **AUSTELL LORATADINE** in children under two years of age has not been established.

Effects on ability to drive and use machines

AUSTELL LORATADINE may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other nervous system depressants (e.g. sedatives and tranquilizers).

Caution should be used when driving a motor vehicle or operating machinery or performing potentially dangerous tasks, where loss of concentration may lead to accidents.

AUSTELL LORATADINE contains lactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take AUSTELL LORATADINE.

Contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS

Concomitant use of **AUSTELL LORATADINE** with:

> Inhibitors of cytochrome P-450 enzyme system such as cimetidine, ketoconazole, clarithromycin and erythromycin may increase the plasma concentrations of **AUSTELL LORATADINE**.

HUMAN REPRODUCTION

Safety and efficacy in pregnancy and lactation has not been established. Loratadine and its metabolites have been detected in breast milk.

Small amounts of **AUSTELL LORATADINE** entering breast milk my cause drowsiness or excitement in infants.

Fertility

There are no data available on male and female fertility.

DOSAGE AND DIRECTIONS FOR USE

Adults : One tablet once daily.

Special populations

Paediatric population

Children 6 years of age and older with a body weight of greater than 30 kg:

One tablet once daily.

Patients with hepatic impairment

Adults with severe liver function impairment: initial dose is 5 mg once daily or 10 mg on alternate days.

Patients with renal impairment

No dosage adjustments are required in patients with renal insufficiency.

Elderly

No dosage adjustments are required in the elderly.

SIDE-EFFECTS

The side-effects below are classified by system organ class and frequency according to the following convention:

Frequencies are defined as very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and unknown (cannot be estimated from the available data).

System organ class	Side effect	Frequency
Immune system disorders	Hypersensitivity reactions (including angioedema and anaphylaxis)	Very rare
Nervous system disorders	Somnolence	Common
	Headache, insomnia	Uncommon
	Dizziness, convulsion	Very rare
Cardiac disorders	Tachycardia, palpitations	Very rare

Gastrointestinal disorders	Nausea, dry mouth, gastritis	Very rare
Hepatobiliary disorders	Abnormal hepatic function	Very rare
Skin and subcutaneous tissue disorders	Rash, alopecia	Very rare
General disorders and administration site conditions	Fatigue	Very rare
Investigations	Increased appetite	Uncommon
	Increased weight	Unknown

Paediatric population

System organ class	**Side effect**	**Frequency**
Nervous system disorders	Headache, nervousness	Common
General disorders and administration site conditions	Fatigue	Common

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms of overdose:

Somnolence; tachycardia; and headaches have been reported. In children, extrapyramidal manifestations and palpitations have been reported.

Treatment is symptomatic and supportive.

IDENTIFICATION

White, oval shaped tablets with a score line on one side and plain on other side.

PRESENTATION

Clear transparent PVC/PVdC aluminium blister packs of 7, 10, 30 or 250 tablets. Bulk: White HDPE bottles of 100 tablets.

Not all pack sizes may be marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Protect from moisture.

Store in the original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

A38/5.7.1/0380

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