

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd  
Laura 10 mg tablets  
Dosage form: Tablets  
Strength: Each tablet contains loratadine 10 mg

## PROFESSIONAL INFORMATION

**SCHEDULING STATUS:** S1

### 1. NAME OF THE MEDICINE

**LAURA 10 Tablets**

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

LAURA 10 TABLETS: Each tablet contains loratadine 10 mg.

Excipients with known effect:

Contains sugar: Lactose (78,25 mg per tablet).

For the full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

*Tablets*

White to off-white, uncoated, round, flat tablets with bevelled edges, debossed with 'R' on one side and '10' on the other.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

LAURA is indicated in adults for the relief of symptoms associated with perennial and /or seasonal allergic rhinitis, chronic urticaria and other allergic skin disorders.

#### 4.2 Posology and method of administration

##### Posology

##### *Adults*

One LAURA tablet orally once daily.

##### Special populations

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**Use in patients with hepatic failure or renal impairment:**

In patients with hepatic failure or renal impairment, an initial dose of 5 mg once daily or 10 mg on alternate days is recommended.

**Use in elderly patients:**

Safety of LAURA in the elderly has not been established (see section 4.3).

**Paediatric population**

Safety and efficacy of LAURA in children under two years of age have not been established (see section 4.3).

**Method of administration**

LAURA is for oral administration.

**LAURA** can be taken with or without meal.

**4.3 Contraindications**

Hypersensitivity or idiosyncratic reaction to loratadine or to any of the excipients listed in section 6.1.

Safety of LAURA in the elderly has not been established.

Safety and efficacy of LAURA in children under two years of age have not been established.

LAURA is contraindicated in **pregnancy and lactation** as the safety has not been established (see section 4.6).

**4.4 Special warnings and precautions for use**

LAURA lacks significant sedative effects. Patients should, however be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.

LAURA should be administered with caution in patients with severe hepatic impairment because they may have a reduced clearance of loratadine. A lower initial dose of 5 mg once daily or 10 mg every other day is recommended in such patients.

LAURA should be discontinued at least two days (48 hours) prior to skin testing procedures, since it may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

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*Geriatrics:* See section 4.3

**The use of LAURA has been associated with the risk of weight gain (see section 4.8).**

Important information about excipients:

**Lactose**

LAURA contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**4.5 Interaction with other medicines and other forms of interaction**

*Medicine/laboratory test interactions*

LAURA should be discontinued about two days prior to skin testing procedures, since it may prevent or diminish otherwise positive reactions to dermal reactivity indicators (see section 4.4).

When administered concurrently with alcohol, LAURA has no potentiating effects. However, concomitant consumption of excessive amounts of alcohol should be avoided (see section 4.4).

Caution should be exercised when other medicines known to inhibit hepatic microsomal enzymes are co-administered with LAURA. Medicines known to inhibit either P450 3A4 or P450 2D6 are quinidine, fluconazole or fluoxetine.

An increase in plasma concentrations of loratadine have been reported after concomitant use with ketoconazole, erythromycin or cimetidine in controlled clinical trials, but without clinically significant changes (including electrocardiographic).

Other medicines known to inhibit hepatic metabolism should be co-administered with caution together with LAURA until definitive interaction studies can be completed or in the absence of formal interaction studies.

**4.6 Fertility, pregnancy and lactation**

Contraindicated in pregnancy and lactation (see section 4.3).

**Fertility**

There is no fertility data available.

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**4.7 Effects on ability to drive and use machines**

LAURA lacks significant sedative effects. However, a few patients treated with non-sedating antihistamines such as LAURA have experienced drowsiness. Therefore, it is prudent that caution should be exercised before driving or operating machinery; the effect of LAURA on a particular patient can be ascertained after the first few doses. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.

**4.8 Undesirable effects**

**Tabulated list of adverse reactions**

<b>MedDRA System organ class</b>	<b>Frequency</b>	<b>Adverse reactions</b>
<i>Blood and lymphatic system disorders</i>	Less frequent	Thrombocytopenia.
<i>Immune system disorders</i>	Less frequent	Hypersensitivity reactions (including skin rash, bronchospasm, angioedema and anaphylaxis) and cross sensitivity.
<i>Psychiatric disorders</i>	Frequent	Insomnia, nervousness.
	Less frequent	Depression.
<i>Nervous system disorders</i>	Frequent	Headache, somnolence,
	Less frequent	Dizziness, convulsions, sweating, paraesthesias, extrapyramidal effects, tremor, sleep disturbances.
<i>Cardiac disorders</i>	Less frequent	Tachycardia, palpitations and dysrhythmias, including ventricular and supraventricular dysrhythmias; hypotension.
<i>Ear and labyrinth disorders</i>	Less frequent	Tinnitus.
<i>Gastrointestinal disorders</i>	Frequent	Increased appetite
	Less frequent	Nausea, vomiting, diarrhoea, dry mouth, gastritis, or epigastric pain, anorexia.

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<i>Hepato-biliary disorders</i>	Less frequent	Abnormal hepatic functions, including jaundice and hepatitis.
<i>Skin and subcutaneous tissue disorders</i>	Less frequent	Rash, alopecia.
<i>Musculoskeletal and connective tissue disorders</i>	Less frequent	Myalgia.
<i>General disorders and administration site conditions</i>	Frequent	Fatigue.
<i>Investigations</i>	Frequency unknown	Weight increase.

*Reporting of suspected adverse reactions*

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

**4.9 Overdose**

Overdosage with loratadine may manifest in any of the symptoms described under section 4.8. There is no specific antidote for loratadine. In case of overdosage, treatment which is symptomatic and supportive should be started immediately.

Consider standard measures to remove any unabsorbed medicine in the stomach, such as adsorption by activated charcoal administered as a slurry with water. The administration of gastric lavage should be considered.

Sodium chloride 0,9 % solution is the lavage solution of choice, particularly in children.

In adults tap water can be used; however, as much as possible of the amount administered should be removed before the next instillation. Sodium chloride or saline cathartics draw water into the bowel by osmosis and therefore, may be valuable for their action in rapid dilution of bowel content.

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Loratadine is not dialysable. After emergency treatment, the patient should continue to be under medical supervision.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

#### **A 5.7.1 Antihistaminics.**

Loratadine is a long acting tricyclic antihistamine with selective peripheral H<sub>1</sub>-receptor antagonistic activity and no central sedative or anticholinergic effects. It acts by competing with histamine for H<sub>1</sub>-receptor sites on effector cells. Loratadine thereby prevents, but does not reverse responses mediated by histamine alone.

### **5.2 Pharmacokinetic properties**

#### *Absorption*

Loratadine is well absorbed from the gastro-intestinal tract after oral administration.

Bioavailability is increased when administered with food.

#### *Biotransformation*

The major metabolite, descarboethoxyloratadine, has histamine-H<sub>1</sub> blocking activity. Reported half-lives for loratadine and descarboethoxyloratadine are  $8 \pm 6$  hours and  $18 \pm 6$  hours respectively.

#### *Distribution*

Loratadine is about 97 % bound to plasma proteins; descarboethoxyloratadine is less extensively bound (73 - 77 %). The volume of distribution is about  $120 \pm 80$  L/kg. Loratadine and its metabolites are detected in breast milk, but do not appear to cross the blood-brain barrier to a significant extent.

#### *Elimination*

Loratadine and its metabolites are excreted in the urine and faeces.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Lactose monohydrate

Maize starch

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Pregelatinized starch

Magnesium stearate

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

24 months.

## **6.4 Special precautions for storage**

Store at or below 25 °C, protected from moisture.

## **6.5 Nature and contents of container**

Blister strips of clear, colourless PVC/PVDC film with aluminium foil backing containing 10 tablets.

Cartons contain 10 and 30 tablets.

## **7. HOLDER OF CERTIFICATE OF REGISTRATION**

Ranbaxy Pharmaceuticals (Pty) Ltd.

a Sun Pharma company

14 Lautre Road, Stormill, Ext. 1

Roodepoort, 1724

South Africa

## **8. REGISTRATION NUMBERS**

36/5.7.1/0232

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

24 October 2003

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#### **10. DATE OF REVISION OF THE TEXT**

15 August 2022

#### **Botswana:**

**S2** Reg. no.: BOT0700980

#### **Namibia:**

**NS1** Reg. no.: 07/5.7.1/0036