

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

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S1**

LAURA 10 TABLETS

Loratadine

Contains sugar: Lactose monohydrate 78,25 mg/tablet.

Read all of this leaflet carefully because it contains important information for you

- LAURA is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use LAURA carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share LAURA with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What LAURA is and what it is used for
2. What you need to know before you take LAURA
3. How to take LAURA
4. Possible side effects
5. How to store LAURA
6. Contents of the pack and other information

1. What LAURA 10 Tablets is and what it is used for

LAURA belong to a class of medicines known as antihistamines.

Adults: LAURA relieve symptoms associated with perennial and /or seasonal allergic rhinitis (for example hay fever), such as sneezing, runny or itchy nose, and burning or itchy eyes. LAURA may also be used to help relieve symptoms of chronic urticaria (itching and redness) which is often known as hives or nettle rash or other allergic skin disorders.

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2. What you need to know before you take LAURA 10 Tablets

Do not take LAURA if:

- you are hypersensitive (allergic) to loratadine or to any of the other ingredients of LAURA (listed in section 6).
- you are pregnant or breastfeeding.
- you are over 65 years of age.
- if your child is under 2 years of age as safety and effectiveness of LAURA have not been established.

Warnings and precautions

Take special care with LAURA if:

- you have liver disease (**see HOW TO TAKE LAURA**).
- LAURA is not known to have sedative effects. However, a small number of patients may experience sedation. This effect may be compounded if you take alcohol or other central nervous system depressants at the same time. It is therefore advisable to determine individual response before driving or performing complicated tasks.

LAURA should be stopped at least two days (48 hours) before skin testing procedures since it may interfere with the results.

The safe and effective use of LAURA in children under two years of age have not been established.

The use of LAURA has been associated with the risk of weight gain (see POSSIBLE SIDE EFFECTS)

Other medicines and LAURA 10 Tablets

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

It is important to tell your doctor if you are taking:

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- excessive amounts of alcohol
- cimetidine (medicine for ulcers)
- erythromycin (antibiotic)
- ketoconazole (antifungal)
- quinidine (medicine for irregular heartbeats)
- fluconazole (antifungal)
- fluoxetine (antidepressant)
- skin test (stop taking LAURA at least 48 hours before skin testing).
- Do not take LAURA with other medicines known to slow or stop liver metabolism until further studies can be undertaken.

LAURA with food or drink

LAURA can be taken with or without a meal.

LAURA has not been shown to add to the effects of an alcoholic drink. Avoid drinking excessive amounts of alcohol.

Pregnancy and breastfeeding

Do not take LAURA if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

LAURA lacks significant sedative effects but may cause drowsiness in some people. This effect may be compounded by taking alcohol or other central nervous system depressants at the same time. Therefore, be careful before driving or operating machinery. You will know after the first few doses how LAURA affects you.

LAURA 10 Tablets contains lactose monohydrate.

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If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take LAURA 10 Tablets

Do not share medicines prescribed for you with any other person.

Always take LAURA exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

Adults: The usual dose is one LAURA by mouth once a day.

The tablets should be swallowed whole with water and may be taken with or without food.

Special dosage instructions for specific populations

Kidney and liver impairment

If you have severe liver or kidney problems, your doctor or pharmacist may advise you to take a dose of 5 mg (half a tablet) once a day or 10 mg (one tablet) every other day.

Elderly patients

Do not take LAURA if you are over 65 years of age

Paediatric patients

Do not give LAURA to children under 2 years of age.

Duration of treatment

The duration of use depends on the type, duration and course of your complaints and is determined by your doctor or pharmacist.

If you take more LAURA 10 Tablets than you should

See section 4 below for the possible side effects that you may experience.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you forget to take LAURA 10 Tablets:

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If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up a forgotten dose.

4. Possible side effects

LAURA can have side effects.

Not all side effects reported for LAURA are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking LAURA please consult your health care provider for advice.

If any of the following happens, stop taking LAURA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- difficulty in breathing,
- skin rash,
- swelling of the face, mouth, lips, neck, tongue or throat.

These are all very serious side effects. If you have them, you may have had a serious reaction to LAURA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- irregular or rapid heartbeat,
- yellowing of the skin and eyes, also called jaundice.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The frequent side effects reported include:

- headache,
- nervousness,
- tiredness,
- drowsiness,
- increased appetite,

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- difficulty sleeping.

Other less frequent side effects reported include:

- low blood pressure,
- tingling or numbness of the hands or feet,
- uncontrollable movements,
- dizziness,
- sweating, sleep disturbances, depression, trembling,
- nausea (feeling sick), upset stomach, vomiting,
- diarrhoea, stomach pain,
- loss of appetite,
- fits,
- ringing in the ears,
- dry mouth,
- liver problems, including jaundice or hepatitis,
- muscle pain,
- lower than normal number of platelets in your blood,
- hair loss,
- rash.

Unknown frequency:

- weight increase.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LAURA.

5. How to store LAURA 10 Tablets

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Store all medicines out of reach of children.

Store at or below 25 °C, protected from moisture in the original carton.

Do not store in a bathroom.

Do not take the medicine after the expiry date stated on the label / carton.

Return any unused tablets to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LAURA contains

The active substance of LAURA is loratadine.

Each tablet contains loratadine (micronized) 10 mg.

The other ingredients are lactose monohydrate, maize starch, pregelatinised maize starch and magnesium stearate.

What LAURA looks like and contents of the pack

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

Contents of the pack:

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

Cartons contain 10 and 30 tablets.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

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