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.

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 EEFECTS)

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:

- 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 **o**ther 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.

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 overdosage, 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:

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,

- 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

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

a Sun Pharma company

14 Lautre Road, Stormill Ext 1

Roodepoort, 1724

South Africa

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PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S1

LAURA 10 Tablets

Loratadien

Bevat suiker: Laktosemonohidraat 78,25 mg/tablet.

Lees hierdie hele inligtingstuk noukeurig deur omdat dit belangrike inligting vir jou bevat.

- **LAURA** is vir jou beskikbaar sonder ‘n dokter se voorskrif om ‘n ligte siektetoestand te behandel. Nietemin moet **LAURA** steeds versigtig gebruik word om die beste resultate daarvan te verkry.
- Hou hierdie inigtingstuk. Dit mag nodig wees om dit weer te lees.
- Moenie **LAURA** met enige ander persoon deel nie.
- Vra jou gesondheidsorgvoorsiener of apteker as jy meer inligting of advies nodig het.
- Jy moet jou dokter gaan sien as jou simptome versleg of nie verbeter nie.

Wat is in hierdie inligtingstuk

1. Wat is **LAURA** en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy **LAURA** neem
3. Hoe om **LAURA** te neem
4. Moontlike newe-effekte
5. Hoe om **LAURA** te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat is LAURA 10 Tablets en waarvoor word dit gebruik

LAURA behoort aan ‘n klas van medisyne wat antihistamiene genoem word.

Volwassenes: LAURA verlig simptome wat geassosieer word met meerjarige en /of seisoenale allergiese rinitis (byvoorbeeld hooikoors), soos nies, loop- of jeukende neus, en branderige of jeukende oë. LAURA kan ook gebruik word om simptome van chroniese urtikarie (gejeuk en rooiheid) wat dikwels bekend staan as galbulte of netelroos of ander allergiese velversteurings te help verlig.

2. Wat jy moet weet voordat jy LAURA 10 Tablets neem

Moenie LAURA neem nie as:

- jy hipersensitief (allergies) is vir loratadien of vir enige van die ander bestanddele van LAURA (gelys in afdeling 6) nie.
- jy swanger is of borsvoed.
- jy bo 65-jarige ouderdom is.
- as jy ‘n kind onder 2-jarige ouderdom is, aangesien veiligheid en doeltreffendheid van LAURA nie vasgestel is nie.

Waarskuwings en voorsorgmaatreëls

Tref spesiale voorsorg met LAURA as:

- jy lewersiekte het **(sien HOE OM LAURA TE NEEM**).
- LAURA is nie bekend om sedatiewe effekte te hê nie.’n Klein aantal pasiënte mag egter sedasie ervaar. Hierdie effek kan vererger word as jy alkohol of ander sentrale senuweestelsel-onderdrukkers tegelykertyd neem. Dit word daarom aangeraai om die individuele respons te bepaal voordat bestuur word of ingewikkelde take uitgevoer word.

LAURA moet vir ten minste twee dae (48 uur) gestaak word voordat veltoets-prosedures uitgevoer word aangesien dit mag inmeng met die resultate.

Die veilige en doeltreffende gebruik van LAURA in kinders onder 2-jarige ouderdom is nie vasgestel nie.

Die gebruik van LAURA is geassosieer met die risiko van gewigstoename (sien MOONTLIKE NEWE-EFFEKTE)

Ander medisyne en LAURA 10 Tablets

Lig jou gesondheidsorgvoorsiener altyd in as jy einge ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in).

Dit is belangrik om jou dokter in te lig as jy die volgende neem:

- oormatige hoeveelhede alkohol

- simetidien (medisyne vir maagsere)
- eritromisien (antibiotikum)
- ketokonasool (antifungusmiddel)
- kinidien (medisyne vir onreëlmatige hartklop)
- flukonasool (antifungusmiddel)
- fluoksetien (antidepressant)
- veltoets (staak die gebruik van LAURA ten minste 48 uur voor veltoetsing).
- Moenie LAURA saam met ander medisyne neem wat bekend is om lewermetabolisme te vertraag of te stop totdat verdere studies onderneem kan word nie.

LAURA met voedsel en drinkgoed

LAURA kan met of sonder ‘n maaltyd geneem word.

Daar is nie aangetoon dat LAURA effekte toevoeg tot ‘n alkoholiese drankie nie. Vermy dit om oormatige alkohol te drink.

Swangerskap en borsvoeding

Moenie LAURA neem as jy swanger is of jou baba borsvoed nie.

Konsulteer asseblief jou dokter, apteker of ander gesondheidsorgvoorsiener vir advies voordat jy hierdie medisyne neem as jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of as jy beplan om ‘n baba te hê nie.

Bestuur en gebruik van masjinerie

LAURA ontbreek noemenswaardige sedatiewe effekte maar mag lomerigheid by sommige persone veroorsaak. Hierdie effek kan vererger word deur die gelyktydige gebruik van alkohol of ander sentrale senuweestelsel-onderdrukkers. Wees daarom versigtig voordat jy bestuur of masjinerie hanteer. Jy sal na die eerste paar dosisse weet hoe LAURA jou affekteer.

LAURA 10 bevat laktosemonohidraat.

As jy deur jou dokter ingelig is dat jy ‘n intoleransie teenoor sommige suikers het, moet jy jou dokter kontak voordat jy hierdie medisyne gebruik.

3. Hoe om LAURA 10 Tablets te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem LAURA altyd presies soos wat dit in hierdie inligtingstuk beskryf word. Kontroleer met jou dokter of apteker as jy onseker is.

Volwassenes: Die normale dosis is een LAURA mondeliks een keer per dag.

Die tablette moet heel ingesluk word met water en kan met of sonder voedsel geneem word.

Spesiale doseringsinstruksies vir spesifieke populasies

Nier- en lewerontoereikendheid

As jy ernstige lewer- of nierprobleme het, kan jou dokter of apteker jou aanraai om ‘n dosis van 5 mg (‘n halwe tablet) een keer per dag of 10 mg (een tablet) elke alternatiewe dag te neem.

Bejaarde pasiënte

Moenie LAURA neem as bo 65-jarige ouderdom is nie.

Pediatriese pasiënte

Moenie LAURA aan kinders onder 2-jarige ouderdom gee nie.

Duur van behandeling

Die duur van gebruik, hang af van die tipe, duur en verloop van jou klagtes en word deur jou dokter of apteker bepaal.

As jy meer LAURA 10 Tablets geneem het as wat jy behoort te neem

Sien afdeling 4 hieronder vir die moontlike newe-effekte wat jy mag ervaar.

Raadpleeg jou dokter of apteker in die geval van oordosering. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Neem hierdie inligtingstuk of sommige van die tablette saam met jou sodat jou dokter kan weet wat jy geneem het.

As jy vergeet het om LAURA 10 Tablets te neem:

As jy vergeet het om jou dosis op die regte tyd te neem, neem dit so gou as moontlik, gaan dan terug na jou normale dosisskedule. Moenie ‘n dubbele dosis neem om te vergoed vir die dosis wat jy vergeet het nie.

4. Moontlike newe-effekte

LAURA kan newe-effekte hê.

Nie alle newe-effekte wat vir LAURA aangemeld word, is in hierdie inligtingstuk ingesluit nie. Indien jou algemene gesondheid verswak, of as jy enige ongewenste effekte ervaar terwyl jy LAURA neem, moet jy asseblief jou gesondheidsorgvoorsiener raadpleeg vir advies.

As enige van die volgende gebeur, staak die gebruik van LAURA en lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal:

- moeilike asemhaling,
- veluitslag,
- swelling van die gesig, mond, lippe, nek, tong of keel.

Hierdie is almal baie ernstuge newe-effekte. As jy dit het, kon jy ‘n ernstige reaksie teen LAURA gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- onreëlmatige of vinnige hartklop,
- vergeling van die vel en oë, ook geelsug genoem.

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

Die dikwelse newe-effekte wat aangemeld word, sluit in:

- hoofpyn,
- senuweeagtigheid,
- moegheid,
- lomerigheid,
- verhoogde aptyt,
- probleme om te slaap.

Ander minder dikwelse newe-effekte wat aangemeld word, sluit in:

- lae bloeddruk,

- tinteling of dooie gevoel van die hande of voete,
- ombeheerbare bewegings,
- duiseligheid,
- sweet, slaapversteurings, depressie, bewerigheid,
- naarheid (voel mislik), omgekrapte maag, braking,
- diaree, maagpyn,
- verlies aan aptyt,
- stuipe,
- gesuis in die ore,
- droë mond,
- lewerprobleme, insluitend geelsug of hepatitis,
- spierpyn,
- laer as normale aantal plaatjies in jou bloed,
- haarverlies,
- uitslag.

Onbekende voorkoms:

- gewigstoename.

Lig asseblief jou dokter of apteker in as jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Aanmelding van newe-effekte

Praat asseblief met jou dokter, apteker of verpleegkundige as jy newe-effekte kry. Jy kan ook newe-effekte aanmeld by SAHPRA *via* die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn beskikbaar is onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van LAURA te verskaf.

5. Hoe om LAURA 10 Tablets te bewaar

Bewaar alle medisyne buite die bereik van kinders.

Bewaar by of onder 25 °C, beskerm teen vog in die oorspronklike karton.

Moenie in 'n badkamer bewaar nie.

Moenie medisyne na die vervaldatum, soos aangedui op die etiket / karton, gebruik nie.

Bring alle ongebruikte medisyne terug na jou apteker toe.

Moenie van ongebruikte medisyne in dreinering-of rioleringstelsels (bv. toilette) ontslae raak nie.

6. Inhou van die verpakking en ander inligting

Wat LAURA bevat

Die aktiewe bestanddeel van LAURA is loratadien.

Elke tablet bevat loratadien (gemikroniseerd) 10 mg.

Die ander bestanddele is laktosemonohidraat, mieliestysel, voorafgegelatiniseerde mieliestysel en magnesiumstearaat.

Hoe LAURA lyk en inhoud van die verpakking

Wit tot naaswit, onbedekte, ronde, plat tablette met skuins rande, ingepers met 'R' op een kant en '10' op die ander.

Inhoud van die verpakking:

Stulpstroke van helder, kleurlose PVC/PVDC-film met ‘n rugkant van aluminiumfoelie bevattende 10 tablette. Kartonne bevat 10 en 30 tablette.

Houer van die Registrasiesertifikaat

RANBAXY PHARMACEUTICALS (PTY) LTD

‘n Sun Pharma maatskappy

Lautreweg 14, Stormill Uitbreiding 1

Roodepoort, 1724

Suid-Afrika

Hierdie inligtingstuk was laas hersien op

Augustus 2022

Registrasienommer

36/5.7.1/0232

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Laura10 mg tablets
Dosage form: Tablets
Strength: Each tablet contains loratadine 10 mg

Botswana:

S2 Reg. nr.: BOT0700980

Namibië:

NS1 Reg. nr.: 07/5.7.1/0036