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

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.

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.

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

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

Hepato-biliary disorders	Less frequent	Abnormal hepatic functions, including jaundice and hepatitis.
Skin and subcutaneous tissue disorders	Less frequent	Rash, alopecia.
Musculoskeletal and connective tissue disorders	Less frequent	Myalgia.
General disorders and administration site conditions	Frequent	Fatigue.
Investigations	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.

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_1-receptor antagonistic activity and no central sedative or anticholinergic effects. It acts by competing with histamine for H_1-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_1 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 ± 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

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

10. DATE OF REVISION OF THE TEXT

15 August 2022

Botswana:

S2 Reg. no.: BOT0700980

Namibia:

NS1 Reg. no.: 07/5.7.1/0036

PROFESSIONELE INLIGTING

SKEDULERINGSTATUS: S1

1. NAAM VAN DIE MEDISYNE

LAURA 10 TABLETS

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

LAURA 10 TABLETS: Elke tablet bevat loratadien 10 mg.

Onaktiewe bestanddele met bekende effek:

Bevat suiker: Laktose (78,25 mg per tablet).

Vir die volledige lys van onaktiewe bestanddele, sien afdeling 6.1.

3. FARMASEUTIESE VORM

Tablette

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

4. KLINIESE BESONDERHEDE

4.1 Terapeutiese indikasies

LAURA word aangedui in volwassenes vir die verligting van simptome wat geassosieer word met meerjarige en / of seisoenale allergiese rinitis, chroniese urtikarie en ander allergiese velversteurings.

4.2 Posologie en metode van toediening

Posologie

Volwassenes

Een LAURA een keer per dag oraal geneem.

Spesiale populasies

Gebruik in pasiënte met lewerversaking of nierinkorting:

In pasiënte met lewerversaking of nierinkorting, word ‘n aanvangsdosis van 5 mg een keer per dag of 10 mg op alternatiewe dae aanbeveel.

Gebruik in bejaarde pasiënte:

Veiligheid van LAURA in die bejaarde is nie vasgestel nie (sien afdeling 4.3).

Pediatriese populasie

Veiligheid en doeltreffendheid van LAURA in kinders onder die ouderdom van twee jaar is nie vasgestel nie (sien afdeling 4.3).

Metode van toediening

LAURA word oraal toegedien.

LAURA kan met of sonder ‘n maaltyd geneem word.

4.3 Kontra-indikasies

Hipersensitiwiteit of idiosinkratiese reaksie teen loratadien of teen enige van die onaktiewe bestanddele gelys in afdeling 6.1.

Veiligheid van LAURA in die bejaarde is nie vasgestel nie.

Veiligheid en doeltreffendheid van LAURA in kinders onder die ouderdom van twee jaar is nie vasgestel nie

LAURA is teenaangedui in swangerskap en laktasie aangesien die veiligheid nie vasgestel is nie (sien afdeling 4.6).

4.4 Spesiale waarskuwings en voorsorgmaatreëls vir gebruik

LAURA ontbreek noemenswaardige sedatiewe effekte. Pasiënte moet egter gewaarsku word dat ‘n klein aantal individue sedasie mag ervaar. Dit word daarom aangeraai om die individuele respons te bepaal voordat bestuur word of ingewikkelde take uitgevoer word. Hierdie effek kan vererger word deur die gelyktydige inname van alkohol of ander sentrale senuweestelsel-onderdrukkers.

LAURA moet met omsigtigheid toegedien word aan pasiënte met ernstige lewerinkorting aangesien hulle ‘n verlaagde opruiming van loratadien mag hê. ‘n Laer aanvangsdosis van 5 mg een keer per dag of 10 mg elke alternatiewe dag word aanbeveel vir sulke pasiënte.

LAURA moet vir ten minste twee dae (48 uur) onttrek word voor veltoets-prosedures uitgevoer word, aangesien dit andersins positiewe reaksies vir velreaktiwiteits-indikatore mag voorkom of verminder.

Geriatriese pasiënte: Sien afdeling 4.3

Die gebruik van LAURA is geassosieer met die risiko van gewigstoename (sien afdeling 4.8).

Belangrike inligting oor onaktiewe bestanddele:

Laktose

LAURA bevat laktose. Pasiënte met seldsame oorerflike probleme van galaktose onverdraagsaamheid, totale laktase-tekort of glukose-galaktose wanabsorpsie moet nie hierdie medisyne gebruik nie.

4.5 Interaksie met ander medisyne en ander vorme van interaksie

Medisyne/laboratorium toetsinteraksies

LAURA moet vir ongeveer twee dae voor veltoetsprosedures onttrek word, aangesien dit andersins postiewe reaksies teen velreaktiwiteits-indikatore kan voorkom of verminder (see afdeling 4.4).

Wanneer gelyktydig met alkohol toegedien word, het LAURA geen kragtige effekte nie. Die gelyktydige gebruik van oormatige hoeveelhede alkohol moet egter vermy word (sien afdeling 4.4).

Versigtigheid moet uitgeoefen word wanneer ander medisyne wat bekend is om hepatiese mikrosomale ensieme te inhibeer saam met LAURA toegedien word. Medisyne wat bekend is om òf P450 3A4 òf P450 2D6 te inhibeer is kinidien, flukonasool of fluoksetien.

‘n Toename in plasmakonsentrasies van loratadien is aangemeld in gekontrolleerde kliniese proewe na gelyktydige gebruik met ketokonasool, eritromisien of simetidien, maar sonder betekenisvolle kliniese veranderinge (insluitend elektrokardiografiese veranderinge).

Ander medisyne wat bekend is om hepatiese metabolisme te inhibeer, moet met omsigtigheid saam met LAURA toegedien word totdat definitiewe interaksie-studies voltooi kan word of in die afwesigheid van formele interaksie-studies.

4.6 Fertiliteit, swangerskap en laktasie

Teenaangedui in swangerskap en laktasie (sien afdeling 4.3).

Fertiliteit

Daar is geen fertiliteitsdata beskikbaar nie.

4.7 Effekte op die vermoë om te betsuur en masjinerie te gebruik

LAURA ontbreek noemenswaardige sedatiewe effekte. ‘n Paar pasiënte wat met nie-sederende antihistamiene soos LAURA behandel is, het egter lomerigheid ervaar. Dit is daarom verstandig om versigtigheid uit te oefen voordat bestuur word of masjinerie hanteer word; die effek van LAURA op ‘n besondere pasiënt kan na die eerste paar dosisse bepaal word. Hierdie effek kan vererger word deur die gelyktydige inname van alkohol of ander sentrale senuweestelsel-onderdrukkers.

4.8 Ongewenste effekte

Getabulleerde lys van ongunstige reaksies

MedDRA Sisteem orgaanklas	**Voorkoms**	**Ongunstige reaksies**
Bloed- en limfatiese stelselversteurings	Minder dikwels	Trombositopenie
Immuunstelselversteurings	Minder dikwels	Hipersensitiwiteitsreaksies (insluitend veluitslag, brongospasma, angio-edeem en anafilakse) en kruissensitiwiteit
Psigiatriese versteurings	Dikwels	Slapeloosheid, senuweeagtigheid
	Minder dikwels	Depressie
Senuweestelselversteurings	Dikwels	Hoofpyn, slaperigheid
	Minder dikwels	Duiseligheid, konvulsies, sweet, parestesie, ekstrapiramidale effekte, bewerigheid, slaapversteurings
Kardiale versteurings	Minder dikwels	Tagikardie, palpitasies en disritmieë, insluitend ventrikulêre en supraventrikulêre disritmieë; hipotensie
Oor- en labirintversteurings	Minder dikwels	Tinnitus
Gastroïntestinale versteurings	Dikwels	Verhoogde aptyt
	Minder dikwels	Naarheid, braking, diaree, droë mond, gastritis, of epigastriese pyn, anoreksie

Hepato-biliêre versteurings	Minder dikwels	Abnormale lewerfunksies, insluitend geelsug en hepatitis
Vel-en subkutane weefselversteurings	Minder dikwels	Uitslag, alopesie
Muskuloskeletale en bindweefselversteurings	Minder dikwels	Mialgie
Algemene versteurings en toedienplektoestande	Dikwels	Uitputting
Ondersoeke	Voorkoms onbekend	Gewigstoename

Aanmelding van vermoedelike ongunstige reaksies

Aaanmelding van vermoedelike ongewenste reaksies na goedkeuring van die medisyne is belangrik. Dit verseker voortdurende monitering van die voordeel/risiko-balans van die medisyne. Gesondheidsorgvoorsieners word versoek om enige vermoedelike ongewenste reaksies by SAHPRA aan te meld *via* die "**6.04 Adverse Drug Reactions Reporting Form**", wat aanlyn beskikbaar is onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.

4.9 Oordosis

Oordosering met loratadien kan in enige van die simptome soos beskryf onder afdeling 4.8 manifesteer. Daar is geen spesifieke teenmiddel vir loratadien nie. In die geval van oordosering, moet onmiddellik met simptomatiese en ondersteunende behandeling begin word.

Oorweeg standaard maatreëls om enige ongeabsorbeerde medisyne in die maag te verwyder, soos adsorpsie deur geaktiveerde houtskool toegedien as 'n suspensie met water. Die toediening van maagspoeling moet oorweeg word.

0,9 % Natriumchloriedoplossing is die maagspoelingsoplossing van keuse veral in kinders.

In volwassenes kan kraanwater gebruik word; so veel as moontlik van die toegediende hoeveelheid moet egter verwyder word voor die volgende instillasie. Natriumchloried of soutkatartika onttrek water deur osmose in die derms in en kan daarom waardevol wees vir hulle werking van vinnige verdunning van die derminhoud.

Loratadien is nie dialiseerbaar nie. Na noodbehandeling, moet die pasiënt steeds onder mediese toesig wees.

5. FARMAKOLOGIESE EIENSKAPPE

5.1 Farmakodinamiese eienskappe

A 5.7.1 Antihistaminika.

Loratadien is 'n langwerkende trisikliese antihistamien met selektiewe periferale H_1-reseptor antagonistiese aktiwiteit en geen sentrale sedatiewe of anticholinergiese effekte nie. Dit werk deur mededinging met histamien vir H_1-reseptorliggings op effektorselle. Loratadien voorkom hierdeur, maar keer nie response om wat alleen deur histamien bemiddel is nie.

5.2 Farmakokinetiese eienskappe

Absorpsie

Loratadien word goed na orale toediening vanuit die gastro-intestinale weg geabsorbeer.

Biobeskikbaarheid word verhoog wanneer met voedsel toegedien word.

Biotransformasie

Die hoofmetaboliet, deskarboëtoksiloratadien, het histamien-H1-blokkerende aktiwiteit. Aangemelde halfleeftye vir loratadien en deskarboëtoksiloratadien is 8 ± 6 uur en 18 ± 6 uur, onderskeidelik.

Verspreiding

Loratadien is ongeveer 97 % gebonde aan plasmaproteïene; deskarboëtoksiloratadien is minder uitgebreid gebonde (73-77 %). Die volume van verspreiding is ongeveer 120 ± 80 L/kg. Loratadien en sy metaboliete word in borsmelk waargeneem, maar dit wil nie voorkom asof dit die bloed-breinskans tot 'n noemenswaardige mate oorsteek nie.

Eliminasie

Loratadien en sy metaboliete word in die urine en feses uitgeskei.

6. FARMASEUTIESE EIENSKAPPE

6.1 Lys van onaktiewe bestanddele

Laktosemonohidraat

Mieliestysel

Voorafgegelatiniseerde stysel

Magnesiumstearaat

6.2 Onverenigbaarhede

Nie van toepassing nie.

6.3 Rakleeftyd

24 maande.

6.4 Spesiale voorsorgmaatreëls vir bewaring

Bewaar by of onder 25 °C, beskerm teen vog.

6.5 Aard en 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.

7. HOUER VAN DIE REGISTRASIESERTIFIKAAT

Ranbaxy Pharmaceuticals (Pty) Ltd.

‘n Sun Pharma maatskappy

Lautreweg 14, Stormill, Uitbreiding 1

Roodepoort, 1724

Suid-Afrika

8. REGISTRASIENOMMER

36/5.7.1/0232

9. DATUM VAN EERSTE GOEDKEURING/HERNUWING VAN DIE GOEDKEURING

24 Oktober 2003

10. DATUM VAN HERSIENING VAN DIE TEKS

15 Augustus 2022

Botswana:

S2 Reg. nr.: BOT0700980

Namibië:

NS1 Reg. nr.: 07/5.7.1/0036