



Lacosamide Film Coated Tablets Ph.Eur.

Section D: Label (Mock-up) For Immediate Container, Outer Carton, Proposed Package Insert,
Consumer Medication Information Leaflet (RiMUP)

D3. Proposed Package Insert

Enclosed on subsequent page:

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

NAME OF THE MEDICINAL PRODUCT

Lacasa 50 Lacosamide Film Coated Tablets Ph. Eur 50 mg

Lacasa 100 Lacosamide Film Coated Tablets Ph. Eur 100 mg

Lacasa 200 Lacosamide Film Coated Tablets Ph. Eur 200 mg

QUALITATIVE AND QUANTITATIVE COMPOSITION

Lacosamide Tablets Ph.Eur. 50mg

Composition:

Each film coated tablet contains:

Lacosamide Ph.Eur 50 mg

Excipients q.s.

Lacosamide Tablets Ph.Eur. 100mg

Composition:

Each film coated tablet contains:

Lacosamide Ph.Eur 100 mg

Excipients q.s.

Lacosamide Tablets Ph.Eur. 200mg

Composition:

Each film coated tablet contains:

Lacosamide Ph.Eur 200 mg

Excipients q.s.

For the complete excipients list, see section List of Excipients.

PHARMACEUTICAL FORM

Film Coated Tablet

DESCRIPTION

Lacosamide Tablets Ph.Eur. 50mg

White to off white, beveled edge, oval shaped film coated tablets debossed with '787' on one side and plain on the other side. The tablets should be free from any physical defects.

Lacosamide Tablets Ph.Eur. 100mg

Light yellow to yellow colored, beveled edge, oval shaped film coated tablets debossed with '788' on one side and plain on the other side. The tablets should be free from any physical defects.

Lacosamide Tablets Ph.Eur. 200mg

Light blue to blue color, beveled edge, oval shaped film coated tablets debossed with '790' on one side and plain on the other side. The tablets should be free from any physical defects.

CLINICAL PARTICULARS**Therapeutic indications**

Lacosamide tablets is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in patients with epilepsy aged 18 years and older.

Posology and method of administrationPosology

Lacosamide Tablets must be taken twice a day. The recommended starting dose is 50 mg twice a day which should be increased to an initial therapeutic dose of 100 mg twice a day after one week.

Depending on response and tolerability, the maintenance dose can be further increased by 50 mg twice a day every week, to a maximum recommended daily dose of 400 mg (200 mg twice a day). Lacosamide Tablets may be taken with or without food.

In accordance with current clinical practice, if Lacosamide Tablets has to be discontinued, it is recommended this be done gradually (e.g. taper the daily dose by 200 mg/week).

Special populations*Renal impairment*

No dose adjustment is necessary in mildly and moderately renally impaired patients (CLCR >30 ml/min). A maximum dose of 250 mg/day is recommended for patients with severe renal impairment (CLCR ≤30 ml/min) and in patients with end stage renal disease. For patients requiring haemodialysis a supplement of up to 50% of the divided daily dose directly after the end of haemodialysis is recommended. Treatment of patients with endstage renal disease should be made with caution as there is little clinical experience and accumulation of a metabolite (with

no known pharmacological activity). In all patients with renal impairment, the dose titration should be performed with caution.

Hepatic impairment

No dose adjustment is needed for patients with mild to moderate hepatic impairment. The dose titration in these patients should be performed with caution considering co-existing renal impairment. The pharmacokinetics of lacosamide has not been evaluated in severely hepatic impaired patients.

Elderly (over 65 years of age)

No dose reduction is necessary in elderly patients. The experience with lacosamide in elderly patients with epilepsy is limited. Age associated decreased renal clearance with an increase in AUC levels should be considered in elderly patients.

Paediatric population

Lacosamide Tablets is not recommended for use in paediatric patients below the age of 18 as there is no data on safety and efficacy in these age groups.

Method of administration

Lacosamide film-coated tablets are for oral use. Lacosamide may be taken with or without food.

Contraindications

Hypersensitivity to the active substance or to any of the excipients of this product.

Known second- or third-degree atrioventricular (AV) block.

Special warnings and precautions for use

Suicidal ideation and behaviour

Suicidal ideation and behaviour have been reported in patients treated with antiepileptic medicinal products in several indications. A meta-analysis of randomised placebo-controlled clinical studies of antiepileptic medicinal products has also shown a small increased risk of suicidal ideation and behaviour. The mechanism of this risk is not known and the available data do not exclude the possibility of an increased risk for lacosamide.

Therefore, patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.

Cardiac rhythm and conduction

Dose-related prolongations in PR interval with lacosamide have been observed in clinical studies. Lacosamide should be used with caution in patients with underlying proarrhythmic conditions such as patients with known cardiac conduction problems or severe cardiac disease (e.g. myocardial ischaemia/infarction, heart failure, structural heart disease or cardiac sodium channelopathies) or patients treated with medicinal products affecting cardiac conduction, including antiarrhythmics and sodium channel blocking antiepileptic medicinal products, as well as in elderly patients.

In these patients it should be considered to perform an ECG before a lacosamide dose increase above 400 mg/day and after lacosamide is titrated to steady-state.

In the placebo-controlled clinical studies of lacosamide in epilepsy patients, atrial fibrillation or flutter were not reported; however, both have been reported in open-label epilepsy studies and in post-marketing experience.

In post-marketing experience, AV block (including second degree or higher AV block) has been reported. In patients with proarrhythmic conditions, ventricular tachyarrhythmia has been reported. In rare cases, these events have led to asystole, cardiac arrest and death in patients with underlying proarrhythmic conditions.

Patients should be made aware of the symptoms of cardiac arrhythmia (e.g. slow, rapid or irregular pulse, palpitations, shortness of breath, feeling lightheaded, fainting). Patients should be counselled to seek immediate medical advice if these symptoms occur.

Dizziness

Treatment with lacosamide has been associated with dizziness which could increase the occurrence of accidental injury or falls. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicine.

Potential for new onset or worsening of myoclonic seizures

New onset or worsening of myoclonic seizures has been reported in both adult and paediatric patients with PGTCS, in particular during titration. In patients with more than one seizure type, the observed benefit of control for one seizure type should be weighed against any observed worsening in another seizure type.

Potential for electro-clinical worsening in specific paediatric epilepsy syndromes

The safety and efficacy of lacosamide in paediatric patients with epilepsy syndromes in which focal and generalised seizures may coexist have not been determined.

Interaction with other medicinal products and other forms of interaction

Lacosamide should be used with caution in patients treated with medicinal products known to be associated with PR prolongation (including sodium channel blocking antiepileptic medicinal products) and in patients treated with antiarrhythmics. However, subgroup analysis in clinical studies did not identify an increased magnitude of PR prolongation in patients with concomitant administration of carbamazepine or lamotrigine.

In vitro data

Data generally suggest that lacosamide has a low interaction potential. In vitro studies indicate that the enzymes CYP1A2, CYP2B6, and CYP2C9 are not induced and that CYP1A1, CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2D6, and CYP2E1 are not inhibited by lacosamide at plasma concentrations observed in clinical studies. An in vitro study indicated that lacosamide is not transported by P-glycoprotein in the intestine. In vitro data show that CYP2C9, CYP2C19 and CYP3A4 are capable of catalysing the formation of the O-desmethyl metabolite.

In vivo data

Lacosamide does not inhibit or induce CYP2C19 and CYP3A4 to a clinically relevant extent. Lacosamide did not affect the AUC of midazolam (metabolised by CYP3A4, lacosamide given 200 mg twice a day), but C_{max} of midazolam was slightly increased (30 %). Lacosamide did not affect the pharmacokinetics of omeprazole (metabolised by CYP2C19 and CYP3A4, lacosamide given 300 mg twice a day).

The CYP2C19 inhibitor omeprazole (40 mg once daily) did not give rise to a clinically significant change in lacosamide exposure. Thus, moderate inhibitors of CYP2C19 are unlikely to affect systemic lacosamide exposure to a clinically relevant extent.

Caution is recommended in concomitant treatment with strong inhibitors of CYP2C9 (e.g. fluconazole) and CYP3A4 (e.g. itraconazole, ketoconazole, ritonavir, clarithromycin), which may lead to increased systemic exposure of lacosamide. Such interactions have not been established in vivo, but are possible based on in vitro data.

Strong enzyme inducers such as rifampicin or St John's wort (*Hypericum perforatum*) may moderately reduce the systemic exposure of lacosamide. Therefore, starting or ending treatment with these enzyme inducers should be done with caution.

Antiepileptic medicinal products

In interaction studies lacosamide did not significantly affect the plasma concentrations of carbamazepine and valproic acid. Lacosamide plasma concentrations were not affected by carbamazepine and by valproic acid. Population pharmacokinetic analyses in different age groups estimated that concomitant treatment with other antiepileptic medicinal products known to be enzyme inducers (carbamazepine, phenytoin, phenobarbital, in various doses) decreased the overall systemic exposure of lacosamide by 25 % in adults and 17 % in paediatric patients.

Oral contraceptives

In an interaction study there was no clinically relevant interaction between lacosamide and the oral contraceptives ethinylestradiol and levonorgestrel. Progesterone concentrations were not affected when the medicinal products were co-administered.

Others

Interaction studies showed that lacosamide had no effect on the pharmacokinetics of digoxin. There was no clinically relevant interaction between lacosamide and metformin.

Co-administration of warfarin with lacosamide does not result in a clinically relevant change in the pharmacokinetics and pharmacodynamics of warfarin.

Although no pharmacokinetic data on the interaction of lacosamide with alcohol are available, a pharmacodynamic effect cannot be excluded.

Lacosamide has a low protein binding of less than 15 %. Therefore, clinically relevant interactions with other medicinal products through competition for protein binding sites are considered unlikely.

Fertility, pregnancy and lactation

Pregnancy

Risk related to epilepsy and antiepileptic medicinal products in general

For all antiepileptic medicinal products, it has been shown that in the offspring of treated women with epilepsy, the prevalence of malformations is two to three times greater than the rate of approximately 3 % in the general population. In the treated population, an increase in malformations has been noted with polytherapy, however, the extent to which the treatment and/or the illness is responsible has not been elucidated.

Moreover, effective antiepileptic therapy must not be interrupted, since the aggravation of the illness is detrimental to both the mother and the foetus.

Risk related to lacosamide

There are no adequate data from the use of lacosamide in pregnant women. Studies in animals did not indicate any teratogenic effects in rats or rabbits, but embryotoxicity was observed in rats and rabbits at maternal toxic doses. The potential risk for humans is unknown. Lacosamide should not be used during pregnancy unless clearly necessary (if the benefit to the mother clearly outweighs the potential risk to the foetus). If women decide to become pregnant, the use of this product should be carefully re-evaluated.

Breastfeeding

It is unknown whether lacosamide is excreted in human breast milk. A risk to the newborns/infants cannot be excluded. Animal studies have shown excretion of lacosamide in breast milk. For precautionary measures, breast-feeding should be discontinued during treatment with lacosamide.

Fertility

No adverse reactions on male or female fertility or reproduction were observed in rats at doses producing plasma exposures (AUC) up to approximately 2 times the plasma AUC in humans at the maximum recommended human dose (MRHD)

Effects on ability to drive and use machines

Lacosamide has minor to moderate influence on the ability to drive and use machines. Lacosamide treatment has been associated with dizziness or blurred vision.

Accordingly, patients should be advised not to drive or to operate other potentially hazardous machinery until they are familiar with the effects of lacosamide on their ability to perform such activities.

Undesirable effects

Tabulated list of adverse reactions

The table below shows the frequencies of adverse reactions which have been reported in clinical studies and post-marketing experience. The frequencies are defined as follows: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$) and not known (frequency cannot be estimated from available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System organ class	Very common	Common	Uncommon	Not known
Blood and lymphatic disorders				Agranulocytosis ⁽¹⁾
Immune system disorders			Drug hypersensitivity ⁽¹⁾	Drug reaction with eosinophilia and systemic symptoms (DRESS) ^(1,2)
Psychiatric disorders		Depression Confusional state Insomnia ⁽¹⁾	Aggression ⁽¹⁾ Agitation ⁽¹⁾ Euphoric mood ⁽¹⁾ Psychotic disorder ⁽¹⁾ Suicide attempt ⁽¹⁾ Suicidal ideation Hallucination ⁽¹⁾	
Nervous system disorders	Dizziness Headache	Myoclonic seizures ⁽³⁾ Ataxia Balance disorder Memory impairment Cognitive disorder Somnolence Tremor Nystagmus Hypoesthesia Dysarthria Disturbance in attention Paraesthesia	Syncope ⁽²⁾ Coordination abnormal Dyskinesia	Convulsion

Eye disorders	Diplopia	Vision blurred		
Ear and labyrinth disorders		Vertigo Tinnitus		
Cardiac disorders			Atrioventricular block ^(1,2) Bradycardia ^(1,2) Atrial Fibrillation ^(1,2) Atrial Flutter ^(1,2)	Ventricular tachyarrhythmia ⁽¹⁾
Gastrointestinal disorders	Nausea	Vomiting Constipation Flatulence Dyspepsia Dry mouth Diarrhoea		
Hepatobiliary disorders			Liver function test abnormal ⁽²⁾ Hepatic enzyme increased (> 2x ULN) ⁽¹⁾	
Skin and subcutaneous tissue disorders		Pruritus Rash ⁽¹⁾	Angioedema ⁽¹⁾ Urticaria ⁽¹⁾	Stevens-Johnson syndrome ⁽¹⁾ Toxic epidermal necrolysis ⁽¹⁾
Musculoskeletal and connective tissue disorders		Muscle spasms		
General disorders and administration site conditions		Gait disturbance Asthenia Fatigue Irritability Feeling drunk		
Injury, poisoning and procedural complications		Fall Skin laceration Contusion		

1. Adverse reactions reported in post marketing experience.
2. See Description of selected adverse reactions.
3. Reported in PGTCS studies.

Description of selected adverse reactions

The use of lacosamide is associated with dose-related increase in the PR interval. Adverse reactions associated with PR interval prolongation (e.g. atrioventricular block, syncope, bradycardia) may occur.

In adjunctive clinical studies in epilepsy patients, the incidence rate of reported first-degree AV Block is uncommon, 0.7 %, 0 %, 0.5 % and 0 % for lacosamide 200 mg, 400 mg, 600 mg or placebo, respectively. No second- or higher degree AV Block was seen in these studies. However, cases with second- and third-degree AV Block associated with lacosamide treatment have been

reported in post-marketing experience. In the monotherapy clinical study comparing lacosamide to carbamazepine CR, the extent of increase in PR interval was comparable between lacosamide and carbamazepine.

The incidence rate for syncope reported in pooled adjunctive therapy clinical studies is uncommon and did not differ between lacosamide (n=944) treated epilepsy patients (0.1 %) and placebo (n=364) treated epilepsy patients (0.3 %). In the monotherapy clinical study comparing lacosamide to carbamazepine CR, syncope was reported in 7/444 (1.6 %) lacosamide patients and in 1/442 (0.2 %) carbamazepine CR patients.

Atrial fibrillation or flutter were not reported in short term clinical studies; however, both have been reported in open-label epilepsy studies and in post-marketing experience.

Laboratory abnormalities

Abnormalities in liver function tests have been observed in placebo-controlled studies with lacosamide in adult patients with partial-onset seizures who were taking 1 to 3 concomitant antiepileptic medicinal products. Elevations of ALT to ≥ 3 x ULN occurred in 0.7 % (7/935) of Lacosamide patients and 0 % (0/356) of placebo patients.

Multiorgan hypersensitivity reactions

Multiorgan hypersensitivity reactions (also known as Drug Reaction with Eosinophilia and Systemic Symptoms, DRESS) have been reported in patients treated with some antiepileptic medicinal products. These reactions are variable in expression, but typically present with fever and rash and can be associated with involvement of different organ systems. If multiorgan hypersensitivity reaction is suspected, lacosamide should be discontinued.

Paediatric population

The safety profile of lacosamide in placebo controlled (255 patients from 1 month to less than 4 years of age and 343 patients from 4 years to less than 17 years of age) and in open-label clinical studies (n=847 patients from 1 month to less than or equal to 18 years of age) in adjunctive therapy in paediatric patients with partial onset seizures was consistent with the safety profile observed in adults. As data available in paediatric patients younger than 2 years of age is limited, lacosamide is not indicated in this age range.

The additional adverse reactions observed in the paediatric population were pyrexia, (nasopharyngitis, pharyngitis, decreased appetite, abnormal behaviour) and lethargy.

Somnolence was reported more frequently in the paediatric population ($\geq 1/10$) compared to the adult population ($\geq 1/100$ to $< 1/10$).

Elderly population

In the monotherapy study comparing lacosamide to carbamazepine CR, the types of adverse reactions related to lacosamide in elderly patients (≥ 65 years of age) appear to be similar to that observed in patients less than 65 years of age. However, a higher incidence ($\geq 5\%$ difference) of fall, diarrhoea and tremor has been reported in elderly patients compared to younger adult patients. The most frequent cardiac-related adverse reaction reported in elderly compared to the younger adult population was first-degree AV block. This was reported with lacosamide in 4.8 % (3/62) in elderly patients versus 1.6 % (6/382) in younger adult patients. The discontinuation rate due to adverse events observed with lacosamide was 21.0 % (13/62) in elderly patients versus 9.2 % (35/382) in younger adult patients. These differences between elderly and younger adult patients were similar to those observed in the active comparator group.

Overdose

Symptoms

Symptoms observed after an accidental or intentional overdose of lacosamide are primarily associated with CNS and gastrointestinal system.

- The types of adverse reactions experienced by patients exposed to doses above 400 mg up to 800 mg were not clinically different from those of patients administered recommended doses of lacosamide.
- Reactions reported after an intake of more than 800 mg are dizziness, nausea, vomiting, seizures (generalised tonic-clonic seizures, status epilepticus). Cardiac conduction disorders, shock and coma have also been observed. Fatalities have been reported in patients following an intake of acute single overdose of several grams of lacosamide.

Management

There is no specific antidote for overdose with lacosamide. Treatment of lacosamide overdose should include general supportive measures and may include haemodialysis if necessary.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: antiepileptics, other antiepileptics, ATC code: N03AX18

Mechanism of action

The active substance, lacosamide (R-2-acetamido-N-benzyl-3-methoxypropionamide) is a functionalised amino acid.

The precise mechanism by which lacosamide exerts its antiepileptic effect in humans remains to be fully elucidated. *In vitro* electrophysiological studies have shown that lacosamide selectively enhances slow inactivation of voltage-gated sodium channels, resulting in stabilization of hyperexcitable neuronal membranes.

Pharmacodynamic effects

Lacosamide protected against seizures in a broad range of animal models of partial and primary generalised seizures and delayed kindling development.

In non-clinical experiments lacosamide in combination with levetiracetam, carbamazepine, phenytoin, valproate, lamotrigine, topiramate or gabapentin showed synergistic or additive anticonvulsant effects.

Pharmacokinetic properties

Absorption

Lacosamide is rapidly and completely absorbed after oral administration. The oral bioavailability of lacosamide tablets is approximately 100 %. Following oral administration, the plasma concentration of unchanged lacosamide increases rapidly and reaches C_{max} about 0.5 to 4 hours post-dose. Food does not affect the rate and extent of absorption.

Distribution

The volume of distribution is approximately 0.6 L/kg. Lacosamide is less than 15 % bound to plasma proteins.

Biotransformation

95 % of the dose is excreted in the urine as lacosamide and metabolites. The metabolism of lacosamide has not been completely characterised.

The major compounds excreted in urine are unchanged lacosamide (approximately 40 % of the dose) and its O-desmethyl metabolite less than 30 %.

A polar fraction proposed to be serine derivatives accounted for approximately 20 % in urine, but was detected only in small amounts (0-2 %) in human plasma of some subjects. Small amounts (0.5-2 %) of additional metabolites were found in the urine.

In vitro data show that CYP2C9, CYP2C19 and CYP3A4 are capable of catalysing the formation of the O-desmethyl metabolite but the main contributing isoenzyme has not been confirmed in vivo. No clinically relevant difference in lacosamide exposure was observed comparing its pharmacokinetics in extensive metabolisers (EMs, with a functional CYP2C19) and poor metabolisers (PMs, lacking a functional CYP2C19).

Furthermore an interaction study with omeprazole (CYP2C19-inhibitor) demonstrated no clinically relevant changes in lacosamide plasma concentrations indicating that the importance of this pathway is minor. The plasma concentration of O-desmethyl-lacosamide is approximately 15 % of the concentration of lacosamide in plasma. This major metabolite has no known pharmacological activity.

Elimination

Lacosamide is primarily eliminated from the systemic circulation by renal excretion and biotransformation. After oral and intravenous administration of radiolabeled lacosamide, approximately 95 % of radioactivity administered was recovered in the urine and less than 0.5 % in the faeces. The elimination half-life of lacosamide is approximately 13 hours. The pharmacokinetics is dose-proportional and constant over time, with low intra- and inter-subject variability. Following twice daily dosing, steady state plasma concentrations are achieved after a 3 day period. The plasma concentration increases with an accumulation factor of approximately 2.

A single loading dose of 200 mg approximates steady-state concentrations comparable to 100 mg twice daily oral administration.

Pharmacokinetics in special patient groups

Gender

Clinical studies indicate that gender does not have a clinically significant influence on the plasma concentrations of lacosamide.

Renal impairment

The AUC of lacosamide was increased by approximately 30 % in mildly and moderately and 60 % in severely renal impaired patients and patients with end-stage renal disease requiring haemodialysis compared to healthy subjects, whereas C_{max} was unaffected.

Lacosamide is effectively removed from plasma by haemodialysis. Following a 4-hour haemodialysis treatment, AUC of lacosamide is reduced by approximately 50 %. Therefore, dosage supplementation following haemodialysis is recommended. The exposure of the O-

desmethyl metabolite was several-fold increased in patients with moderate and severe renal impairment. In absence of haemodialysis in patients with end-stage renal disease, the levels were increased and continuously rising during the 24-hour sampling. It is unknown whether the increased metabolite exposure in end-stage renal disease subjects could give rise to adverse effects but no pharmacological activity of the metabolite has been identified.

Hepatic impairment

Subjects with moderate hepatic impairment (Child-Pugh B) showed higher plasma concentrations of lacosamide (approximately 50 % higher AUC_{norm}). The higher exposure was partly due to a reduced renal function in the studied subjects. The decrease in non-renal clearance in the patients of the study was estimated to give a 20 % increase in the AUC of lacosamide. The pharmacokinetics of lacosamide has not been evaluated in severe hepatic impairment.

Elderly (over 65 years of age)

In a study in elderly men and women including 4 patients > 75 years of age, AUC was about 30 and 50 % increased compared to young men, respectively. This is partly related to lower body weight. The body weight normalized difference is 26 and 23 %, respectively. An increased variability in exposure was also observed. The renal clearance of lacosamide was only slightly reduced in elderly subjects in this study.

A general dose reduction is not considered to be necessary unless indicated due to reduced renal function.

Paediatric population

The paediatric pharmacokinetic profile of lacosamide was determined in a population pharmacokinetic analysis using sparse plasma concentration data obtained in six placebo-controlled randomised clinical studies and five open-label studies in 1655 adult and paediatric patients with epilepsy aged 1 month to 17 years. Three of these studies were performed in adults, 7 in pediatric patients, and 1 in a mixed population. The administered lacosamide doses ranged from 2 to 17.8 mg/kg/day in twice daily intake, not to exceed 600 mg/day.

The typical plasma clearance was estimated to be 0.46 L/h, 0.81 L/h, 1.03 L/h and 1.34 L/h for paediatric patients weighing 10 kg, 20 kg, 30 kg and 50 kg respectively. In comparison, plasma clearance was estimated at 1.74 L/h in adults (70 kg body weight).

Population pharmacokinetic analysis using sparse pharmacokinetic samples from PGTCS study showed a similar exposure in patients with PGTCS and in patients with partial-onset seizures.

Pharmaceutical particulars:**List of Excipients:**

Microcrystalline Cellulose 101

Crospovidone (Type-B)

Hydroxypropyl Cellulose

Purified water

Colloidal silicon dioxide

Microcrystalline Cellulose 102

Magnesium stearate

Opadry White 03F58750 (for Lacasa 50mg) (Hypromellose, Titanium Dioxide, Macrogol & Talc)

Opadry Yellow 03F520087 (for Lacasa 100mg) (Hypromellose, Titanium Dioxide, Macrogol, Talc, Iron Oxide Yellow & Iron Oxide Red)

Opadry Blue 03F505020 (for Lacasa 200mg) (Hypromellose, Titanium Dioxide, Macrogol, Talc, FD&C Blue #2/Indigo Carmine Aluminum lake, Iron Oxide Red, FD&C Blue #2/Indigo Carmine AL3% - 5% & FD&C Blue #1/Brilliant Blue FCF aluminum lake)

Incompatibilities

Not applicable

Shelf Life

24 Months

Storage

Do not store above 30°C.

Keep out of the reach of children.

Nature and contents of container

Lacasa 50 mg

Each Alu-PVC/PVDC blister contains 10 tablets and such 6 blisters packed in carton along with the package insert.

Lacasa 100 mg

Each Alu-PVC/PVDC blister contains 10 tablets and such 6 blisters packed in carton along with the package insert.

Lacasa 200 mg

Each Alu-PVC/PVDC blister contains 10 tablets and such 6 blisters packed in carton along with the package insert.

Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

Manufactured by:

Zydus Lifesciences Limited

Survey No. 417, 419 & 420

Sarkhej - Bavla National Highway No.8 A,

Village - Moraiya, Taluka - Sanand,

Dist. - Ahmedabad - 382 210,

Gujarat State, INDIA.

Product Registration Holder:

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