FORMULATION:
Film-coated tablets
Each film-coated tablet contains 50 mg lacosamide.
Each film-coated tablet contains 100 mg lacosamide.
Each film-coated tablet contains 150 mg lacosamide.
Each film-coated tablet contains 200 mg lacosamide.

THERAPEUTIC INDICATIONS
• Lacosamide (Vimpat) is indicated as: monotherapy in the treatment of partial-onset seizures in patients with epilepsy aged 16 years and older
• Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in patients with epilepsy aged 16 years and older.

POSOLOGY
• Monotherapy
  Initial monotherapy
  Patients not currently being treated with antiepileptic drugs may have monotherapy initiated with lacosamide (Vimpat).
  The recommended starting dose is 100 mg twice a day (200 mg/day) which should be increased to a therapeutic dose of 150 mg twice a day (300 mg/day) after one week.
  Depending on response and tolerability, the dose can be further increased at weekly interval by 50 mg twice a day (100 mg/day), to a maximum recommended maintenance daily dose of 200 mg twice a day (400 mg/day).
  Conversion to monotherapy
  For patients who will convert to lacosamide (Vimpat) monotherapy, the recommended starting dose is 100 mg twice a day (200 mg/day) which should be increased to a therapeutic dose of 150 mg twice a day (300 mg/day) after one week.
  Depending on response and tolerability, the dose can be further increased at weekly interval by 50 mg twice a day (100 mg/day), to a maximum recommended maintenance daily dose of 200 mg twice a day (400 mg/day).
  The recommended maintenance daily dose should be maintained for at least 3 days before initiating conversion to lacosamide monotherapy. A gradual withdrawal of the concomitant antiepileptic drug over at least 6-weeks is recommended. If the patient is on more than one antiepileptic drug, the antiepileptic drugs should be withdrawn sequentially.
  Safety and efficacy of Lacosamide (Vimpat) have not been established for simultaneous conversion to monotherapy from two or more concomitant antiepileptic drugs.

• Adjunctive therapy
  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).

Initiation of lacosamide treatment with a loading dose
Lacosamide (Vimpat) treatment (i.e. for adjunctive therapy, initial monotherapy and conversion to monotherapy) may also
be initiated with a single loading dose of 200 mg, followed approximately 12 hours later by a 100 mg twice daily (200 mg/day) maintenance dose regimen. A loading dose should be administered under medical supervision with consideration of the lacosamide pharmacokinetics (see section Pharmacokinetic properties) and the potential for increased incidence of CNS adverse reactions (see section Undesirable effects). Administration of a loading dose has not been studied in acute conditions such as status epilepticus. 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).

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

Method of administration
Lacosamide (Vimpat) must be taken twice a day.
Lacosamide (Vimpat) therapy can be initiated with either oral or i.v. administration.
Lacosamide (Vimpat) solution for infusion is also an alternative for patients when oral administration is temporarily not feasible.
Lacosamide (Vimpat) may be taken with or without food.

Special population
Elderly population
No dose reduction is necessary in elderly patients.
The experience with lacosamide (Vimpat) in elderly patients with epilepsy is limited. Age associated decreased renal clearance with an increase in AUC levels should be considered in elderly patients (see ‘Use in patients with renal impairment’ above and section Pharmacokinetic properties).

Renal impairment
No dose adjustment is necessary in mildly and moderately renally impaired patients (CLCR >30 ml/min).
A maximum dose of 300 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 hemodialysis a supplement of up to 50% of the divided daily dose directly after the end of hemodialysis should be considered.
Treatment of patients with end-stage 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 (see section Pharmacokinetic properties).

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 (Vimpat) has not been evaluated in severely hepatic impaired patients (see section Pharmacokinetic properties).

Pediatric population
Lacosamide (Vimpat) is not recommended for use in children and adolescents below the age of 16 as there is no data on safety and efficacy in these age groups.

CONTRAINDICATION
Hypersensitivity to the active substance or to any of the excipients.

SPECIAL WARNINGS AND PRECAUTION FOR USE
Dizziness
Treatment with lacosamide (Vimpat) 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 (see section Undesirable effects).

Cardiac Rhythm and Conduction
Prolongations in PR interval with lacosamide (Vimpat) have been observed in clinical studies.
Lacosamide (Vimpat) should be used with caution in patients with known conduction problems or severe cardiac disease such as a history of myocardial infarction or heart failure.

Second degree or higher AV block has been reported in post-marketing experience. In the placebo-controlled trials of lacosamide in epilepsy patients, atrial fibrillation or flutter were not reported; however both have been reported in open-label epilepsy trials and in post-marketing experience (see section Undesirable effects).
Patients should be made aware of the symptoms of second-degree or higher AV block (e.g. slow or irregular pulse, feeling of lightheaded and fainting) and of the symptoms of atrial fibrillation and flutter (e.g. palpitations, rapid or irregular pulse, shortness of breath). Patients should be counseled to seek medical advice should any of these symptoms occur.

Suicidal ideation and behavior
Suicidal ideation and behavior have been reported in patients treated with anti-epileptic agents in several indications. A meta-analysis of randomized placebo controlled trials of anti-epileptic drugs has also shown a small increased risk of suicidal ideation and behavior. The mechanism of this risk is not known and the available data do not exclude the possibility of an increased risk for lacosamide (Vimpat).
Therefore patients should be monitored for signs of suicidal ideation and behaviors and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behavior emerge.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
Lacosamide (Vimpat) should be used with caution in patients treated with medicinal products known to be associated with PR prolongation (e.g. carbamazepine, lamotrigine, pregabalin) and in patients treated with class I antiarrhythmic drugs. However, subgroup analysis did not identify an increased magnitude of PR prolongation in patients with concomitant administration of carbamazepine or lamotrigine in clinical trials.

In vitro data
Data generally suggest that lacosamide (Vimpat) has a low interaction potential.
In vitro metabolism studies indicate that lacosamide (Vimpat) does not induce the enzyme activity of drug metabolizing cytochrome P450 isoforms CYP1A2, 2B6, 2C9, 2C19 and 3A4. Lacosamide (Vimpat) did not inhibit CYP 1A1, 1A2, 2A6, 2B6, 2C8, 2C9, 2D6, 2E1, 3A4/5 at plasma concentrations observed in clinical studies.
In vitro data suggest that lacosamide has the potential to inhibit CYP2C19 at therapeutic concentrations.
Lacosamide (Vimpat) was not a substrate or inhibitor for P-glycoprotein.

In vivo data
Clinical data indicate that lacosamide does not inhibit or induce CYP2C19 and 3A4.
Furthermore an interaction trial with omeprazole (CYP2C19-inhibitor) demonstrated no clinically relevant changes in Lacosamide (Vimpat) plasma concentrations and no inhibitory effect on omeprazole pharmacokinetics.

Antiepileptic drugs
In interaction trials Lacosamide (Vimpat) (400 mg/day) did not significantly affect the plasma concentrations of carbamazepine (400 mg/day) and valproic acid (600 mg/day). Lacosamide (Vimpat) plasma concentrations were not affected by carbamazepine and by valproic acid.

The placebo-controlled clinical studies in patients with partial-onset seizures showed that steady-state plasma concentrations of levetiracetam, carbamazepine, carbamazepine epoxide, lamotrigine, topiramate, oxcarbazepine monohydroxy derivative (MHD), phenytoin, valproic acid, phenobarbital, gabapentin, clonazepam, and zonisamide were not affected by concomitant
intake of Lacosamide (Vimpat) at anydose.
A population PK analysis estimated that concomitant treatment with other anti-epileptic drugs known to be enzyme inducers (carbamazepine, phenytoin, phenobarbital, in various doses) decreased the overall systemic exposure of Lacosamide (Vimpat) by 25%.

Oral contraceptives
In an interaction trial there was no clinically relevant interaction between Lacosamide (Vimpat) (400 mg/day) and the oral contraceptives ethinylestradiol (0.03 mg) and levonorgestrel (0.15 mg). Progesterone concentrations were not affected when the medicinal products were co-administered.

Others
Interaction trials showed that Lacosamide (Vimpat) (400 mg/day) had no effect on the pharmacokinetics of digoxin (0.5 mg once daily). There was no clinically relevant interaction between Lacosamide (Vimpat) (400 mg/day) and metformin (500 mg three times a day).
Omeprazole (40 mg once daily) increased the AUC of Lacosamide (Vimpat) by 19% (300 mg, single dose) and thus within accepted bioequivalence range. Therefore, the effect is considered as of no clinical relevance. Lacosamide (Vimpat) (600 mg/day) did not affect the single-dose pharmacokinetics of omeprazole (40 mg).
Co-administration of warfarin with Lacosamide (Vimpat) does not result in a clinically relevant change in the pharmacokinetic and pharmacodynamic effects of warfarin.

Protein binding
Lacosamide (Vimpat) has a low protein binding of less than 15%. Therefore, clinically relevant interactions with other drugs through competition for protein binding sites are considered unlikely.

FERTILITY, PREGNANCY AND LACTATION
Women of childbearing potential / Contraception in males and females
There was no clinically relevant interaction between Lacosamide (Vimpat) and oral contraceptives (ethinylestradiol and levonorgestrel) in clinical studies (see section Interaction with other medicinal products and other forms of interaction).

Pregnancy
There are no adequate data from the use of Lacosamide (Vimpat) 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 (Vimpat) should not be used during pregnancy unless clearly necessary (if the benefit to the mother clearly outweighs the potential risk to the fetus). If women decide to become pregnant, the use of this product should be carefully re-evaluated.

Lactation
It is unknown whether Lacosamide (Vimpat) is excreted in human breast milk. Animal studies have shown excretion of Lacosamide (Vimpat) in breast milk.
Because many drugs are excreted into human milk, a decision should be made whether to discontinue nursing or to discontinue Lacosamide (Vimpat), taking into account the importance of the drug to the mother.

Fertility
No adverse effects 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 MRHD.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Lacosamide (Vimpat) may have minor to moderate influence on the ability to drive and use machines. Lacosamide (Vimpat) treatment has been associated with dizziness or blurred vision. Accordingly, patients should be advised not to drive a car or to operate other potentially hazardous machinery until they are familiar with the effects of Lacosamide (Vimpat) on their
ability to perform such activities.

**UNDESIRABLE EFFECTS**

**Clinical studies**

- **Overview**
  Based on the analysis of pooled placebo-controlled clinical trials in adjunctive therapy in 1,308 patients with partial-onset seizures, a total of 61.9% of patients randomized to Lacosamide (Vimpat) and 35.2% of patients randomized to placebo reported at least 1 adverse reaction.
  The most frequently reported adverse reactions with Lacosamide (Vimpat) treatment were dizziness, headache, nausea and diplopia. They were usually mild to moderate in intensity. Some were dose-related and could be alleviated by reducing the dose.
  Incidence and severity of CNS and gastrointestinal adverse reactions usually decreased over time.
  Over all controlled studies, the discontinuation rate due to adverse reactions was 12.2% for patients randomized to Lacosamide (Vimpat) and 1.6% for patients randomized to placebo. The most common adverse reaction resulting in discontinuation of Lacosamide (Vimpat) therapy was dizziness.
  The safety profile of Lacosamide (Vimpat) reported in the conversion to monotherapy clinical trial was similar to the safety profile reported from the pooled placebo-controlled clinical trials in adjunctive therapy. The discontinuation rate due to adverse reactions was 16.2% for patients randomized to Lacosamide (Vimpat) at the recommended doses of 300 and 400 mg/day. The most common adverse reaction resulting in discontinuation of Lacosamide (Vimpat) therapy was dizziness. Dizziness, headache, nausea, somnolence, and fatigue were all reported at lower incidences during the antiepileptic drug withdrawal phase and monotherapy phase compared with the titration phase.

- **Listing of ADRs**
  The list below shows the frequencies of adverse reactions by system organ class which have been reported in clinical trials. The frequencies are defined as follows: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.
  **Psychiatric disorders**
  Common: depression, confusional state, insomnia
  **Nervous system disorders**
  Very Common: dizziness, headache
  Common: cognitive disorder, nystagmus, balance disorder, coordination abnormal, memory impairment, tremor, somnolence, dysarthria, disturbance in attention, hypoesthesia, paresthesia
  **Eye disorders**
  Very Common: diplopia
  Common: vision blurred
  **Ear and labyrinth disorders**
  Common: vertigo, tinnitus
  **Gastrointestinal disorders**
  Very Common: nausea
  Common: vomiting, constipation, flatulence, dyspepsia, dry mouth, diarrhea
  **Skin and subcutaneous tissue disorders**
  Common: pruritus
  **Musculoskeletal and connective tissue disorders**
  Common: muscle spasms
  **General disorders and administration site conditions**
  Common: gait disturbance, asthenia, fatigue, irritability, feeling drunk
  **Injury, poisoning and procedural complications**
  Common: fall, skin laceration, contusion
• **Description of selected adverse reactions**

The use of Lacosamide (Vimpat) 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 epilepsy patients the incidence rate of reported first degree AV Block is uncommon, 0.7%, 0%, 0.5% and 0% for Lacosamide (Vimpat) 200 mg, 400 mg, 600 mg or placebo, respectively. No second or higher degree AV Block was seen in Lacosamide (Vimpat) treated epilepsy patients. The incidence rate for syncope is uncommon and did not differ between Lacosamide (Vimpat) treated epilepsy patients (0.1%) and placebo treated epilepsy patients (0.3%).

In the short-term investigational trials of Lacosamide (Vimpat) in epilepsy patients, there were no cases of atrial fibrillation or flutter, however both have been reported in open-label epilepsy trials.

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

**Loading dose administration**

Incidence of CNS adverse reactions such as dizziness may be higher after a loading dose.

**Post-marketing experience**

In addition to the adverse reactions reported during clinical studies and listed above, the following adverse reactions have been reported in post-marketing experience. Data are insufficient to support an estimate of their incidence in the population to be treated.

**Blood and lymphatic system disorders**

Agranulocytosis,

**Immune system disorders**

Drug 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 agents. These reactions are variable in expression but typically present with fever and rash and can be associated with involvement of different organ systems. Potential cases have been reported rarely with Lacosamide (Vimpat) and if multiorgan hypersensitivity reaction is suspected, Lacosamide (Vimpat) should be discontinued.

**Psychiatric disorders**

Suicide attempt, suicidal ideation, psychotic disorder, hallucination, aggression, agitation, insomnia, euphoric mood

**Cardiac disorders**

Atrioventricular block, atrial flutter, atrial fibrillation, bradycardia

**Hepatobiliary disorders**

Liver function test abnormal

**Skin and subcutaneous tissue disorders**

Toxic epidermal necrolysis, Stevens-Johnson syndrome, angioedema, urticaria, rash

**OVERDOSE**

**Symptoms**

In clinical trials

The types of adverse events experienced by patients exposed to supratherapeutic doses were not clinically different from those of patients administered recommended doses of Lacosamide (Vimpat).

Following doses of 1200 mg/day, symptoms related to the central nervous system (dizziness) and the gastrointestinal system (nausea) were observed and resolved with dose adjustments. The highest reported overdose for Lacosamide (Vimpat) was 12000 mg taken in conjunction with toxic doses of multiple other antiepileptic drugs. The subject was initially comatose with AV block and then fully recovered without permanent sequelae.

In post-marketing experience

Following acute single overdoses ranging between 1000 mg and 12000 mg, seizures (generalized tonic-clonic seizures,
status epilepticus) and cardiac conduction disorders were observed. Fatal cardiac arrest was reported after an acute overdose of 7000 mg of Lacosamide (Vimpat) in a patient with cardiovascular risk factors.

Management
There is no specific antidote for overdose with Lacosamide (Vimpat). Treatment of Lacosamide (Vimpat) overdose should include general supportive measures and may include hemodialysis if necessary (see section Pharmacokinetic properties).

PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: Other antiepileptics, ATC code: N03AX18
The active substance, Lacosamide (Vimpat) (R-2-acetamido-N-benzyl-3-methoxypropionamide) is a functionalized amino acid.

Mechanism of action
The precise mechanism by which Lacosamide (Vimpat) exerts its antiepileptic effect in humans remains to be fully elucidated.

In vitro electrophysiological studies have shown that Lacosamide (Vimpat) selectively enhances slow inactivation of voltage-gated sodium channels, resulting in stabilization of hyperexcitable neuronal membranes.

Pharmacodynamics
Lacosamide (Vimpat) protected against seizures in a broad range of animal models of partial and primary generalized seizures and delayed kindling development. In non-clinical experiments Lacosamide (Vimpat) in combination with levetiracetam, carbamazepine, phenytoin, valproate, lamotrigine, topiramate or gabapentin showed synergistic or additive anticonvulsant effects.

Cardiac Electrophysiology
Electrocardiographic effects of Lacosamide (Vimpat) were determined in a double-blind, randomized clinical pharmacology trial of 247 healthy subjects. Chronic oral doses of 400 and 800 mg/day were compared with placebo and a positive control (400 mg moxifloxacin). Lacosamide (Vimpat) did not prolong QTc interval and did not have a dose-related or clinically important effect on QRS duration. Lacosamide (Vimpat) produced a small, dose-related increase in mean PR interval. At steady-state, the time of the maximum observed mean PR interval corresponded with tmax. The placebo-subtracted maximum increase in PR interval (at tmax) was 7.3 ms for the 400 mg/day group and 11.9 ms for the 800 mg/day group. For patients who participated in the controlled trials, the placebo-subtracted mean maximum increase in PR interval for a 400 mg/day Lacosamide (Vimpat) dose was 3.1 ms in patients with partial-onset seizures and 9.4 ms for patients with diabetic neuropathy.

Pharmacokinetic properties
Absorption
Lacosamide (Vimpat) is rapidly and completely absorbed after oral administration. The oral bioavailability of Lacosamide (Vimpat) tablets is approximately 100%. Following oral administration, the plasma concentration of unchanged Lacosamide (Vimpat) increases rapidly and reaches Cmax about 0.5 to 4 hours post-dose. Lacosamide (Vimpat) tablets and oral syrup are bioequivalent. Food does not affect the rate and extent of absorption.

After intravenous administration, Cmax is reached at the end of infusion. The plasma concentration increases proportionally with dose after oral (100-800 mg) and intravenous (50-300 mg) administration.

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

Metabolism
95% of the dose is excreted in the urine as drug and metabolites. The metabolism of Lacosamide (Vimpat) has not been...
completely characterized. The major compounds excreted in urine are unchanged Lacosamide (Vimpat) (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.

CYP2C19, 2C9 and 3A4 are mainly responsible for the formation of the O-desmethyl metabolite. No clinically relevant difference in Lacosamide (Vimpat) exposure was observed comparing its pharmacokinetics in extensive metabolizers (EMs, with a functional CYP2C19) and poor metabolizers (PMs, lacking a functional CYP2C19). No other enzymes have been identified to be involved in the metabolism of Lacosamide (Vimpat).

The plasma concentration of O-desmethyl-lacosamide is approximately 15% of the concentration of Lacosamide (Vimpat) in plasma. This major metabolite has no known pharmacological activity.

**Elimination**

Lacosamide (Vimpat) is primarily eliminated from the systemic circulation by renal excretion and biotransformation. After oral and intravenous administration of radiolabeled Lacosamide (Vimpat), approximately 95% of radioactivity administered was recovered in the urine and less than 0.5% in the feces. The elimination half-life of the unchanged drug 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.

**Special population**

**Elderly**

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 (Vimpat) 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 (see section Posology and method of administration).

**Renal impairment**

The AUC of Lacosamide (Vimpat) was increased by approximately 30% in mildly and moderately and 60% in severely renal impaired patients and patients with endstage renal disease requiring hemodialysis compared to healthy subjects, whereas Cmax was unaffected.

Lacosamide (Vimpat) is effectively removed from plasma by hemodialysis. Following a 4-hour hemodialysis treatment, AUC of Lacosamide (Vimpat) is reduced by approximately 50%. Therefore dosage supplementation following hemodialysis is recommended (see section Posology and method of administration). The exposure of the O-desmethyl metabolite was several-fold increased in patients with moderate and severe renal impairment. In absence of hemodialysis in patients with endstage renal disease, the levels were increased and continuously rising during the 24-hour sampling. It is unknown whether the increased metabolite exposure in endstage 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 (Vimpat) (approximately 50% higher AUCnorm). 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 (Vimpat). The pharmacokinetics of Lacosamide (Vimpat) has not been evaluated in severe hepatic impairment (see section Posology and method of administration).

**Gender**
Clinical trials indicate that gender does not have a clinically significant influence on the plasma concentrations of Lacosamide (Vimpat).

Race
There are no clinically relevant differences in the pharmacokinetics of Lacosamide (Vimpat) between Asian, Black, and Caucasian subjects.

PHARMACEUTICAL PARTICULARS

List of excipients
Tablets
Tablet core
Microcrystalline cellulose, hydroxypropylcellulose, hydroxypropylcellulose (low substituted), silica colloidal anhydrous, crospovidone, magnesium stearate
Tablet coat
Polyvinyl alcohol, polyethylene glycol 3350, talc, titanium dioxide (E171)
50 mg tablet: red iron oxide (E172), black iron oxide (E172), indigo carmine aluminium lake (E132)
100 mg tablet: yellow iron oxide (E172)
150 mg tablet: yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172)
200 mg tablet: indigo carmine aluminium lake (E132)

Incompatibilities
Not applicable.

Shelf life
48 months

STORAGE CONDITION
Store at temperatures not exceeding 30°C.

AVAILABILITY
Blister packs of 14’s; Box of 56’s

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Manufactured by:
Aesica Pharmaceuticals GmbH
Galileistrasse 6 08056 Zwickau
Germany

Packed by:
Aesica Pharmaceutical GmbH
Mittelstrasse 15 40789 Monheim am Rhein
Germany

Imported by:
Abbott Laboratories
Venice Corporate Center, 8 Turin St.
Mckinley Town Center, Fort Bonifacio
Taguig City, Philippines

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