For the use only of a Neurologist or a Hospital or a Laboratory

ESLIFY

(Eslicarbazepine Acetate Tablets I.P.)

COMPOSITION

ESLIFY 200

Each uncoated tablet contains:

Eslicarbazepine Acetate I.P. 200 mg

ESLIFY 400

Each uncoated tablet contains:

Eslicarbazepine Acetate I.P. 400 mg

ESLIFY 600

Each uncoated tablet contains:

Eslicarbazepine Acetate I.P. 600 mg

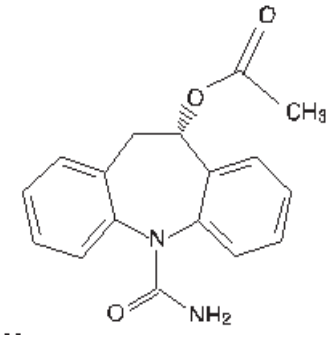
ESLIFY 800

Each uncoated tablet contains:

Eslicarbazepine Acetate I.P. 800 mg

DESCRIPTION

Eslicarbazepine acetate is described chemically as 10-Acetoxy-10,11-dihydro-5H-dibenz (b,f)azepine-5-carboxamide. Molecular weight is 296.32 and molecular formula is $C_{17}H_{16}N_2O_3$.



CLINICAL PHARMACOLOGY

Mechanism of action

The precise mechanisms of action of eslicarbazepine acetate are unknown. However, in vitro electrophysiological studies indicate that both eslicarbazepine acetate and its metabolites stabilise the inactivated state of voltage-gated sodium channels, preventing their return to the activated state and thereby sustaining repetitive neuronal firing.

Pharmacodynamic effect

Eslicarbazepine acetate and its active metabolites prevented the development of seizures in nonclinical models predictive of anticonvulsant efficacy in man. In humans, the pharmacological activity of eslicarbazepine acetate is primarily exerted through the active metabolite eslicarbazepine.

Pharmacokinetic properties

Eslicarbazepine follows linear and dose-proportional pharmacokinetic.

Absorption

The Absorption of eslicarbazepine is not affected by food. Plasma levels of eslicarbazepine acetate usually remain below the limit of quantification, following oral administration. Eslicarbazepine ^{t}max is attained at 2 to 3 hour post-dose. Bioavailability may be assumed as high because the amount of metabolites recovered in urine corresponded to more than 90% of an eslicarbazepine acetate dose.

Distribution

The binding of eslicarbazepine to plasma proteins is relatively low (<40%) and independent from concentration.

Metabolism

Eslicarbazepine acetate is rapidly and extensively biotransformed to its major active metabolite eslicarbazepine by hydrolytic first-pass metabolism. Peak plasma concentrations (C_{max}) of eslicarbazepine are attained at 2-3 h post-dose and steady state plasma concentrations are

attained after 4 to 5 days of once daily dosing, consistent with an effective half-life (t½) in the order of 20-24 h. In studies in healthy subjects and epileptic adult patients, the apparent t½ of eslicarbazepine was 10-20 h and 13-20 h, respectively. Minor metabolites in plasma are R-licarbazepine and oxcarbazepine, which were shown to be active, and the glucuronic acid conjugates of eslicarbazepine acetate, eslicarbazepine, R-licarbazepine and oxcarbazepine. Eslicarbazepine acetate does not affect its own metabolism or clearance. In vitro study on fresh human hepatocytes showed a mild activation of UGT1A1 mediated glucuronidation.

Excretion

Eslicarbazepine acetate metabolites are eliminated from the systemic circulation primarily by renal excretion (90%), in the unchanged ($2/3^{rd}$) and glucuronide conjugate ($1/3^{rd}$) forms.

Elderly (over 65 years of age)

The pharmacokinetic profile of eslicarbazepine acetate is unaffected in the elderly patients with creatinine clearance >60 ml/min

Renal impairment

Eslicarbazepine acetate metabolites are eliminated from the systemic circulation primarily by renal excretion and dose adjustment is recommended in patients with creatinine clearance <60 ml/min. Haemodialysis removes eslicarbazepine acetate metabolites from plasma.

Hepatic impairment

No dose adjustment is recommended in patients with mild to moderate liver impairment. The Pharmacokinetics of eslicarbazepine has not been evaluated in patients with severe hepatic impairment.

Preclinical safety data

Adverse affects reported in animal studies occurred at exposure levels appreciably lower than the clinical exposure levels to eslicarbazepine (the principal and pharmacologically active metabolite of eslicarbazepine acetate). Safety margins based on comparative exposure have thus not been established.

Evidence of nephrotoxicity was reported in repeated dose toxicity studies in the rat, but was not reported in studies in mice or dogs, and is consistent with an exacerbation of spontaneous chronic progressive nephropathy in this species.

Liver centrilobular hypertrophy was reported in repeated dose toxicity studies in mice and rats and an increased incidence of liver tumours was reported in the carcinogenicity study in mice; these findings are consistent with an induction of hepatic microsomal enzymes, an effect which has not been reported in patients receiving eslicarbazepine acetate.

Genotoxicity studies with eslicarbazepine acetate indicate no special hazards for humans.

INDICATIONS

Eslicarbazepine is indicated as adjunctive therapy in adults with partial-onset seizures with or without secondary generalization.

CONTRAINDICATION

Hypersensitivity to the active substance, to other carboxamide derivatives (e.g. carbamazepine, oxcarbazepine) or to any of the excipients.

Known second or third degree atrioventricular (AV) block.

WARNINGS AND PRECAUTIONS FOR USE

Suicidal ideation

Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic activesubstances in several indications. A meta-analysis of randomised placebo controlled trials of anti-epileptic medicinal products has also reported 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 eslicarbazepine acetate. 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.

Nervous system disorders

Eslicarbazepine acetate has been associated with some central nervous system adverse reactions, such as dizziness and somnolence, which could increase the occurrence of accidental injury.

Oral contraceptives

Eslicarbazepine acetate may decrease the effectiveness of hormonal contraceptives. Additional non-hormonal forms of contraception are recommended when using eslicarbazepine.

Other warnings and precautions

If eslicarbazepine is to be discontinued it is recommended to withdraw it gradually to minimise the potential of increased seizure frequency.

Concomitant use of eslicarbazepine acetate with oxcarbazepine is not recommended because this may cause overexposure to the active metabolites.

There is no experience regarding the withdrawal of concomitant use of anti-epileptic medicinal products during treatment with eslicarbazepine (i.e. switching to monotherapy).

Cutaneous reactions

Rash developed as an adverse reaction in 1.1% of total population treated with carbazepine in placebo-controlled add-on studies in epileptic patients. If signs or symptoms of hypersensitivity develop, eslicarbazepine acetate must be discontinued.

HLA-B* 1502 allele - in Han Chinese, Thai and other Asian populations

HLA-B* 1502 in individuals of Han Chinese and Thai origin has been reported to be strongly associated with the risk of developing the severe cutaneous reactions known as Stevens Johnson syndrome (SJS) when treated with carbamazepine. The chemical structure of eslicarbazepine acetate is similar to that of carbamazepine, and it is possible that patients who are positive for HLA-B*1502 may also be at risk for SJS after treatment with Eslicarbazepine acetate. The prevalence of HLA-B*1502 carrier is about 10% in Han Chinese and Thai populations. Whenever possible, these individuals should be screened for this allele before starting treatment with carbamazepine or chemically-related compounds. If patients of these acetate origins are tested positive for HLA- B*1502 allele, the use of eslicarbazepine acetate may be considered if the benefits are thought to exceed risks.

Because of the prevalence of this allele in other Asian populations (e.g, above 15% in the Philippines and Malaysia), testing genetically at risk populations for the presence of HLA-B*1502 may be considered.

The prevalence of the HLA-B*1502 allele is negligible in e.g. European descent, African, Hispanic populations sampled, and in Japanese and Koreans (<1%).

HLA-A*3101 allele- European descent and Japanese populations

There are some data that suggest HLA-A*3101 is associated with an increased risk of carbamazepine induced cutaneous adverse drug reactions including SJS, TEN, Drug rash with eosinophilia (DRESS), or less severe acute generalized exanthematous pustulosis (AGEP) and maculopapular rash in people of European descent and the Japanese.

The frequency of the HLA-A*3101 allele varies widely between ethnic populations. HLA-A*3101 allele has a prevalence of 2 to 5% in European populations and about 10% in Japanese population.

The presence of HLA-A*3101 allele may increase the risk for carbamazepine induced cutaneous reactions (mostly less severe) from 5.0% in general population to 26.0% among subjects of European ancestry, whereas its absence may reduce the risk from 5.0% to 3.8%.

There are insufficient data supporting a recommendation for HLA-A*3101 screening before starting carbamazepine or chemically-related compounds treatment.

If patients of European descent or Japanese origin are known to be positive for HLA-A*3101 allele, the use of carbamazepine or chemically-related compounds may be considered if the benefits are thought to exceed risks.

Hyponatraemia

Hyponatraemia has been reported as an adverse reaction in 1.2% of patients treated with eslicarbazepine. Hyponatraemia is asymptomatic in most cases; however, it may be accompanied by clinical symptoms like worsening of seizures, confusion, decreased consciousness. Frequency of hyponatraemia increased with increasing eslicarbazepine acetate dose. In patients with pre-existing renal disease leading to hyponatraemia, or in patients concomitantly treated with medicinal products which may themselves lead to hyponatraemia (e.g. diuretics, desmopressin, carbamazepine), serum sodium levels should be examined before and during treatment with eslicarbazepine acetate. Furthermore, serum sodium levels should be determined if clinical signs of hyponatraemia occur. Apart from this, sodium levels should be determined during routine laboratory examination. If clinically relevant hyponatraemia develops, eslicarbazepine acetate should be discontinued.

PR interval

Prolongations in PR interval have been reported in clinical studies with eslicarbazepine acetate. Caution should be exercised in patients with medical conditions (e.g. low levels of thyroxine, cardiac conduction abnormalities), or when taking concomitant medicinal products known to be associated with PR prolongation.

Renal impairment

Caution should be exercised in the treatment of patients with renal impairment and the dose should be adjusted according to creatinine clearance. In patients with CLCR <30 ml/min use is not recommended due to insufficient data.

Hepatic impairment

As clinical data are limited in patients with mild to moderate hepatic impairment and pharmacokinetic and clinical data are missing in patients with severe hepatic impairment, eslicarbazepine acetate should be used with caution in patients with mild to moderate hepatic impairment and is not recommended in patients with severe hepatic impairment

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. Some patients might experience dizziness, somnolence or visual disorders, particularly on initiation of treatment. Therefore, patients should be advised that their physical and/ or mental abilities needed for operating machinery or driving may be impaired and they are recommended not to do so until it has been established that their ability to perform such activities is not affected.

ADVERSE EFFFECTS

The adverse effects generally reported with eslicarbazepine are as follows as per system organ class. The adverse reaction were classified as very common 1/10, common 1/100 to <1/10, uncommon 1/1,000 to <1/100, rare 1/10,000 to <1/1,000. Within each frequency category, adverse reactions are presented in order of decreasing seriousness. Within each frequency category, adverse reactions are presented in order of decreasing seriousness.

System Organ Class (MedDRA terminology)	Very Common	Common	Uncommon	Very Rare
Blood and			Anemia	Thrombocyto

Anemia lymphatic system disorders				penia, Leucopenia
Immune system Disorders			Hypersensitivity	
Endocrime disorders			Hypothyroidism	
Metabolism and nutrition disorders		Hyponatraemia ,decreased appetite	Electrolyte imbalance, dehydration, hypochloremia	
Psychiatric disorders		Insomnia	Apathy, depression, nervousness, agitation, irritability, attention deficit/ hyperactivity disorder, confusional state, mood swings, crying, psychomotor retardation, psychotic disorder	
Nervous system	Dizziness, Somnolence	Headache, disturbance in attention, tremor, ataxia, balance disorder	Coordination abnormal, memory impairment, amnesia, hypersomnia, sedation, aphasia, dysaesthesia, dystonia, lethargy, parosmia, cerebellar syndrome, convulsion, peripheral neuropathy,	

			nystagmus, speech disorder, dysarthria, burning sensation, paresthesia, migraine	
Eye disorders		Diplopia, Vision Blurred	Vision impairment, oscillopsia, binocular eye movement disorder, ocular hyperemia	
Ear and labyrinth disorders		Vertigo	Hypoacusis, Tinnitus	
Cardiac disorders			Palpitations, bradycardia,	
Vascular disorders			Hypertension ((including hypertensive crisis), hypotension, orthostatic hypotension, flushing, peripheral coldness	
Respiratory, thoracic and mediastinal disorders			Epistaxis, chest pain	
Gastrointestinal disorders		Nausea, vomiting, diarrhea	Constipation, Dyspepsia, gastritis, abdominal pain, dry	

			mouth, abdominal discomfort, abdominal distension, gingivitis, melaena, toothache	
Hepatobiliary disorders			Liver disorder	
Skin and subcutaneous tissue disorders		Rash	Alopecia, dry skin, hyperhidrosis, erythema, skin disorder, pruritus	
Musculoskeletal and connective tissue disorders			Myalgia, bone metabolism disorder, muscular weakness, pain in extremity	
Renal and urinary disorders			Urinary tract infection	
General disorders and administration site conditions		Fatigue, gait Disturbance, asthenia	Malaise, chills, edema peripheral	
Investigations			Blood pressure decreased, weight decreased, blood pressure increased, blood sodium decreased, blood chloride decreased, osteocalcin increased, haematocrit decreased,	

			haemoglobin decreased, transaminases increased	
Injury, poisoning and procedural complications			Drug toxicity, fall thermal burn	

Description of selected adverse reactions

Eye and nervous system disorders

In patients concomitantly treated with carbamazepine and eslicarbazepine acetate in placebo-controlled studies, the following adverse reactions were reported: diplopia (11.4% of subjects with concomitant carbamazepine, 2.4% of subjects without concomitant carbamazepine), abnormal coordination (6.7% with concomitant carbamazepine, 2.7% without concomitant carbamazepine), and dizziness (30.0% with concomitant carbamazepine, 11.5% without concomitant carbamazepine)

PR interval

The use of eslicarbazepine acetate is associated with increase in the PR interval. Adverse reactions associated with PR interval prolongation (e.g. AV block, syncope, bradycardia) may occur. No second or higher degree AV block was reported in eslicarbazepine acetate treated patients.

Class related adverse reactions

Rare adverse reactions such as bone marrow depression, anaphylactic reactions, severe cutaneous reactions (e.g. Stevens-Johnson Syndrome), systemic lupus erythematosus or serious cardiac arrhythmias did not report during the placebo-controlled studies of the epilepsy program with eslicarbazepine acetate. However, they have been reported with oxcarbazepine. Therefore, their occurrence after treatment with eslicarbazepine acetate cannot be excluded.

There have been reports of decreased bone mineral density, osteopenia, osteoporosis and fractures in patients on long-term therapy with the structurally related antiepileptic drugs

carbamazepine and oxcarbazepine. The mechanism by which bone metabolism is affected has not been identified.

Overdose

Central nervous symptoms such as vertigo, walking instability and hemi-paresis have been observed with accidental eslicarbazepine overdose. There is no known specific antidote. Symptomatic and supportive treatment should be administered as appropriate. Eslicarbazepine acetate metabolites can effectively be cleared by haemodialysis, if necessary.

Drug-Interaction

Interaction studies have only been reported in adults.

Eslicarbazepine acetate is extensively converted to eslicarbazepine, which is mainly eliminated by glucuronidation. *In vitro* eslicarbazepine is a weak inducer of CYP3A4 and UDP-glucuronyl transferases. *In vivo* eslicarbazepine reported an inducing effect on the metabolism of medicinal products that are mainly eliminated by metabolism through CYP3A4. Thus, an increase in the dose of the medicinal products that are mainly metabolised through CYP3A4 may be required, when used concomitantly with eslicarbazepine. Eslicarbazepine *in vivo* may have an inducing effect on the metabolism of medicinal products that are mainly eliminated by conjugation through the UDP-glucuronyl transferases. When initiating or discontinuing treatment with eslicarbazepine or changing the dose, it may take 2 to 3 weeks to reach the new level of enzyme activity. This time delay must be taken into account when eslicarbazepine is being used just prior to or in combination with other medicines that require dose adjustment when co-administered with eslicarbazepine. Eslicarbazepine has inhibiting properties with respect to CYP2C19. Thus, interactions can arise when co-administering high doses of eslicarbazepine acetate with medicinal products that are mainly metabolised by CYP2C19.

<u>Interactions with other antiepileptic medicinal products</u>

<u>Carbamazepine</u>

In a reported study in healthy subjects, concomitant administration of eslicarbazepine acetate 800 mg once daily and carbamazepine 400 mg twice daily resulted in an average decrease of 32% in exposure to the active metabolite eslicarbazepine, most likely caused by an induction of glucuronidation. No change in exposure to carbamazepine or its metabolite carbamazepine-

epoxide was noted. Based on individual response, the dose of eslicarbazepine acetate may need to be increased if used concomitantly with carbamazepine. Results from patient studies reported that concomitant treatment increased the risk of the following adverse reactions: diplopia, abnormal coordination and dizziness. The risk of increase of other specific adverse reactions caused by co-administration of carbamazepine and eslicarbazepine acetate cannot be excluded.

Phenytoin

In a reported study in healthy subjects, concomitant administration of eslicarbazepine acetate 1,200 mg once daily and phenytoin resulted in an average decrease of 31-33% in exposure to the active metabolite, eslicarbazepine, most likely caused by an induction of glucuronidation, and an average increase of 31-35% in exposure to phenytoin, most likely caused by an inhibition of CYP2C19. Based on individual response, the dose of eslicarbazepine may need to be increased and the dose of phenytoin may need to be decreased.

Lamotrigine

Glucuronidation is the major metabolic pathway for both eslicarbazepine and lamotrigine and therefore an interaction could be expected. A reported study in healthy subjects with eslicarbazepine acetate 1,200 mg once daily showed a minor average pharmacokinetic interaction (exposure of lamotrigine decreased 15%) between eslicarbazepine acetate and lamotrigine and consequently no dose adjustments are required. However, due to interindividual variability, the effect may be clinically relevant in some individuals.

Topiramate

In a reported study in healthy subjects, concomitant administration of eslicarbazepine acetate 1,200 mg once daily and topiramate showed no significant change in exposure to eslicarbazepine but an 18% decrease in exposure to topiramate, most likely caused by a reduced bioavailability of topiramate. No dose adjustment is required.

Valproate and levetiracetam

A population pharmacokinetics analysis of phase III studies in epileptic adult patients indicated that concomitant administration with valproate or levetiracetam did not affect the exposure to eslicarbazepine but this has not been verified by conventional interaction studies.

Other medicinal products

Oral contraceptives

Administration of eslicarbazepine acetate 1,200 mg once daily to female subjects using a combined oral contraceptive reported an average decrease of 37% and 42% in systemic exposure to levonorgestrel and ethinyloestradiol, respectively, most likely caused by an induction of CYP3A4. Therefore, women of childbearing potential must use adequate contraception during treatment with eslicarbazepine, and up to the end of the current menstruation cycle after the treatment has been discontinued.

Simvastatin

A study in healthy subjects reported an average decrease of 50% in systemic exposure to simvastatin when co-administered with eslicarbazepine acetate 800 mg once daily, most likely caused by an induction of CYP3A4. An increase of the simvastatin dose may be required when used concomitantly with eslicarbazepine acetate.

Rosuvastatin

There was an average decrease of 36-39% in systemic exposure in healthy subjects when co-administered with eslicarbazepine acetate 1,200 mg once daily. The mechanism for this reduction is unknown, but could be due to interference of transporter activity for rosuvastatin alone or in combination with induction of its metabolism. Since the relationship between exposure and drug activity is unclear, the monitoring of response to therapy (e.g., cholesterol levels) is recommended.

Warfarin

Co-administration of eslicarbazepine acetate 1,200 mg once daily with warfarin reported a small (23%) but statistically significant decrease in exposure to S-warfarin. There was no effect on the R-warfarin pharmacokinetics or on coagulation. However, due to inter-individual variability in the interaction, special attention on monitoring of INR should be performed the first weeks after initiation or ending concomitant treatment of warfarin and eslicarbazepine acetate.

Digoxin

A study in healthy subjects reported no effect of eslicarbazepine acetate 1,200 mg once daily on digoxin pharmacokinetics, suggesting that eslicarbazepine acetate has no effect on the transporter P-glycoprotein.

Monoamino Oxidase Inhibitors (MAOIs)

Based on a structural relationship of eslicarbazepine acetate to tricyclic antidepressants, an interaction between eslicarbazepine acetate and MAOIs is theoretically possible.

DOSAGES AND ADMINISTRATION

Eslicarbazepine must be added to existing anticonvulsant therapy. The recommended starting dose is 400 mg once daily which should be increased to 800 mg once daily after one or two weeks. Based on individual response, the dose may be increased to 1200 mg once daily. It may be taken with or without food.

Elderly (over 65 years of age)

Caution should be exercised in the treatment of elderly patients as there is limited safety information on the use of eslicarbazepine in these patients.

Pediatric population

Eslicarbazepine is not recommended for use in children below 18 years due to a lack of data on safety and efficacy.

Patients with renal impairment

Caution should be exercised in the treatment of patients with renal impairment and the dose should be adjusted according to creatinine clearance (CL_{CR}) as follows:

CL_{CR} > 60 ml/min	No dose adjustment required
CL_{CR} 30-60 ml/min	Initial dose of 400 mg every other day for 2 weeks followed by a once daily dose of 400 mg. However, based on individual response, the dose may be increased
CL_{CR} < 30 ml/min	Not recommended due to insufficient data in patient with severe renal impairment patient

Patients with hepatic impairment

No dose adjustment is needed in patients with mild to moderate hepatic impairment and not recommended in severe hepatic impairment patient due to lack of pharmacokinetic data.

Use in Pregnancy and Nursing Mother

Risk related to epilepsy and antiepileptic medicinal products in general

It has been reported that in the offspring of women with epilepsy, the prevalence of malformations is two to three times greater than the rate of approximately 3 % in the general population. Most frequently reported are cleft lip, cardiovascular malformations and neural tube defects. Multiple antiepileptic medicinal product Therapy may be associated with a higher risk of congenital malformations than monotherapy, therefore it is important that monotherapy is practised whenever possible. Specialist advice should be given to women who are likely to become pregnant or who are of child-bearing potential. The need for antiepileptic therapy should be reviewed when a woman is planning to become pregnant. No sudden discontinuation of antiepileptic therapy should be undertaken as this may lead to breakthrough seizures which could have serious consequences for both mother and child.

Women of childbearing potential/contraception

Eslicarbazepine acetate adversely interacts with oral contraceptives. Therefore, an alternative, effective and safe method of contraception should be used during treatment and up to the end of the current menstrual cycle after treatment has been stopped.

Pregnancy

There are no data from the use of eslicarbazepine acetate in pregnant women. Studies in animals have reported reproductive toxicity. If women receiving eslicarbazepine acetate become pregnant or plan to become pregnant, the use of eslicarbazepine should be carefully re-evaluated. Minimum effective doses should be given, and monotherapy whenever possible should be preferred at least during the first three months of pregnancy. Patients should be counselled regarding the possibility of an increased risk of malformations and given the opportunity to antenatal screening.

Monitoring and prevention

Antiepileptic medicinal products may contribute to folic acid deficiency, a possible contributory cause of foetal abnormality. Folic acid supplementation is recommended before and during pregnancy. As the efficacy of this supplementation is not proven, a specific antenatal diagnosis can be offered even for women with a supplementary treatment of folic acid.

In the newborn child

Bleeding disorders in the newborn caused by antiepileptic medicinal products have been reported. As a precaution, vitamin K1 should be administered as a preventive measure in the last few weeks of pregnancy and to the newborn.

Breastfeeding

It is unknown whether eslicarbazepine acetate is excreted in human breast milk. Animal studies have reported excretion of eslicarbazepine in breast milk. As a risk to the breast-fed child cannot be excluded breastfeeding should be discontinued during treatment with eslicarbazepine acetate.

Fertility

Eslicarbazepine acetate was evaluated in rats and mice for potential adverse effects on fertility of the parental and F1 generation. Reportedly, in a fertility study in male and female rats, impairment of female fertility by eslicarbazepine acetate was shown. In a fertility study in mice, developmental effects were reported in embryos; however, effects could also result from lower *corpora lutea* count and thus show impairment of fertility. Reportedly in the mouse, the overall incidence of major abnormalities and the incidence for major skeletal abnormalities were increased. No effects on F1 fertility parameters were reported in rats and mice.

Expiry Date

Do not use later than the date of expiry.

Storage

Store at a temperature not exceeding 30^{o}C, protected from moisture.

Presentation

Eslify 200, Eslify 400, Eslify 600 and Eslify 800 are available in blister strips pack of 10's tablets.

MARKETED BY

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

IN/ESLIFY 200,400,600,800mg/Apr-2015/01/PI