Seipil
(P r e g a b a l i n)
Capsules B.P.
50mg
75mg
100mg

سیپِل
(پریگیبالِن)
کیپسولز بی-پی-
۵۰ ملی گرام
۷۵ ملی گرام
۱۰۰ ملی گرام

QUALITATIVE & QUANTITATIVE COMPOSITION

Seipil™ Capsules B.P. 50mg: Each capsule contains:
Pregabalin U.S.P. 50mg

Seipil™ Capsules B.P. 75mg: Each capsule contains:
Pregabalin U.S.P. 75mg

Seipil™ Capsules B.P. 100mg: Each capsule contains:
Pregabalin U.S.P. ...100mg

DESCRIPTION:

Pregabalin is described chemically as (S)-3-(aminomethyl)-5-methylhexa-noic acid. The molecular formula is C8H17NO2 and the molecular weight is 159.23.

CLINICAL PHARMACOLOGY:

Mechanism of Action: Pregabalin binds with high affinity to the al-pha2-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. Pregabalin is a structural derivative of the inhibitory neurotransmitter gamma aminobutyric acid (GABA), it does not bind directly to GABAA, GABAB, or benzodiazepine receptors. Pregabalin does not block sodium channels, is not active at opiate receptors, and does not alter cyclooxygenase enzyme activity. It is inactive at serotonin and do-pamine receptors and does not inhibit dopamine, serotonin, or noradrena-line reuptake.

Pharmacodynamics: Multiple oral doses of pregabalin were co-adminis-tered with oxycodone, lorazepam, or ethanol. Although no pharmacokinetic interactions were seen, additive effects on cognitive and gross motor func-tioning were seen when pregabalin was co-administered with these drugs. No clinically important effects on respiration were seen.

Pharmacokinetics: Absorption and distribution: Following oral administra-tion of pregabalin capsules under fasting conditions, peak plasma concen-trations occur within 1.5 hours. Pregabalin oral bioavailability is greater than or equal to 90% and is independent of dose. The rate of pregabalin absorp-tion is decreased when given with food, resulting in a decrease in Cmax of approximately 25% to 30% and an increase in Tmax to approximately 3 hours. However, administration of pregabalin with food has no clinically rel-evant effect on the total absorption of pregabalin. Therefore, pregabalin can be taken with or without food. Pregabalin does not bind to plasma proteins. The apparent volume of distribution of pregabalin following oral administra-tion is approx-imately 0.5L/kg. Pregabalin is a substrate for system L trans-porter which is responsible for the transport of large amino acids across.

Metabolism and Elimination: Pregabalin undergoes negligible metabo-lism in humans. Pregabalin is eliminated from the systemic circulation pri-marily by renal excretion as unchanged drug with a mean elimination half-life of 6.3 hours in subjects with normal renal function. Pregabalin elimi-nation is nearly proportional to creatinine clearance (CLcr).

INDICATIONS AND USAGE:

Seipil™ is indicated for: • Management of neuropathic pain associated with diabetic peripheral neuropathy(DPN).
• Management of postherpetic neuralgia (PHN). Adjunctive therapy for adult patients with partial onset seizures.
• Management of fibromyalgia.
• Management of neuropathic pain associated with spinal cord injury. For the treatment of Generalised anxiety disorder (GAD) in adults.

CONTRAINDICATIONS:

Pregabalin is contraindicated in patients with known hypersensitivity to pregabalin or any of its components.Angioedema and hypersensitivity reactions have occurred in patients receiving pregabalin therapy.

DRUG INTERACTIONS:

There are no pharmacokinetic interactions between pregabalin and the following antiepileptic drugs: carbamazepine, valproic acid, lamotrigine, phenytoin, phenobarbital, and topiramate and also with commonly used antiepileptic.

USE IN SPECIFIC POPULATION:

Pregnancy: There are no adequate and well-controlled studies with pregabalin in pregnant women.
Breastfeeding: Because of the potential risk of tumorigenicity, breastfeeding is not recommended during treatment with pregabalin
Pediatric use: Safety and effectiveness in pediatric patients have not been established.
Geriatric use: No overall differences in safety and efficacy were observed between these patients and younger patients.
Renal patient: Seipil™ is eliminated primarily by renal excretion and dose adjustment is recommended for adult patients with renal impairment.

WARNINGS AND PRECAUTIONS:

Angioedema: There have been post marketing reports of angioedema in patients during initial and chronic treatment with pregabalin. Specific symptoms included swelling of the face, mouth (tongue, lips, and gums), and neck (throat and larynx).
Hypersensitivity: Skin redness, blisters, hives, rash, dyspnea and wheezing may occur. Discontinue pregabalin immediately in patients with these symptoms.
Withdrawal of antiepileptic drugs (AEDs): Withdrawal of pregabalin have potential to increase seizure frequency in patients with seizure disorders. If pregabalin is discontinued, taper the drug gradually over a minimum of 1 week.
Suicidal behaviour and ideation: Antiepileptic drugs (AEDs), including pregabalin, increase the risk of suicidal thoughts or behaviour in patients taking these drugs for any indication.
Peripheral edema: Pregabalin treatment may cause peripheral edema.
Dizziness and somnolence: Pregabalin may cause dizziness and somnolence.
Weight gain: Pregabalin treatment may cause weight gain.
Abrupt or rapid discontinuation: Following abrupt or rapid discontinuation of pregabalin, some patients reported symptoms including insomnia, nausea, headache, anxiety, hyperhidrosis, and Diarrhea.
Tumorigenic potential: Tumorigenic potential is present.
Ophthalmological Effects: It causes blurred vision.
Creatine kinase elevations: Pregabalin treatment is associated with creatine kinase elevations.

Decreased platelet Count: Pregabalin treatment is associated with a decrease in platelet count.
PR Interval prolongation: Pregabalin treatment is associated with PR interval prolongation.
CNS depressants: Care should be taken with CNS depressants as they may cause somnolence.
Alcohol: Avoid consuming alcohol while taking pregabalin, as it may potentiate the impairment of motor skills and sedating effects of alcohol.
Male Fertility: Inform men being treated with pregabalin who plan to father a child of the potential risk of male-mediated teratogenicity.
Dermatopathy: Diabetic patients should pay particular attention to skin integrity while being treated with pregabalin.
Lactose intolerant patients: Pregabalin contains lactose monohydrate. Care must be taken for lactose intolerant.
Congestive heart failure: Congestive heart failure in some patients receiving pregabalin is reported.
Encephalopathy: Cases of encephalopathy have been reported.
Reduced lower gastrointestinal tract function: Intestinal obstruction, paralytic ileus, constipation have been reported when pregabalin was co-administered with medications that have the potential to produce constipation, such as opioid analgesics.

ADVERSE REACTIONS:

Common or very common: Abdominal distension, appetite abnormal, asthenia, cervical spasm. concentration impaired, confusion, constipation, diarrhoea, dizziness, drowsiness, dry mouth, feeling abnormal, gait abnormal, gastrointestinal disorders, headache, increased risk of infection, joint disorders, memory loss, mood altered, movement disorders, muscle complaints, nausea , oedema, pain, sensation abnormal, sexual dysfunction, sleep disorders, speech impairment, vertigo, vision disorders. vomiting, weight changes.
Uncommon: Aggression, anxiety, arrhythmias, atrioventricular block, breast abnormalities, chest tightness, chills, consciousness impaired, cough, depression, dry eye, dyspnoea, epistaxis, eye discomfort, eye disorders, eye inflammation, fever, hallucination, hyperacusia, hypertension, hypoglycaemia, hypotension, malaise , menstrual cycle, irregularities, nasal complaints, neutropenia. oral disorders, peripheral coldness, psychiatric disorders, reflexes decreased, skin reactions, snoring. sweat changes, syncope, taste loss, thirst, urinary disorders, vasodilation.
Rare or very rare: Altered smell sensation, ascites, dysgraphia, dysphagia, gynaecomastia, hepatic disorders, pancreatitis, QT interval prolongation, renal impairment, rhabdomyolysis. Stevens-Johnson syndrome. throat tightness

DOSAGE AND ADMINISTRATION:

Peripheral and central neuropathic pain
BY MOUTH:
Adult: Initially 150 mg daily in 2–3 divided doses, then increased if necessary to 300 mg daily in 2–3 divided doses, dose to be increased after 3–7 days, then increased if necessary up to 600 mg daily in 2–3 divided doses, dose to be increased after 7 days. Adjunctive therapy for focal seizures with or without secondary generalization.
BY MOUTH Adult: Initially 25 mg twice daily, then increased in steps of 50 mg daily, dose to be increased at 7 day intervals, increased to 300 mg daily in 2–3 divided doses for 7 days, then increased if necessary up to 600 mg daily in 2–3 divided doses . Generalized anxiety disorder
BY MOUTH Adult: Initially 150 mg daily in 2–3 divided doses, then increased in steps of 150 mg daily if required, dose to be increased at 7 day

intervals, increased if necessary up to 600 mg daily in 2–3 divided doses.

RENAL IMPAIRMENT:

Dose adjustments: Initially 75 mg daily and maximum 300mg daily if eGFR 30–60 mL/minute/1.73m2. Initially 25–50 mg daily and maximum 150mg daily in 1–2 divided doses if eGFR 15– 30mL / minute/ 1.73m2. Initially 25 mg once daily and maximum 75mg once daily if eGFR less than 15 mL/ minute/1.73m2.

Overdosage: Treatment or Management of Overdose: There is no specific antidote for overdose with Seipil™. If indicated, elimination of unabsorbed drug may be attempted by emesis or gastric lavage; observe usual precautions to maintain the airway. General supportive care of the patient is indicated including monitoring of vital signs and observation of the clinical status of the patient. Although hemodialysis has not been performed in the few known cases of overdose, it may be indicated by the patient's clinical state or in patients with significant renal impairment. Standard hemodialysis procedures result in significant clearance of pregabalin (approximately 50% in 4 hours)

DOSAGE:

As directed by the physician.

INSTRUCTIONS:

Store at 25°C, excursions permitted to 15°C - 30°C.
Protect from sunlight and moisture.
Keep all medicines out of the reach of children.

PRESENTATION:

Seipil™ (Pregabalin) Capsules B.P. 50mg, 75mg & 100mg are available in Alu-Alu blister pack of 2 x 7's.

علامات/طریقہ استعمال: سیپِل مختلف اقسام کے اعصابی امراض کے علاج میں تجویز کردہ ہے۔

مضر اثرات: پیٹ کے امراض، سر درد، کمزوری، سینے کا جکڑنا، قبض، دست، غنودگی، سر درد، جوڑوں کے امراض۔

احتیاطی تدابیر: حاملہ خواتین اور دودھ پلانے والی مائیں سیپِل کے استعمال سے گریز کریں۔
بچے، بزرگ اور جگر کے امراض میں مبتلا افراد صرف ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: ۲۵ ڈگری سینٹی گریڈ پر رکھیں،
محفوظ رکھنے کی حد ۱۵ سے ۳۰ ڈگری سینٹی گریڈ ہے۔
سورج کی روشنی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

For detailed information:

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ISO 9001:2015 ISO 14001:2015 ISO 45001:2018

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