Capsules

DyGab®

(Pregabalin)

DESCRIPTION:

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

COMPOSITION:

Each capsule of DyGab 25mg contains:
Pregabalin 25mg
Each capsule of DyGab 50mg contains:
Pregabalin 50mg
Each capsule of DyGab 100mg contains:
Pregabalin 100mg
Each capsule of DyGab 150mg contains:
Pregabalin 150mg

CLINICAL PHARMACOLOGY:

Mode of Action:

Pregabalin binds with high affinity to the alpha 2-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. Still the mechanism of action of Pregbalin is unknown, results with genentically modified mice and with compounds structurally related to Pregabalin (such as Gabapentin) suggest that binding to the alpha 2-delta subunit may be involved in pregabalin's antinociceptive and antiseizure effects in animal models. In vitro, Pregabalin reduces the calcium –dependent release of several neurotransmitters, possibly by modulation of calcium channel function.

While Pregabalin is a structural derivative of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA), it does not bind directly to $GABA_A$, $GABA_B$, or benzodiazepine receptors, does not augment $GABA_A$ responses in cultured neurons, does not alter rat brain GABA concentration or have acute effects on GABA uptake or degradation. However, in cultured neurons prolonged application of Pregabalin increases the density of GABA transporter protein and increases the rate of functional GABA transport. Pregabalin does not block sodium channels, is not active at receptors and does not alter activity. It is inactive at and receptors and does not inhibit dopamine, Serotonin, or noradrenaline reuptake.

INDICATIONS:

Pregabalin in indicated for:
Neuropathic pain associated with diabetic peripheral neuropathy, Post herpetic neuralgia, adjunctive therapy for adult patients with partial onset seizures and fibromyalgia.

CONTRAINDICATIONS:

Pregabalin in contraindicated in patients with known hypersensitivity to pregabalin or any of its components.

PRECAUTIONS:

Angioedema, Hypersensitivity, withdrawal of Antiepileptic drugs (AEDs), Peripheral edema, Dizziness, Somnolence, Weight gain, Ophthalmological Effects, Creatinine Kinase Elevations, Decreased Platelet Count, PR Interval Prolongation, Nonclinical toxicology: Carcinogenesis, Mutagenesis, Impairment of Fertility.

PEDIATRIC USE:

The safety and efficacy of Pregabalin in pediatric patients have not been established.

SIDE EFFECTS:

The most side effects Pregabalin in 1 out 10 people are :
Tiredness and dizziness
Side effects of Pregabalin in 1 out of 100 people are:
Increased appetite, feeling of confusion, changes in sexual interest, irritability, distribution of attention, clurnsiness, memory impairment, tremor, difficulty with speaking, tingling feeling, blurred vision, double vision, vertigo, dry mouth, constipation, vomiting, flatulence, difficulty with erection, swelling of extremities, feeling drunk, abnormal style of walking and weight gain.

OVERDOSAGE:

There is no specific treatment of antidote for overdose with Pregabalin. If indicated, elimination of unabsorbed drug may be attempted by emesis or gastric lavage, usual precautions should be observed 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. A certified should be contacted for up to dated information on the management of overdose with Pregabalin.

DOSAGE AND ADMINISTRATION:

Neuropathic pain associated with diabetic peripheral neuropathy:
The maximum recommended dose of Pregabalin is 100mg three times a day (300mg/day) in patients with creatinine clearance of at least 60ml/min. Dosing should start at 50mg three times a day (150mg/day) and may be gradually increased to 300mg/day within one week based on efficacy and tolerability. Since Pregabalin is eliminated primarily by renal excretion, the dose should be adjusted for patients with reduced renal functions.

POSTHERPETIC NEURALGIA:

Dose of Pregabalin is 75 to 150mg two times a day, or 50 to 100mg three times a day (150 to 300mg/day) in patients with creatinine clearance of at least 60ml/min. Dose should be started at 75mg two times a day. Or 50mg three times a day (150mg/day) and may be increased to 300mg/day within 1 week based on efficacy and tolerability. Patients who does not have sufficient pain relief following 2 to 4 weeks of treatment with 300mg/day. And who are able to tolerate Pregabalin, may be treated with up to 300mg two times a day, or 200mg three times a day (600mg/day).

Adjunctive Therapy for adult patients with partial onset seizure:

Dose of Pregabalin 150 to 600mg/day has been shown to be effective as adjunctive therapy in the treatment of partial onset seizure in adults. The total daily dose should be divided into two or three times daily. Since Pregabalin is eliminated primarily by renal system, the dose should be adjusted for patients with reduced renal function.

MANAGEMENT OF FIBROMYALGIA:

Recommended dose of Pregabalin for the treatment of fibromyalgia is 300 to 450mg/day. Dosing should start at 75mg two times a day. (150mg/day) and may be increased to 150mg two times a day (300mg/day) within one week based on efficacy and tolerability.

PATIENTS WITH RENAL IMPAIRMENT:

With reference to dose-dependent adverse reactions and as Pregabalin is eliminated primarily by renal excretion, the dose should be adjusted in patients with reduced renal functions.
Dosage and adjustment in patients with renal impairment should be based on creatinine clearance (CLcr).

USE IN PREGNANCY:

Patients should be instructed to notify their physicians if they become pregnant or intend to become pregnant during therapy, and to notify their physicians if they are breast feeding or intended to breast feed during therapy.

DRUG INTERACTIONS:

As Pregabalin is excreted unchanged in the urine, undergoes negligible metabolism in human (<2% of a those recovered in urine as metabolites), and dose not bind with plasma proteins, its pharmacokinetics are unlikely to be affected by other agents through metabolic interactions or protein binding displacement. In Vitro & Vivo studies showed that Pregabalin is unlikely to be involved in significant pharmacokinetic drug interactions. Specially, there are no pharmacokinetics interactions between Pregabalin the following antiepileptic drugs: carbamazepine, valproic acid, lamotrigine, phenytoin, Phenobarbital, and topiramate.
Important pharmacokinetics interaction would also not be expected to occure between Pregabalin and commonly used antiepileptic drugs.

STORAGE:

Store in a cool, dry place and protect from sunlight. Keep away from the reach of children.

PRESENTATION:

Dygab 25mg Capsules: pack of 14 capsules
Dygab 50mg Capsules: pack of 14 capsules
Dygab 100mg Capsules: pack of 14 capsules
Dygab 150mg Capsules: pack of 14 capsules

ہدایات:

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
خشک جگہ پر ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
بچوں کی دسترس سے دور رکھیں۔ سورج کی روشنی سے بچائیں۔

Manufactured by:
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