Gibli
(Pregabalin)

گِبلی کیپسول

25mg, 50mg, 75mg, 100mg, 150mg, 300mg Capsules

DESCRIPTION:
GIBLI(Pregabalin) is an analogue of the neurotransmitter gamma-aminobutyric acid (GABA). It has analgesic and anticonvulsant activity.

QUALITATIVE & QUANTITATIVE COMPOSITION:
GIBLI (Pregabalin) is available for oral administration as:

1.GIBLI 25mg Capsules
Each capsule contains:
Pregabalin...25mg
(Product Specs.: BP)

2.GIBLI 50mg Capsules
Each capsule contains:
Pregabalin...50mg
(Product Specs.: BP)

3.GIBLI 75mg Capsules
Each capsule contains:
Pregabalin...75mg
(Product Specs.: BP)

4.GIBLI 100mg Capsules
Each capsule contains:
Pregabalin...100mg
(Product Specs.: BP)

5.GIBLI 150mg Capsules
Each capsule contains:
Pregabalin...150mg
(Product Specs.: BP)

6.GIBLI 300mg Capsules
Each capsule contains:
Pregabalin...300mg
(Product Specs.: BP)

CLINICAL PHARMACOLOGY:
Mechanism of Action:
Pregabalin reduces neuronal calcium currents by binding to the alpha-2 delta subunit of voltage gated calcium channels in CNS tissues and this particular mechanism may be responsible for effects in neuropathic pain, anxiety and other pain syndromes.
Pharmacokinetics:
Absorption:
Following oral administration under fasting conditions, peak plasma concentrations occur within 1.5 hours. Following repeated administration, steady state is achieved within 24 to 48 hours.
Distribution:
Pregabalin does not bind to plasma proteins. The apparent volume of distribution following oral administration is approximately 0.5L/kg.
Metabolism:
Pregabalin undergoes negligible metabolism in humans.
Eliminaiton:
Pregabalin mean elimination half-life is 6.3 hours and is eliminated from the systemic circulation primarily by renal excretion as unchanged drug.
Special Populations:
Renal Impairment:
Pregabalin clearance is reduced in renally impaired patients. Dose adjustments are required in these patients. Pregabalin is effectively removed by hemodialysis (following 4 hours hemodialysis treatment plasma pregabalin concentrations are reduced by approximately 50%). Dose adjustments are required for patients on hemodialysis.
Elderly (Over 65 years of age):
Dose reduction may be required in patients who have age related compromised renal function.
THERAPEUTIC INDICATIONS:
GIBLI (Pregabalin) is indicated for the;
- Management of neuropathic pain associated with diabetic peripheral neuropathy.
- Management of postherpetic neuralgia.
- Treatment of pain associated with spinal cord injury.
- As adjunctive therapy in adults with partial seizures with or without secondary generalization.
- Treatment of Generalized Anxiety Disorder (GAD) in adults.
- Treatment of fibromyalgia syndrome (FMS).

DOSAGE AND ADMINISTRATION:
GIBLI is given orally with or without food.
When discontinuing **GIBLI**, taper gradually over a minimum of 1 week irrespective of the indication.
Neuropathic Pain Associated with Diabetic Peripheral Neuropathy:
150mg/day, in 2-3 divided doses. Based on individual patient response and tolerability, the dosage may be increased to 300mg/day, after an interval of 3 to 7 days, and if needed, to a maximum dose of 600mg/day after an additional 7 days interval.
Postherpetic Neuralgia:
Started at 75mg BID or 50mg TID, dosage may be increased to 300mg/day within 1 week based on efficacy and tolerability. Patients who do not experience sufficient pain relief following 2 to 4 weeks of treatment with 300mg/day, the dose may be increased up to 300mg BID according to patient tolerability.
Neuropathic Pain Associated with Spinal Cord Injury:
The recommended starting dose is 75mg BID. The dose may be increased to 150mg BID within 1 week based on efficacy and tolerability. Patients who do not experience sufficient pain relief following 2 to 4 weeks of treatment with 300mg/day, the dose may be increased up to 300mg BID according to patient tolerability.
Adjunctive therapy in adults with partial seizure with or without secondary generalization:
The recommended starting dose is 150mg/day in 2-3 divided doses. Based on individual patient response and tolerability, the dosage may be increased to 300mg/day after 1 week. The maximum dosage of 600mg/day may be achieved after an additional week.
General Anxiety Disorder:
The recommended starting dose is 150mg/day in 2-3 divided doses. Based on individual patient response and tolerability, the dosage may be increased to 300mg/day after 1 week. Following an additional week the dosage may be increased to 450mg/day. The maximum dosage of 600mg/day may be achieved after an additional week.
Fibromyalgia Syndrome (FMS):
Dosing should begin at 75mg BID or 50mg TID and may be increased to 300mg/day within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300mg/day may be further increased to 225mg BID.
Renally Impaired Patients:
As pregabalin clearance is directly proportional to creatinine clearance, dosage reduction in patients with compromised renal function must be individualised according to creatinine clearance, as indicated in table below:

Creatinine Clearance (CL_{cr}) (ml/min)	Total Pregabalin Daily dose *		Dose Regimen
	Starting dose (mg/day)	Maximum dose (mg/day)	
≥ 60	150	600	BID or TID
≥ 30 - <60	75	300	BID or TID
≥ 15 - <30	25-50	150	OD or BID
< 15	25	75	OD
Supplementary dosage following hemodialysis (mg)			
	25	100	Single Dose **

* Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose.
** Supplementary dose is a single additional dose.

CONTRAINDICATIONS:
- Contraindicated in patients with a known hypersensitivity to pregabalin or any component of the product.
- Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.
- Children below the age of 12 years and adolescents (12-17 years).

PRECAUTIONS:
- Pregabalin should be withdrawn gradually to minimize the potential of increased seizure frequency in patients with seizure disorders.
- Pregabalin should be discontinued immediately if symptoms of angioedema, such as facial, perioral or upper airway swelling occur.
- Some diabetic patients who gain weight on pregabalin treatment may need to adjust hypoglycemic medications.
- Pregabalin should be discontinued if myopathy is diagnosed or suspected or if markedly elevated creatine kinase levels occur.
- There have been reports of congestive heart failure in some patients receiving pregabalin. These reactions are mostly seen in elderly cardiovascular compromised patients during pregabalin treatment for a neuropathic indication. Discontinuation of pregabalin may resolve the reaction.
- Avoid alcohol consumption while on pregabalin, as it may potentiate the impairment of motor skills and sedation of alcohol.
- Pregabalin may cause dizziness and somnolence and therefore may have an influence on the ability to drive or use machines.

Withdrawal symptoms:
After discontinuation of short-term and long-term treatment with pregabalin withdrawal symptoms have been observed in some patients. The following events have been mentioned: insomnia, headache, nausea, diarrhea, flu syndrome, nervousness, depression, pain, sweating and dizziness.
Pregnancy:
Pregabalin should not be used during pregnancy unless clearly necessary.
Nursing Mothers:
It is not known whether pregabalin is excreted into human milk. Caution should be exercised when pregabalin is administered to a nursing woman.
DRUG INTERACTIONS:
- Somnolence may experience when use concomitantly with CNS depressants such as ***opiates or benzodiazepines.***
- There are some reports of respiratory failure and coma in patients taking pregabalin and other ***CNS depressant*** medications.
- Pregabalin may potentiate the effects of ethanol and ***lorazepam.***
- Pregabalin appears to be additive in the impairment of cognitive and gross motor functions caused by ***oxycodone.***

ADVERSE REACTIONS:
Very common: Dizziness, drowsiness and somnolence.
Common: Increased appetite, euphoric mood, confusion, irritability, decreased libido, disorientation, insomnia, abnormal coordination, tremor, dysarthria, memory impairment, paraesthesia, sedation, lethargy, headache, blurred vision, diplopia, vertigo, vomiting, dry mouth, constipation, flatulence, erectile dysfunction, abnormal gait, feeling drunk, fatigue, peripheral oedema and weight increased.
Uncommon: hypoglycemia, hallucination, panic attack, tremor, cognitive disorder, visual disturbance, cardiovascular disorder, dyspnoea, GI disturbances, muscle & joint problems, back pain, urinary incontinence, ejaculation delayed, increased creatine phosphokinase, increased liver enzymes and platelet count decreased.
OVERDOSAGE:
Overdosage symptoms include somnolence, confusional state, agitation and restlessness. In rare occasions, coma have been reported. Treatment include general supportive measures and may include hemodialysis if necessary.
INSTRUCTIONS:
- Store below 30˚C.
- Protect from light & moisture.
- Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.
HOW SUPPLIED:
GIBLI (Pregabalin) 25mg Capsules are available in pack of 14's.
GIBLI (Pregabalin) 50mg Capsules are available in pack of 14's.
GIBLI (Pregabalin) 75mg Capsules are available in pack of 14's.
GIBLI (Pregabalin) 100mg Capsules are available in pack of 14's.
GIBLI (Pregabalin) 150mg Capsules are available in pack of 14's.
GIBLI (Pregabalin) 300mg Capsules are available in pack of 14's.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
انتباہ: صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

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