Size: 160mm (w) x 250mm (h)

PREGAVID CAPSULES

VIPRE11-var14

DESCRIPTION

Pregavid Capsules 300mg
Size 0 capsule with brown opaque cap and white opaque body, printed with "hovid" on cap and "PB 300" on body in black ink, containing white to off-white powder.

Pregavid Capsules 225mg
Size 1 capsule with light brown opaque cap and white opaque body, printed with "hovid" on cap and "PB 225" on body in black ink, containing white to off-white powder.

Pregavid Capsules 200mg
Size 1 capsule with light orange opaque cap and light orange opaque body, printed with "hovid" on cap and "PB 200" on body in black ink, containing white to off-white powder.

Pregavid Capsules 150mg
Size 2 capsule with white opaque cap and white opaque body, printed with "hovid" on cap and "PB 150" on body in black ink, containing white to off-white powder.

Pregavid Capsules 100mg
Size 4 capsule with light brown opaque cap and light brown opaque body, printed with "hovid" on cap and "PB 100" on body in black ink, containing white to off-white powder. The body is also marked with a black band.

Pregavid Capsules 75mg
Size 4 capsule with brown opaque cap and white opaque body, printed with "hovid" on cap and "PB 75" on body in black ink, containing white to off-white powder.

Pregavid Capsules 50mg
Size 2 capsule with white opaque cap and white opaque body, printed with "hovid" on cap and "PB 50" on body in black ink, containing white to off-white powder. The body is also marked with a black band.

Pregavid Capsules 25mg
Size 4 capsule with white opaque cap and white opaque body, printed with "hovid" on cap and "PB 25" on body in black ink, containing white to off-white powder.

COMPOSITION

Pregavid Capsules 300mg
Each Pregavid Capsules 300mg contains pregabalin 300mg.

Pregavid Capsules 225mg
Each Pregavid Capsules 225mg contains pregabalin 225mg.

Pregavid Capsules 200mg
Each Pregavid Capsules 200mg contains pregabalin 200mg.

Pregavid Capsules 150mg
Each Pregavid Capsules 150mg contains pregabalin 150mg.

Pregavid Capsules 100mg
Each Pregavid Capsules 100mg contains pregabalin 100mg.

Pregavid Capsules 75mg
Each Pregavid Capsules 75mg contains pregabalin 75mg.

Pregavid Capsules 50mg
Each Pregavid Capsules 50mg contains pregabalin 50mg.

Pregavid Capsules 25mg
Each Pregavid Capsules 25mg contains pregabalin 25mg.

PHARMACODYNAMICS

Phamacotherapeutic group: Other analgesics & antipyretics

The active substance, pregabalin, is a gamma-aminobutyric acid analogue ((S)-3-(aminomethyl)-5-methylhexanoic acid).

Mechanism of action
Pregabalin binds to an auxillary subunit (α2-δ protein) of voltage-gated calcium channels in the central nervous system.

PHARMACOKINETICS

Pregabalin steady-state pharmacokinetics are similar in healthy volunteers, patients with epilepsy receiving anti-epileptic drugs, and patients with chronic pain.

Absorption
Pregabalin is rapidly absorbed when administered in the fasted state, with peak plasma concentrations occurring within 1 hour following both single and multiple dose administration. Pregabalin oral bioavailability is estimated to be ≥ 90% and is independent of dose. Following repeated administration, steady state is achieved within 24 to 48 hours. The rate of pregabalin absorption is decreased when given with food resulting in a decrease in Cmax by approximately 25-30% and a delay in tmax to approximately 2.5 hours. However, administration of pregabalin with food has no clinically significant effect on the extent of pregabalin absorption.

Distribution
The apparent volume of distribution of pregabalin following oral administration is approximately 0.56 l/kg. Pregabalin is not bound to plasma proteins.

Metabolism
Pregabalin undergoes negligible metabolism in humans. Following a dose of radiolabelled pregabalin, approximately 98% of the radioactivity recovered in the urine was unchanged pregabalin. The N-methylated derivative of pregabalin, the major metabolite of pregabalin found in urine, accounted for 0.9% of the dose.

Elimination
Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug.

Pregabalin mean elimination half-life is 6.3 hours. Pregabalin plasma clearance and renal clearance are directly proportional to creatinine clearance.

Dose adjustment in patients with reduced renal function or undergoing haemodialysis is necessary.

Linearity/Non-linearity
Pregabalin pharmacokinetics are linear over the recommended daily dose range. Inter-subject pharmacokinetic variability for pregabalin is low (<20%). Multiple dose pharmacokinetics are predictable from single-dose data. Therefore, there is no need for routine monitoring of plasma concentrations of pregabalin.

Pharmacokinetics in special patient groups
Gender
Clinical trials indicate that gender does not have a clinically significant influence on the plasma concentrations of pregabalin.

Renal impairment
Pregabalin clearance is directly proportional to creatinine clearance. In addition, pregabalin is effectively removed from plasma by haemodialysis (following a 4-hour haemodialysis treatment plasma pregabalin concentrations are reduced by approximately 50%). Because renal elimination is the major elimination pathway, dose reduction in patients with renal impairment and dose supplementation following haemodialysis is necessary.

Hepatic impairment
No specific pharmacokinetic studies were carried out in patients with impaired liver function. Since pregabalin does not undergo significant metabolism and is excreted predominantly as unchanged drug in the urine, impaired liver function would not be expected to significantly alter pregabalin plasma concentrations.

Elderly (over 65 years of age)
Pregabalin clearance tends to decrease with increasing age. This decrease in pregabalin oral clearance is consistent with decreases in creatinine clearance associated with increasing age. Reduction of pregabalin dose may be required in patients who have age related compromised renal function.

Breast-feeding mothers
Lactation had little to no influence on pregabalin pharmacokinetics. Pregabalin was excreted into breast milk with average steady-state concentrations approximately 76% of those in maternal plasma. The estimated average daily infant dose of pregabalin from breast milk (assuming mean milk consumption of 150 mL/kg/day) was 0.31 mg/kg/day, which on a mg/kg basis would be approximately 7% of the maternal dose.

INDICATIONS

Neuropathic pain
Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.

Epilepsy
Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

Generalised Anxiety Disorder
Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

Fibromyalgia
Pregabalin is indicated for the management of fibromyalgia.

RECOMMENDED DOSE

Method of administration: Oral. Shallow as whole.

The dose range is 150 to 600 mg per day given in either two or three divided doses.

Pregabalin may be taken with or without food.

Neuropathic pain
Pregabalin treatment can be started at a dose of 150 mg per day. Based on individual patient response and tolerability, the dose may be increased to 300 mg per day after an interval of 3 to 7 days, and if needed, to a maximum dose of 600 mg per day after an additional 7-day interval.

Fibromyalgia
The usual dose range for most patients is 300 to 450 mg per day given in two divided doses. Some patients may derive additional benefit at 600 mg per day. Dosing should begin at 75 mg two times a day (150 mg/day) and may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300 mg/day may be further increased to 225 mg two times a day (450 mg/day). If needed, in some patients, based on individual response and tolerability, the dose may be increased to maximum dosage of 600 mg/day after an additional week.

Epilepsy
Pregabalin treatment can be started with a dose of 150 mg per day. Based on individual patient response and tolerability, the dosage may be increased to 300 mg per day after 1 week. The maximum dosage of 600 mg per day may be achieved after an additional week.

Generalised Anxiety Disorder
The dose range is 150 to 600 mg per day given as two or three divided doses. The need for treatment should be reassessed regularly.

Pregabalin treatment can be started with a dose of 150 mg per day. Based on individual patient response and tolerability, the dosage may be increased to 300 mg per day after 1 week. Following an additional week the dosage may be increased to 450 mg per day. The maximum dosage of 600 mg per day may be achieved after an additional week.

Discontinuation of pregabalin
If pregabalin has to be discontinued, it is recommended this should be done gradually over a minimum of 1 week.

Patients with renal impairment
Dosage reduction in patients with compromised renal function must be individualised according to creatinine clearance (CLcr), as indicated in table below determined using the following formula:

$$CL_{cr}\left(\frac{ml}{min}\right) = \left[\frac{[140 - \text{age (years)}] \times \text{weight (kg)}}{72 \times \text{serum creatinine (mg/dL)}}\right] \quad (\times 0.85 \text{ for female patients})$$

For patients receiving hemodialysis, the pregabalin daily dose should be adjusted based on renal function. In addition to the daily dose, a supplementary dose should be given immediately following every 4-hour haemodialysis treatment (see table below).

Table: Pregabalin dose adjustment based on renal function

Creatinine clearance (CLcr) (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 haemodialysis (mg)			
	25	100	SIngle dose+

TID = Three divided doses
BID = Two divided doses
OD = single daily 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

Use in patients with hepatic impairment
No dosage adjustment is required for patients with hepatic impairment.

Use in children and adolescents (12 to 17 years of age)
The safety and effectiveness of pregabalin in pediatric patients below the age of 12 years and adolescent had not been established.

The use in children is not recommended.

Use in the elderly (over 65 years of age)
Elderly patients may require a dose reduction of pregabalin due to a decreased renal function.

Note: The information given here is limited. For further information consult your doctor or pharmacist.

ROUTE OF ADMINISTRATION

Oral

CONTRAINDICATIONS

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

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). There were reports of life-threatening angioedema with respiratory compromise requiring emergency treatment. Discontinue pregabalin immediately in patients with these symptoms. Discontinue pregabalin immediately in patients with these symptoms.

Exercise caution when prescribing pregabalin to patients who have had a previous episode of angioedema. In addition, patients who are taking other drugs associated with angioedema (e.g., angiotensin converting enzyme inhibitors [ACE-inhibitors]) may be at increased risk of developing angioedema.

Hypersensitivity
There have been post-marketing reports of hypersensitivity in patients shortly after initiation of treatment with pregabalin. Adverse reactions included skin redness, blisters, hives, rash, dyspnea, and wheezing. Discontinue pregabalin immediately in patients with these symptoms.

Suicidal Behavior and Ideation
Antiepileptic drugs (AEDs), including pregabalin, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Monitor patients treated with any AED for any indication for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

The increased risk of suicidal thoughts or behavior with AEDs was observed as early as one week after starting drug treatment with AEDs and persisted for the duration of treatment assessed.

The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The risk did not vary substantially by age (5-100 years) in the clinical trials analyzed.

Anyone considering prescribing pregabalin or any other AED must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment, the prescriber needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

Respiratory Depression
There is evidence from case reports, human studies, and animal studies associating pregabalin with serious, life-threatening, or fatal respiratory depression when co-administered with central nervous system (CNS) depressants, including opioids, or in the setting of underlying respiratory impairment. When the decision is made to co-prescribe pregabalin with another CND depressant, particularly an opioid, or to prescribe pregabalin to patients with underlying respiratory impairment, monitor patients for symptoms of respiratory depression and sedation, and consider initiating pregabalin at a low dose. The management of respiratory depression may include close observation, supportive measures, and reduction or withdrawal of CNS depressants (including pregabalin).

There is more limited evidence from case reports, animal studies, and human studies associating pregabalin with serious respiratory depression, without co-administered CNS depressants or without underlying respiratory impairment.

Dizziness and Somnolence
Pregabalin may cause dizziness and somnolence. Inform patients that pregabalin-related dizziness and somnolence may impair the ability to perform tasks such as driving or operating machinery and could increase the occurrence of accidental injury (fall) in the elderly population.

In the reported pregabalin controlled trials in adult patients, dizziness was experienced by 30% pregabalin-treated patients compared to 8% of placebo-treated patients; somnolence was experienced by 23% of pregabalin-treated patients compared to 8% of placebo-treated patients. Dizziness and somnolence generally began shortly after the initiation of pregabalin therapy and occurred more frequently at higher doses. Dizziness and somnolence were the adverse reactions most frequently associated with leading to withdrawal (4% each) from reported controlled studies. In pregabalin-treated patients reporting these adverse reactions in short-term, reported controlled studies, dizziness persisted until the last dose in 30% and somnolence persisted until the last dose in 42% of patients (see Interactions with other medicaments).

There have also been post-marketing reports of loss of consciousness, confusion and mental impairment. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medication.

Pregabalin is not known to be active at receptor sites associated with drugs of abuse. Cases of misuse and abuse have been reported in the post-marketing database. As with any CNS active drug, carefully evaluate patients for history of drug abuse and/or psychiatric disorders. Caution should be applied when considering pregabalin use in patients with current substance abuse or a history of substance abuse, who are at higher risk for pregabalin abuse (see Pharmacodynamic).

Increased Risk of Adverse Reactions with Abrupt or Rapid Discontinuation
As with all antiepileptic drugs (AEDs), withdraw pregabalin gradually to minimize the potential of increased seizure frequency in patients with seizure disorders.

Following abrupt or rapid discontinuation of Pregavid Capsules, some patients reported symptoms including insomnia, nausea, headache, anxiety, hyperhidrosis, and diarrhea.

If Pregavid Capsules is discontinued, taper the drug gradually over a minimum of 1 week rather than discontinue the drug abruptly.

Peripheral Edema
Pregabalin treatment may cause peripheral edema. Peripheral edema was not associated with laboratory changes suggestive of deterioration in renal or hepatic function.

As the thiazolidinedione class of antidiabetic drugs can cause weight gain and/or fluid retention, possibly exacerbating or leading to heart failure, exercise caution when co-administering pregabalin and these agents.

Although there has been no causal relationship identified between exposure to pregabalin and congestive heart failure, there has been post-marketing reports of congestive heart failure in some patients receiving pregabalin.

Because there are limited data on congestive heart failure patients with New York Heart Association (NYHA) Class III or IV cardiac status, exercise caution when using pregabalin in these patients.

Weight Gain
Pregabalin treatment may cause weight gain. Pregabalin associated weight gain was related to dose and duration of exposure, but did not appear to be associated with baseline BMI, gender, or age. Weight gain was not limited to patients with edema.

While the effects of pregabalin-associated weight gain on glycemic control have not been systematically assessed, pregabalin treatment did not appear to be associated with loss of glycemic control (as measured by HbA1C).

Some diabetic patients who gain weight on pregabalin treatment may need to adjust hypoglycemic medications.

Abrupt and Rapid Discontinuation
Following abrupt or rapid 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, anxiety, diarrhoea, flu syndrome, nervousness, depression, pain, convulsion, hyperhidrosis and dizziness suggestive of physical dependence. The patient should be informed about this at the start of the treatment.

Convulsions, including status epilepticus and grand mal convulsions, may occur during pregabalin use or shortly after discontinuing pregabalin.

Concerning discontinuation of long-term treatment of pregabalin, data suggest that the incidence and severity of withdrawal symptoms may be dose-related.

Tumorigenic Potential
In reported standard preclinical in vivo carcinogenicity studies of pregabalin, an unexpectedly high incidence of hemangiosarcoma was identified in two different strains of mice. The clinical significance of this finding is unknown. Clinical experience during pregabalin's pre-marketing development provides no direct means to assess its potential for inducing tumors in humans.

In reported clinical studies across various patient populations, comprising 6396 patient-years of exposure in patients greater than 12 years of age, new- or worsening-preexisting tumors were reported in 57 patients. Without knowledge if the background incidence and recurrence in similar populations not treated with pregabalin, it is impossible to know whether the incidence seen in these cohorts is or is not affected by treatment.

Ophthalamological Effects
Although the clinical significance of the ophthalmologic findings is unknown, inform patients to notify their physician if changes in vision occur. If visual disturbance persists, consider further assessment. Consider more frequent assessment for patients who are already routinely monitored for ocular conditions.

In the post-marketing experience, visual adverse reactions have also been reported, including loss of vision, visual blurring or other changes of visual acuity, many of which were transient. Discontinuation of pregabalin may result in resolution or improvement of these visual symptoms.

Creatinine Kinase Elevations
Pregabalin treatment was associated with creatine kinase elevations. The relationship between these myopathy events and pregabalin is not completely understood because the cases had documented factors that may have caused or contributed to these events. Instruct patients to promptly report unexplained muscle pain, tenderness, or weakness, particularly if these muscle symptoms are accompanied by malaise or fever. Discontinue treatment with pregabalin if myopathy is diagnosed or suspected or if markedly elevated creatine kinase levels occur.

Decrease Platelet Count
Pregabalin treatment was associated with a decrease in platelet count.

PR Interval Prolongation
Pregabalin treatment was associated with PR interval prolongation.

Women of childbearing potential/Contraception
Pregabalin use in the first trimester of pregnancy may cause major birth defects in the unborn child. Pregabalin should not be used during pregnancy unless the benefit to the mother clearly outweighs the potential risk to the fetus. Women of childbearing potential must use effective contraception during treatment.

Others
Although the effects of discontinuation on the reversibility of renal failure have not been systematically studied, improved renal failure following discontinuation or dose reduction of pregabalin has been reported.

Misuse, abuse potential or dependence
Cases of misuse, abuse and dependence have been reported. Caution should be exercised in patients with a history of substance abuse and the patient should be monitored for symptoms of pregabalin misuse, abuse or dependence (development of tolerance, dose escalation, drug seeking behaviour have been reported).

Encephalopathy
Cases of encephalopathy have been reported, mostly in patients with underlying conditions that may precipitate encephalopathy.

Treatment of central neuropathic pain due to spinal cord injury
In the treatment of central neuropathic pain due to spinal cord injury the incidence of adverse reactions in general, central nervous system adverse reactions and especially somnolence was increased. This may be attributed to an additive effect due to concomitant medicinal products (e.g., anti-spasticity agents) needed for this condition. This should be considered when prescribing pregabalin in this condition.

Suicidal behavior and ideation
Potential for an increase in risk of suicidal thoughts or behaviors.

INTERACTIONS WITH OTHER MEDICAMENTS

Since pregabalin is predominantly excreted unchanged in the urine, undergoes negligible metabolism in humans (<2% of a dose recovered in urine as metabolites), does not inhibit drug metabolism in vitro, and is not bound to plasma proteins, it is unlikely to produce, or be subject to, pharmacokinetic interactions.

Accordingly, in in vivo studies no clinically relevant pharmacokinetic interactions were observed between pregabalin and phenytoin, carbamazepine, valproic acid, lamotrigine, gabapentin, lorazepam, oxycodone or ethanol. Population pharmacokinetic analysis indicated that oral antidiabetics, diuretics, insulin, phenobarbital, tiagabine and topiramate had no clinically significant effect on pregabalin clearance.

Co-administration of pregabalin with the oral contraceptives norethisterone and/or ethinyl estradiol does not influence the steady-state pharmacokinetics of either substance. Pregabalin may potentiate the effects of ethanol and lorazepam. In controlled clinical trials, multiple oral doses of pregabalin co- administered with oxycodone, lorazepam, or ethanol did not result in clinically important effects on respiration. Pregabalin appears to be additive in the impairment of cognitive and gross motor function caused by oxycodone.

In the post-marketing experience, there are reports of respiratory failure, coma and deaths in patients taking pregabalin and other CNS depressant medications including in patients who are substance abusers. There are post-marketing reports of events related to reduced lower gastrointestinal tract function (e.g., intestinal obstruction, paralytic ileus, constipation) when pregabalin was co- administered with medications that have the potential to produce constipation, such as opioid analgesics.

No specific pharmacodynamic interaction studies were conducted in elderly volunteers.

PREGNANCY/LACTATION

Pregnancy
There is a limited amount of data on the use of pregabalin in pregnant women.

There were no statistically significant findings for stillbirth, low birth weight, preterm birth, small for gestational age, low Apgar score, and microcephaly.

Studies in animals have shown reproductive toxicity. Pregabalin should not be used during pregnancy unless the benefit to the mother clearly outweighs the potential. Risk to the foetus. Effective contraception must be used in women of child bearing potential.

Lactation
Pregabalin is excreted in the milk of lactating women. As the safety of pregabalin in infants is not known, breast-feeding is not recommended during treatment with pregabalin. A decision must be made whether to discontinue breast-feeding or to discontinue from pregabalin therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

ADVERSE EFFECTS/UNDESIRABLE EFFECTS

The adverse reactions listed may also be associated with the underlying disease and/or concomitant medications.

Table: Adverse Drug Reactions from Clinical Trial Experience

System Organ Class	Adverse Drug Reactions
Infections and infestations	
Common	Nasopharyngitis
Blood and lymphatic system disorders	
Uncommon	Neutropenia
Metabolism and nutrition disorders	
Common	Appetite increased
Uncommon	Anorexia, hypoglcemia
Psychiatric disorders	
Common	Euphoric mood, confusion, irritability, depression, disorientation, insomnia, libido decreased
Uncommon	Hallucination, restlessness, agitation, depressed mood, elevated mood, mood swings, depersonalization, abnormal dreams, word finding difficulty, libido increased, anorgasmia
Rare	Panic attack, disinhibition, apathy
Nervous system disorders	
Very common	Dizziness, somnolence
Common	Ataxia, coordination abnormal, tremor, dysarthria, amnesia, memory impairment, disturbance in attention, paraesthesia, hypoesthesia, sedation, balance disorder, lethargy
Nervous system disorders	
Uncommon	Syncope, myoclonus, psychomotor hyperactivity, dyskinesia, dizziness postural, intention tremor, nystagmus, cognitive disorder, speech disorder, hyporeflexia, hyperaesthesia, burning sensation
Very common	Stupor, parosmia, hypokinesia, ageusia, dysgraphia
Eye disorders	
Common	Vision blurred, diplopia
Uncommon	Peripheral vision loss, visual disturbance, eye swelling, visual field defect, visual acuity reduced, eye pain, asthenopia, photopsia, dry eye, lacrimation increased, eye irritation
Rare	Oscillopsia, altered visual depth perception, mydriasis, strabismus, visual brightness
Ear and labyrinth disorders	
Common	Vertigo
Uncommon	Hyperacusis
Cardiac disorders	
Uncommon	Tachycardia, atrioventricular block first degree, sinus bradycardia
Rare	Sinus tachycardia, sinus arrhythmia
Vascular disorders	
Uncommon	Hypotension, hypertension, hot flushes, flushing, peripheral coldness
Respiratory, thoracic and mediastinal disorders	
Uncommon	Dyspnoea, epistaxis, cough, nasal congestion, rhinitis, snoring
Rare	Throat tightness, nasal dryness
Gastrointestinal disorders	
Common	Vomiting, constipation, flatulence, abdominal distension, dry mouth
Uncommon	Gastrooesophageal reflux disease, salivary hypersecretion, hypoesthesia oral
Rare	Ascites, pancreatitis, dysphagia
Renal and urinary disorders	
Uncommon	Urinary incontinence, dysuria
Rare	Renal failure, oliguria
Reproductive system and breast disorders	
Uncommon	Erectile dysfunction, sexual dysfunction, ejaculation delayed, dysmenorrhoea
Rare	Breast pain, amenorrhoea, breast discharge, breast enlargement
General disorders and administration site conditions	
Common	Oedema peripheral, oedema, gait abnormal, fall, feeling drunk, feeling abnormal, fatigue
Uncommon	Generalised oedema, chest tightness, pain, pyrexia, thirst, chills, asthenia
Investigations	
Common	Weight increased
Uncommon	Blood creatine phosphokinase increased, alanine aminotransferase increased, aspartate aminotransferase increased, blood glucose increased, platelet count decreased, blood potassium decreased, weight decreased
Rare	White blood cell count decreased, blood creatinine increased
Skin and subcutaneous tissue disorders	
Uncommon	Rash papular, urticaria, sweating
Rare	Cold sweat, Stevens-Johnson Syndrome
Musculoskeletal and connective tissue disorders	
Common	Muscle cramp, arthralgia, back pain, pain in limb, cervical spasm
Uncommon	Joint swelling, myalgia, muscle twitching, neck pain, muscle stiffness
Rare	Rhabdomyolysis

The following adverse drug reactions were reported during post-marketing surveillance (done by innovator brand):

Immune system disorder
Uncommon: Hypersensitivity; Rare: Angioedema, allergic reaction.

Nervous system disorders
Very Common: Headache; Uncommon: Loss of consciousness, mental impairment.

Eye disorders
Rare: Keratitis.§

Cardiac disorders
Rare: Congestive heart failure.

Respiratory, thoracic and mediastinal disorders
Rare: Pulmonary oedema.§

Gastrointestinal disorders
Common: Nausea, diarrhoea; Rare: Swollen tongue.

Skin and subcutaneous tissue disorders
Uncommon: Face swelling, pruritus.

Renal and urinary disorders
Rare: Urinary retention.

Reproductive system and breast disorders
Rare: Gynaecomastia.§

General disorders and administration site conditions:
Uncommon: Malaise.
§Adverse drug reaction frequency estimated using "The Rule of 3".

OVERDOSE AND TREATMENT

In overdoses up to 15 g, no unexpected adverse reactions were reported.

In the post-marketing experience (done by innovator brand), the most commonly reported adverse events observed when pregabalin was taken in overdose included affective disorder, somnolence, confusional state, depression, agitation and restlessness. Seizures were also reported.

Treatment of pregabalin overdose should include general supportive measures and may include haemodialysis if necessary.

EFFECT ON ABILITY TO DRIVE AND USE MACHINE

Pregabalin may cause dizziness and somnolence and therefore may influence the ability to drive or use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medication affects their ability to perform these activities.

Storage Condition : Store below 30°C.
Keep in a cool, dry place away from sunlight.

Presentation/Packing : Blister packaging of 30's, 60's, 90's and 100's
(not all presentation available locally)

Product Registration Holder
(Malaysia)/Product Owner : **Hovid Berhad**
121 Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.

Manufactured by : **Hovid Berhad**
Lot 56442, 7½ Miles, Jalan Ipoh/Chemor,
31200 Chemor, Perak, Malaysia.

Revision date : November 2025

hovid

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Sub Header: Arial Bold - 7pt
Body Content: Arial Regular - 3.9pt