PREGABA 50

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for PREGABA 50 [Pregabalin 50 mg Capsules]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Pregabalin binds to an auxiliary subunit (α2-δ protein) of voltage-gated calcium channels in the central nervous system.

INDICATIONS: It is indicated for neuropathic pain and management of fibromyalgia syndrome

DOSAGE AND ADMINISTRATION: The dose range is 150 to 600 mg per day given in either two or three divided doses, as directed by the physician. In accordance with current clinical practice, if pregabalin has to be discontinued, it is recommended this should be done gradually over a minimum of 1 week independent of the indication. As pregabalin clearance is directly proportional to creatinine clearance, dose reduction in patients with compromised renal function must be individualized. For patients receiving haemodialysis, 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. Elderly patients may require a dose reduction of pregabalin due to a decreased renal function. PREGABA is for oral use only.

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

WARNINGS & PRECAUTIONS: In accordance with current clinical practice, some diabetic patients who gain weight on pregabalin treatment may need to adjust hypoglycemic medicinal products. There have been reports in the post marketing experience of hypersensitivity reactions, including cases of angioedema. Pregabalin should be discontinued immediately if symptoms of angioedema, such as facial, perioral, or upper airway swelling occur. Pregabalin treatment has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in the elderly population. loss of consciousness, confusion and mental impairment. Patients treated with pregabalin reported blurred vision. Discontinuation of pregabalin may result in resolution or improvement of these visual symptoms. Cases of renal failure have been reported and in some cases discontinuation of pregabalin did show reversibility of this adverse reaction. insomnia, headache, nausea, anxiety, diarrhea, 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, reported data suggest that the incidence and severity of withdrawal symptoms may be dose related. There have been post marketing 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. 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. Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic agents in several indications.

DRUG INTERACTIONS: Pregabalin may potentiate the effects of ethanol and lorazepam. There are reports of respiratory failure and coma in patients taking pregabalin and other central nervous system (CNS) depressant medicinal products. Pregabalin appears to be additive in the impairment of cognitive and gross motor function caused by oxycodone.

ADVERSE REACTIONS: Nasopharyngitis, Neutropaenia, Hypersensitivity, Angioedema, allergic reaction, Appetite increased, Anorexia, hypoglycaemia, Euphoric mood, confusion, irritability, disorientation, insomnia, libido decreased, Hallucination, panic attack, restlessness, agitation, depression, depressed mood, elevated mood, aggression, mood swings, depersonalisation, word finding difficulty,

abnormal dreams, libido increased, anorgasmia, apathy, Disinhibition, Dizziness, somnolence, headache, Ataxia, coordination abnormal, tremor, dysarthria, amnesia, memory impairment, disturbance in attention, paraesthesia, hypoaesthesia, sedation, balance disorder, lethargy, Syncope, stupor, myoclonus, loss of consciousness, psychomotor hyperactivity, dyskinesia, dizziness postural, intention tremor, nystagmus, cognitive disorder, mental impairment, speech disorder, hyporeflexia, hyperaesthesia, burning sensation, ageusia, malaise , Convulsions, parosmia, hypokinesia, dysgraphia, Vision blurred, diplopia, Peripheral vision loss, visual disturbance, eye swelling, visual field defect, visual acuity reduced, eye pain, asthenopia, photopsia, dry eye, lacrimation increased, eye irritation, Vision loss, keratitis, oscillopsia, altered visual depth perception, mydriasis, strabismus, visual brightness, Vertigo, Hyperacusis, Tachycardia, atrioventricular block first degree, sinus bradycardia, congestive heart failure, QT prolongation, sinus tachycardia, sinus arrhythmia, Hypotension, hypertension, hot flushes, flushing, peripheral coldness , Dyspnoea, epistaxis, cough, nasal congestion, rhinitis, snoring, nasal dryness, Pulmonary oedema, throat tightness, Vomiting, nausea, constipation, diarrhoea, flatulence, abdominal distension, dry mouth, Gastroesophageal reflux disease, salivary hypersecretion, hypoaesthesia oral, Ascites, pancreatitis, swollen tongue, dysphagia, Rash papular, urticaria, hyperhidrosis, pruritus, Stevens Johnson syndrome, cold sweat, Muscle cramp, arthralgia, back pain, pain in limb, cervical spasm, Joint swelling, myalgia, muscle twitching, neck pain, muscle stiffness, Rhabdomyolysis, Urinary incontinence, dysuria, Renal failure, oliguria, urinary retention, Erectile dysfunction, Sexual dysfunction, ejaculation delayed, dysmenorrhoea, breast pain, Amenorrhoea, breast discharge, breast enlargement, gynaecomastia, Oedema peripheral, oedema, gait abnormal, fall, feeling drunk, feeling abnormal, fatigue, Generalised oedema, face oedema, chest tightness, pain, pyrexia, thirst, chills, asthenia, Weight increased, Blood creatine phosphokinase increased, alanine aminotransferase increased, aspartate aminotransferase increased, blood glucose increased, platelet count decreased, blood creatinine increased, blood potassium decreased, weight decreased, White blood cell count decreased.

MARKETED BY:

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)