PREGALIN

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

Abbreviated Prescribing information for PREGALIN [Pregabalin Capsules I.P.]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: The active substance, pregabalin, is a gamma-aminobutyric acid analogue [(S)-3- (aminomethyl)-5-methylhexanoic acid]. Pregabalin binds to an auxiliary subunit (α2-δ protein) of voltage-gated calcium channels in the central nervous system.

INDICATIONS: Pregabalin is indicated the management of fibromyalgia syndrome and for neuropathic pain.

DOSAGE AND ADMINISTRATION: The dose range is 150 to 600 mg per day given in either two or three divided doses. Treatment should be given for the shortest possible duration. Pregabalin may be taken with or without food. Pregabalin 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 hypoglycaemic medicinal products. Pregabalin should be discontinued immediately if symptoms of angioedema, such as facial, perioral, or upper airway swelling occur. SCARs including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), which can be life-threatening or fatal, have been reported rarely in association with pregabalin treatment. Pregabalin treatment has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in the elderly population. In the postmarketing 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. Cases of renal failure have been reported and in some cases discontinuation of pregabalin did show reversibility of this adverse reaction. There have been postmarketing reports of congestive heart failure in some patients receiving pregabalin. 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. There have been reports of severe respiratory depression in relation to pregabalin use. Patients should be monitored for signs of suicidal ideation and behaviour and appropriate treatment should be considered. Cases of encephalopathy have been reported, mostly in patients with underlying conditions that may precipitate encephalopathy.

DRUG 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. Pregabalin may potentiate the effects of ethanol and lorazepam. In the postmarketing experience, there are reports of respiratory failure, coma and deaths in patients taking pregabalin and opioids and/or 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, suicidal behaviour, suicidal ideation, drug dependence, 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, parkinsonism, 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, 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, respiratory depression, vomiting, nausea, constipation, diarrhoea, flatulence, abdominal distension, dry mouth, gastrooesophageal reflux disease, salivary hypersecretion, hypoaesthesia oral, ascites, pancreatitis, swollen tongue, dysphagia, elevated liver enzymes, jaundice, hepatic failure, hepatitis, rash papular, urticaria, hyperhidrosis, pruritus, drug dependence, 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, blood glucose increased, platelet count decreased, blood creatinine increased, blood potassium decreased, weight decreased, white blood cell count decreased.

MARKETED BY:

TORRENT
PHARMA

Torrent Pharmaceuticals Limited.

IN/PREGALIN 50, 75 and 150 mg/MAY-2026/02/ABPI

(Additional information is available on request)