PREGABA SR 75

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

Abbreviated Prescribing information for PREGABA SR 75 [Pregabalin sustained release 75 mg Tablets]
[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: For the treatment of peripheral neuropathic pain in adults.

DOSAGE AND ADMINISTRATION: The starting dose of Pregaba SR Tablets is 75 mg once daily, administered in the evening. Dose increases above 150 mg/day should be made only after clinical assessment and generally should occur at intervals of 7 days with increment of 150mg/day. Maximum safe dose of Pregabalin is 600 mg/day. Pregaba SR Tablets can be taken with or without food. Pregaba SR must be swallowed whole with the aid of liquids. In view of dose-dependent adverse events and since pregabalin is eliminated primarily by renal excretion, the dose should be adjusted in patients with reduced renal function.

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

WARNINGS & PRECAUTIONS: Some diabetic patients who gain weight on pregabalin treatment may need to adjust hypoglycaemic medicinal products. There have been reports in the postmarketing 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. In controlled trials, a higher proportion of patients treated with pregabalin reported blurred vision than did patients treated with placebo which resolved in a majority of cases with continued dosing. Cases of renal failure have been reported and in some cases discontinuation of pregabalin did show reversibility of this adverse reaction. 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, anxiety, diarrhoea, flu syndrome, nervousness, depression, pain, convulsion, hyperhidrosis and dizziness, suggestive of physical dependence. 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. There have been postmarketing 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. A meta-analysis of randomised placebo controlled studies of antiepileptic drugs has also shown a small increased risk of suicidal ideation and behaviour. Therefore, patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge. There are postmarketing reports of events related to reduced lower gastrointestinal tract function (e.g. intestinal obstruction, paralytic ileus, constipation) when pregabalin was coadministered with medications that have the potential to produce constipation, such as opioid analgesics. 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. Cases of encephalopathy have been reported, mostly in patients with underlying conditions

that may precipitate encephalopathy.

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 PHARMA

Torrent Pharmaceuticals Limited.

IN/PREGABA SR 75 mg/DEC-18/01/PI

(Additional information is available on request)