TORPANEL SUSPENSION

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

Abbreviated Prescribing information for TORPANEL SUSPENSION (Perampanel Oral Suspension 0.5 mg/ml)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Perampanel is a first-in-class selective, non-competitive antagonist of the ionotropic α-amino-3-hydroxy-5- methyl-4-isoxazolepopionic acid (AMPA) glutamate receptor on post-synaptic neurons. Glutamate is the primary excitatory neurotransmitter in the central nervous system and it is implicated in a number of neurological disorders caused by neuronal over excitation. Activation of AMPA receptors by glutamate is thought to be responsible for most fast excitatory synaptic transmission in the brain. The precise mechanism by which perampanel exerts its antiepileptic effects in humans remains to be fully elucidated.

INDICATIONS: It is Indicated as adjunctive therapy for the treatment of: (a) Partial-onset Seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older. (b) Primary Generalized Tonic-Clonic Seizures in patients with epilepsy 12 years of age and older.

DOSAGE AND ADMINISTRATION: Perampanel Oral Suspension, 0.5 mg/mL should be taken orally once daily at bedtime by shaking well before every administration. It may be taken with or without food, but preferably always under the same conditions. *Partial-Onset Seizures* Perampanel at doses of 4 mg/day to 12 mg/day has been shown to be effective therapy in partial-onset seizures. *Primary Generalised Tonic-Clonic Seizures:* Perampanel at a dose up to 8 mg/day has been shown to be effective in primary generalised tonic-clonic seizures. In Partial-Onset Seizures and Primary Generalised Tonic-Clonic Seizures recommended starting dose for adult/adolescent (12 years and older) is 2mg/day (4ml/day).

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

WARNINGS & PRECAUTIONS: *Suicidal ideation* Patients (children, adolescents, and adults) should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. *Severe cutaneous adverse reactions (SCARs)* If the patient has developed a serious reaction such as SJS or DRESS, perampanel should be withdrawn immediately and an alternative treatment considered (as appropriate). Treatment with perampanel must not be restarted in this patient at any time. If signs and symptoms suggestive of these reactions appear, *Absence and myoclonic seizures* Patients with myoclonic seizures and absence seizures should be monitored while on Perampanel. *Nervous system disorders* Perampanel may cause dizziness and somnolence and therefore may influence the ability to drive or use machines. *Abuse potential* Patient should be monitored for symptoms of perampanel abuse. *Falls* an increased risk of falls, particularly in the elderly, the underlying reason is unclear.

DRUG INTERACTIONS: *Hormonal contraceptives:* The possibility of decreased efficacy of hormonal progestative-containing contraceptives should be considered for women needing Perampanel 12 mg/day and an additional reliable method (intra-uterine device (IUD), condom) is to be used, *Other anti-epileptic drugs (AEDs) co-administered*: *Influence of AED on Perampanel concentration:* Carbamazepine (3 fold decrease), Oxcarbazepine (2 fold decrease), Phenobarbital (20% decrease), Phenytoin (2 fold decrease), Topiramate (20% decrease). *Influence of Perampanel on AED concentration:* <10% decrease in: Carbamazepine, Clobazam, Lamotrigine, Oxcarbazepine and Valproic acid ((35% increase). *Alcohol:* The effects of perampanel on tasks involving alertness and vigilance such as driving ability were additive or supra-additive to the effects of alcohol itself, as found in a pharmacodynamic interaction study in healthy subjects. *CYP50 inhibitors*: Larger effects cannot be excluded when perampanel is combined with a CYP3A inhibitor with longer half-life than ketoconazole or when the inhibitor is given for a longer treatment duration.

ADVERSE REACTIONS: Decreased appetite, Dizziness, Somnolence, Increase appetite, Aggression, Anger, Anxiety, Confusional state, Ataxia, Dysarthria, Balance disorder, Irritability, Diplopia Vision blurred, Vertigo, Nausea, Back pain, Gait disturbance, Fatigue, Weight increased, Fall, Suicidal ideation, Suicide attempt, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) Stevens – Johnson Syndrome (SJS)

MARKETED BY:

TORRENT PHARMA

TORRENT PHARMACEUTICALS LTD.

IN/TORPANEL SUSPENSION 100 ml/MAY 2026/01/ABPI

(Additional information is available on request)