

TORPANEL

“To be sold by retail on the prescription Neurologist only”.

Abbreviated Prescribing information for TORPANEL (Perampanel Tablets I.P.)

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

Warning: serious psychiatric and behavioral reactions.

- **Serious or life-threatening psychiatric and behavioral adverse reactions including aggression, hostility, irritability, anger, and homicidal ideation and threats have been reported in patients taking perampanel tablet.**
- **Monitor patients for these reactions as well as for changes in mood, behavior, or personality that are not typical for the patient, particularly during the titration period and at higher doses.**
- **Perampanel tablet should be reduced if these symptoms occur and should be discontinued immediately if symptoms are severe or are worsening.**

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-isoxazolepropionic acid (AMPA) glutamate receptor on post-synaptic neurons. Glutamate is the primary excitatory neurotransmitter in the central nervous system and is implicated in a number of neurological disorders caused by neuronal overexcitation. Activation of AMPA receptors by glutamate is thought to be responsible for most fast excitatory synaptic transmission in the brain. In in vitro studies, perampanel did not compete with AMPA for binding to the AMPA receptor, but perampanel binding was displaced by noncompetitive AMPA receptor antagonists, indicating that perampanel is a noncompetitive AMPA receptor antagonist. In vitro, perampanel inhibited AMPA-induced (but not NMDA-induced) increase in intracellular calcium. In vivo, perampanel significantly prolonged seizure latency in an AMPA-induced seizure model. The precise mechanism by which perampanel exerts its antiepileptic effects in humans remains to be fully elucidated.

DOSAGE AND ADMINISTRATION: Perampanel should be taken orally once daily at bedtime. The physician should prescribe the most appropriate formulation and strength according to weight and dose. It should not be chewed, crushed or split. The tablets cannot be split accurately as there is no break line.

CONTRAINDICATION: Hypersensitivity to active substances or to any of the excipients of this product.

WARNINGS & PRECAUTIONS: Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic medicinal products in several indications, Severe cutaneous adverse reactions (SCARs) including drug reaction with eosinophilia and systemic symptoms (DRESS), dizziness and somnolence, falls, Aggression, may decrease the effectiveness of progestative-containing hormonal contraceptives, Abuse potential, Concomitant CYP3A inducing anti-epileptic medicinal products (carbamazepine, phenytoin, oxcarbazepine), Other concomitant (non- anti-epileptic) cytochrome P450 inducing or inhibiting medicinal products.

DRUGS INTERACTIONS: Oral contraceptives, Interactions between Perampanel and other anti-epileptic medicinal products, Effect of perampanel on CYP3A substrates, Effect of cytochrome P450 inducers on perampanel pharmacokinetics, Effect of cytochrome P450 inhibitors on perampanel pharmacokinetics, Levodopa, Alcohol.

ADVERSE REACTIONS: Decreased appetite, increased appetite, aggression, anger, anxiety, confusional state, suicidal ideation, suicidal attempt, hallucinations, psychotic disorder,

dizziness, somnolence, ataxia, dysarthria, balance disorder, irritability, diplopia, vision blurred, vertigo, nausea, drug interaction with eosinophilia and systemic (DRESS), Steven Johnson Syndrome (SJS), back pain, gait disturbance, fatigue, weight increased, fall.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/TORPANEL 2mg and 4mg/DEC-2025 /04/ABPI

(Additional information is available on request)