

LACOSAM SYRUP

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for LACOSAM SYRUP (Lacosamide syrup 15 mg/ml)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: The active substance, lacosamide (R-2-acetamido-N-benzyl-3-methoxypropionamide) is a functionalised amino acid. The precise mechanism by which lacosamide exerts its antiepileptic effect in humans remains to be fully elucidated. In vitro electrophysiological studies have shown that lacosamide selectively enhances slow inactivation of voltage-gated sodium channels, resulting in stabilization of hyper excitable neuronal membranes.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. Known second- or third-degree atrioventricular (AV) block.

WARNINGS & PRECAUTIONS: Suicidal ideation and behaviour, Cardiac rhythm and conduction, Dizziness.

DRUG INTERACTION: Lacosamide should be used with caution in patients treated with medicinal products known to be associated with PR prolongation (e.g. carbamazepine, lamotrigine, eslicarbazepine, pregabalin) and in patients treated with class I antiarrhythmics. Caution is recommended in concomitant treatment with strong inhibitors of CYP2C9 (e.g. fluconazole) and CYP3A4 (e.g. itraconazole, ketoconazole, ritonavir, clarithromycin), which may lead to increased systemic exposure of lacosamide, Antiepileptic medicinal products, Oral contraceptives.

ADVERSE REACTIONS: Dizziness, Headache, Agranulocytosis, Drug hypersensitivity, Drug reaction with eosinophilia and systemic symptoms (DRESS), Depression Confusional state Insomnia, Aggression, Agitation, Euphoric mood, Psychotic disorder, Suicide attempt, Suicidal ideation, Hallucination, Myoclonic seizures, Ataxia, Balance disorder Memory impairment Cognitive disorder Somnolence Tremor Nystagmus Hypoesthesia Dysarthria, Disturbance in attention Paraesthesia, Syncope, Coordination abnormal, Convulsion, Diplopia, Vision blurred, Vertigo, Tinnitus, Atrioventricular block, Bradycardia, Atrial Fibrillation, Atrial Flutter, Ventricular Tachyarrhythmia, Nausea, Vomiting Constipation Flatulence Dyspepsia, Dry mouth, Diarrhoea, Pruritus, Rash, Angioedema, Urticaria, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Muscle spasms, Gait disturbance Asthenia, Fatigue, Irritability, Feeling drunk, Discomfort, Irritation, Fall, Skin laceration, Contusion.

Manufactured by:

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IN/Lacosam Syrup 15mg/ml/APR-2021/03/ABPI
(Additional information is available on request)