LUMAVIBE

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

Abbreviated Prescribing information for LUMAVIBE [Lumateperone Capsules 42 mg]
[Please refer the complete prescribing information available at www.torrentpharma.com]

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; and SUICIDAL THOUGHTS AND BEHAVIORS

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Lumateperone is not approved for the treatment of patients with dementia-related psychosis.**
- **Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients. Closely monitor all antidepressant-treated patients for worsening and emergence of suicidal thoughts and behaviors. Safety and effectiveness of Lumateperone have not been established in pediatric patients**.

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: The mechanism of action of lumateperone for the treatment of depressive episodes associated with bipolar depression (as monotherapy or as adjunctive therapy with lithium or valproate), is unknown. However, the mechanism of action of lumateperone could be mediated through a combination of antagonist activity at central serotonin 5-HT_{2A} receptors, and partial agonist activity at central dopamine D_2 receptors.

INDICATIONS: Indicated for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults as monotherapy and as adjunctive therapy with lithium or valproate.

DOSAGE AND ADMINISTRATION: The recommended dosage of Lumateperone is 42 mg once daily with or without food. Dose titration is not required. It is for oral use.

CONTRAINDICATION: It is contraindicated in patients with history of hypersensitivity reaction to lumateperone or any components of lumateperone. Reactions have included pruritus, rash (e.g. allergic dermatitis, papular rash, and generalized rash), and urticaria.

WARNINGS & PRECAUTIONS: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Monitor all antidepressant-treated patients, especially during the initial few months of anti-depressant drug therapy, and at times of dosage changes. Lumateperone is not approved for the treatment of patients with dementia-related psychosis. If NMS is suspected, immediately discontinue Lumateperone and provide intensive symptomatic treatment and monitoring. If signs and symptoms of TD appear in lumateperone -treated patients, consider drug discontinuation. Antipsychotic drugs have caused metabolic changes, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. In patients with a pre-existing low WBC or ANC or a history of drug-induced leukopenia or neutropenia, perform complete blood count (CBC) monitoring during the first few months of lumateperone therapy. Consider discontinuing lumateperone in patients who have a clinically significant decline in WBC or clinically significant neutropenia. Atypical antipsychotics cause orthostatic hypotension and syncope. Antipsychotics, including lumateperone, may cause somnolence, postural hypotension, and motor and sensory instability, which may lead to falls and, consequently, fractures and other injuries. Patients should be cautioned about operating hazardous machinery and motor vehicles until they are reasonably certain that therapy with lumateperone does not affect them adversely.

Antipsychotic drugs, including lumateperone, should be used cautiously in patients at risk for aspiration. Atypical antipsychotics may disrupt the body's ability to reduce core body temperature. Atypical antipsychotics may disrupt the body's ability to reduce core body temperature. Strenuous exercise, exposure to extreme heat, dehydration, and anticholinergic drugs may contribute to an elevation in core body temperature. Use lumateperone with caution in patients who may experience these conditions.

DRUG INTERACTIONS: Increased monitoring for SRI- associated adverse reactions is recommended. Concomitant use of lumateperone with CYP3A4 inducers decreases the exposure of lumateperone. Concomitant use of lumateperone with moderate or strong CYP3A4 inhibitors increases lumateperone exposure, which may increase the risk of adverse reactions.

ADVERSE REACTIONS: Increased mortality in elderly patients with dementia-related psychosis**,** suicidal thoughts and behaviours**,** cerebrovascular adverse reactions, including stroke, neuroleptic malignant syndrome, tardive dyskinesia, metabolic changes, leukopenia, neutropenia, and agranulocytosis, orthostatic hypotension, syncope, falls, seizures, potential for cognitive and motor impairment, body temperature dysregulation, dysphagia, somnolence/sedation, nausea, dry mouth, dizziness, creatine phosphokinase increased, fatigue, vomiting, headache, upper respiratory tract infection, diarrhea, tremor, vertigo, insomnia, akathisia, restlessness, extrapyramidal disorder, muscle spasms, restlessness, musculoskeletal stiffness, dyskinesia, dystonia, muscle twitching, tardive dyskinesia, tremor, drooling, involuntary muscle contractions, dystonic symptoms include spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue, hepatic transaminases increased, decreased appetite, blurred vision, increased blood prolactin, and burning sensation, including skin burning sensation.

MARKETED BY:

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(Additional information is available on request)