

CARIQUEL

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for CARIQUEL (Cariprazine Capsules 1.5mg, 3mg, 4.5mg & 6mg)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: The mechanism of action of cariprazine in schizophrenia and bipolar I disorder is unknown. However, the efficacy of cariprazine could be mediated through a combination of partial agonist activity at central dopamine D2 and serotonin 5-HT1A receptors and antagonist activity at serotonin 5-HT2A receptors. Cariprazine forms two major metabolites, desmethyl cariprazine (DCAR) and didesmethyl cariprazine (DDCAR), that have in vitro receptor binding profiles similar to the parent drug.

Therapeutic indication: Cariprazine Capsules are indicated for the treatment of Schizophrenia in adults. Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults

DOSAGE AND ADMINISTRATION: *Dosage:* CARIQUEL is given orally once daily. Because of the long half-life of cariprazine and its active metabolites, changes in dose will not be fully reflected in plasma for several weeks. Prescribers should monitor patients for adverse reactions and treatment response for several weeks after starting CARIQUEL and after each dosage change. *Administration:* It can be taken with or without food.

CONTRAINDICATION: Cariprazine is contraindicated in patients with history of a hypersensitivity reaction to cariprazine. Reactions have ranged from rash, pruritus, urticaria, and events suggestive of angioedema (e.g., swollen tongue, lip swelling, face edema, pharyngeal edema, and swelling face).

WARNINGS & PRECAUTIONS: *Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis:* Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack). *Neuroleptic Malignant Syndrome:* Manage with immediate discontinuation and close monitoring. *Tardive Dyskinesia:* Discontinue if appropriate. *Late-Occurring Adverse Reactions:* Because of CARIQUEL's long half-life, monitor for adverse reactions and patient response for several weeks after starting CARIQUEL and with each dosage change. *Metabolic Changes:* Monitor for hyperglycemia/diabetes mellitus, dyslipidemia and weight gain. *Leukopenia, Neutropenia, and Agranulocytosis:* Perform complete blood counts (CBC) in patients with pre-existing low white blood cell counts (WBC) or history of leukopenia or neutropenia. Consider discontinuing CARIQUEL if a clinically significant decline in WBC occurs in absence of other causative factors. *Orthostatic Hypotension:* Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease, and risk of dehydration or syncope. *Seizures:* Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. *Potential for Cognitive and Motor Impairment:* Use caution when operating machinery.

DRUG INTERACTION: Clinically Important Drug Interactions with CARIQUEL Strong CYP3A4 Inhibitors. Many drugs may alter the metabolism or bioavailability of pyridoxine, including isoniazid, penicillamine and oral contraceptives, which may increase the requirements for pyridoxine. Pyridoxine hydrochloride may reduce the effect of levodopa, a drug used in the treatment of Parkinsons Disease unless a dopa decarboxylase inhibitor is also given. If CARIQUEL is used with a strong CYP3A4 inhibitor (examples: itraconazole, ketoconazole), reduce CARIQUEL dosage. CYP3A4 is responsible for the formation and elimination of the active metabolites of cariprazine. The effect of CYP3A4 inducers on the exposure of CARIQUEL has not been evaluated, and the net effect is unclear. Concomitant use of CARIQUEL with a CYP3A4 inducer (examples: rifampin, carbamazepine) is not recommended.

ADVERSE REACTIONS: Neuroleptic malignant syndrome (NMS) is a serious condition that can lead to death. Call your healthcare provider or go to the nearest hospital emergency room right away if you have some or all of the following signs and symptoms of NMS: high fever confusion, changes in your breathing, heart rate, and blood pressure, stiff muscles, increased sweating. Uncontrolled body movements (tardive dyskinesia), high blood sugar (hyperglycemia) and diabetes, increased fat levels (cholesterol and triglycerides) in your blood, weight gain, Low white blood cell count, decreased blood pressure (orthostatic hypotension), falls and seizures. The most common side effects of CARIQUEL include: difficulty moving or slow movements, tremors, uncontrolled body movements, restlessness and feeling like you need to move around, sleepiness, nausea, vomiting, and indigestion.

MARKETED BY:



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IN/ CARIQUEL 1.5mg, 3mg, 4.5mg & 6mg /Aug-22/01/ABPI

(Additional information is available on request)