165mm

155mm

DRUG INTERACTIONS
Some medicines should not be taken with CARIPRAZINE as they may interfere with how well it works.
CARIPRAZINE should not be taken with these medicines as they may increase the effect of CARIPRAZINE and you are more likely to get side effects:

• boceprevir, clarithromycin, cobicistat, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole, diltiazem, erythromycin, fluconazole, verapamil.

CARIPRAZINE should not be taken with these medicines as it may reduce how well this medicine works.

• carbamazepine, phenobarbital, phenytoin, rifampicin, St. John's wort (Hypericum perforatum), bosentan, efavirenz, etravirine, modafinil, nafcillin.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CARIPRAZINE.

Cariprazine with food, drink and alcohol
You should not drink grapefruit juice during treatment with Cariprazine.
Alcohol should be avoided when taking Cariprazine.

OVERDOSAGE
There have been no reports of toxicity from Cariprazine overdosage. Overdosage should be treated with supportive care.

HOW SUPPLIED
Caripro Capsules 1.5mg, 3mg, 4.5mg and 6mg are available in pack size of 10's. 14's & 30's

INSTRUCTIONS:
Store below 30˚C in a dry place, protect from light.
To be dispensed on the prescription of a registered medical practitioner only.
Keep out of the reach of children.

خوراک : ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات : دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔

Kaizen Pharmaceuticals (Pvt.) Ltd.

Manufactured by:
Kaizen Pharmaceuticals (Pvt.) Ltd.
E-127-129, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

Caripro

(Cariprazine Hydrochloride)

1.5mg, 3mg, 4.5mg, 6mg Capsules

کیریپرو

(کیریپرازین ہائیڈروکلورائیڈ)

۱.۵ ملی گرام، ۳ ملی گرام، ۴.۵ ملی گرام، ۶ ملی گرام کیپسولز

COMPOSITION:
Caripro 1.5mg Capsule
Each Capsule contains:
Cariprazine Hydrochloride Eq. to Cariprazine 1.5mg

Caripro 3mg Capsule
Each Capsule contains:
Cariprazine Hydrochloride Eq. to Cariprazine 3mg

Caripro 4.5mg Capsule
Each Capsule contains:
Cariprazine Hydrochloride Eq. to Cariprazine 4.5mg

Caripro 6mg Capsule
Each Capsule contains:
Cariprazine Hydrochloride Eq. to Cariprazine 6mg

CLINICAL PHARMACOLOGY
Mechanism of Action:
The mechanism of action of cariprazine 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, desmethylcariprazine (DCAR) and didesmethyl-cariprazine (DDCAR), that have in vitro receptor binding profiles similar to the parent drug.

PHARMACOKINETICS
Cariprazine has two pharmacologically active metabolites with similar activities as Cariprazine, desmethyl Cariprazine (DCAR) and didesmethyl Cariprazine (DDCAR). After multiple dose administration of Cariprazine, mean cariprazine and DCAR concentrations reached steady state at around Week 1 to Week 2 and mean DDCAR concentrations appeared to be approaching steady state at around Week 4 to Week 8 in a 12-week study.

Absorption
Absolute bioavailability of cariprazine is unknown. Cariprazine is well absorbed after oral administration. Following multiple-dose administration, peak plasma concentrations for cariprazine and the major active metabolites generally occur at approximately 3-8 hours post dose.

Distribution
Cariprazine and its major active metabolites are highly bound (91 to 97%) to plasma proteins.

Metabolism
Cariprazine is extensively metabolized by CYP3A4 and, to a lesser extent, by CYP2D6 to DCAR and DDCAR. DCAR is further metabolized into DDCAR by CYP3A4 and CYP2D6. DDCAR is then metabolized by CYP3A4 to a hydroxylated metabolite.

Excretion
Following administration of 12.5 mg/day cariprazine to patients with schizophrenia for 27 days, about 21% of the daily dose was found in urine, with approximately 1.2% of the daily dose was excreted in urine as unchanged cariprazine.

PHARMACODYNAMIC
In vivo non-clinical studies demonstrated that cariprazine occupies D3 receptors to a similar extent as D2 receptors at pharmacologically effective doses. There was a dose-dependent occupancy of brain dopamine D3 and D2 receptors (with preferential occupancy in regions with higher D3 expression) in patients with schizophrenia within the therapeutic dose range of cariprazine for 15 days. The effects of cariprazine on the QT interval were evaluated in patients with schizophrenia or schizoaffective disorder. Holter monitor-derived electrocardiographic assessments were obtained in 129 patients over a twelve hour period at baseline and steady state. No QT interval prolongation was detected following supratherapeutic doses (9 mg/day or 18 mg/day). No patients treated with cariprazine experienced QTc increases ≥ 60 msec from baseline, nor did any patient experience a QTc of > 500 msec in the study.

THERAPEUTIC INDICATIONS
Caripro Capsule is indicated for the treatment of schizophrenia in adult patients,Acute treatment of manic or mixed episodes associated with bipolar I disorder.

DOSAGE & ADMINISTRATION
CARIPRAZINE capsules are given orally once daily and can be taken with or without food Alcohol should be avoided when taking Cariprazine.
The recommended starting dose of CARIPRAZINE is 1.5 mg once daily. Thereafter the dose can be increased in 1.5 mg increments according to efficacy and tolerability to a maximum dose of 6 mg/day, if needed. Patients should be monitored for adverse reactions and treatment response for several weeks after starting CARIPRAZINE and after each dosage change.

Switching from other antipsychotics to CARIPRAZINE
When switching from another antipsychotic to CARIPRAZINE gradual decrease in dose should be considered, with gradual discontinuation of the previous treatment while CARIPRAZINE treatment is initiated.

Missed dose
If the patient misses a dose, the patient should take the missed dose as soon as possible. However, if it is almost time for the next dose, the missed dose should be skipped and the next dose should be taken according to the regular schedule. It is not recommended to take a double dose to make up for the forgotten dose.

Switching to another antipsychotic from CARIPRAZINE
When switching from cariprazine to another antipsychotic the new medicine can be started at its lowest dose. While cariprazine can be stopped without slowly reducing the dose.

Special population:
Renal Impairment
No dose adjustment is required in patients with mild to moderate renal impairment. Use of CARIPRAZINE is not recommended in patients with severe renal impairment.

Hepatic Impairment
No dose adjustment is required in patients with mild to moderate hepatic impairment (Child- Pugh score between 5-9). Safety and efficacy of cariprazine have not been evaluated in patients with severe hepatic impairment (Child-Pugh score between 10 and 15). Use of CARIPRAZINE is not recommended in patients with severe hepatic impairment.

Elderly Patients
Available data in elderly patients aged ≥ 65 years treated with CARIPRAZINE are not sufficient to determine whether or not they respond differently from younger patients). Dose selection for an elderly patient should be more cautious.

Paediatric Patients
The safety and efficacy of CARIPRAZINE in children and adolescents aged less than 18 years have not been established. No data are available.

ROUTE OF ADMINISTRATION
For oral administration only.

ADVERSE REACTIONS
The most common side effects are restlessness and Parkinsonism. Serious side effects include severe allergic reaction, neuroleptic malignant syndrome, kidney problems, blood clots and suicidal thoughts.

CONTRAINDICATIONS
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).

SPECIAL WARNINGS AND PRECAUTIONS
Suicidal behavior:
People with psychotic illnesses may have thoughts about suicide or may attempt suicide. This risk can be higher, especially when starting a new antipsychotic medicine or changing from one to another.

Akathisia and Restlessness
Akathisia is a movement disorder characterized by a feeling of inner restlessness. As cariprazine causes akathisia and restlessness, it should be used cautiously in patients who are prone to or already exhibit symptoms of akathisia.

Tardive Dyskinesia
Tardive dyskinesia is a condition that causes repeated, uncontrolled movements, usually of the tongue or face. It can happen in people taking antipsychotic medicines and may be permanent.

Elderly patients with dementia
Cariprazine has not been studied in elderly patients with dementia and is not recommended to treat elderly patients with dementia due to increased risk of overall mortality.

Seizures and convulsions
Cariprazine should be used cautiously in patients with history of seizures or with conditions that potentially lower the seizure threshold.

Pregnancy
Do not take this medicine during pregnancy unless your doctor has told you to do so.
If your doctor decides that you should take this medicine during pregnancy, your doctor will monitor your baby closely after birth. This is because the following symptoms may occur in newborn babies of mothers who have used this medicine in the last trimester (last three months) of their pregnancy:
- shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding.
If your baby develops any of these symptoms you should contact your doctor.

Caripro

References:

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