Front

160 mm

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

## CILACAR *20

**INDICATIONS AND USAGE**
Cilnidipine is used for treatment of hypertension.

**DOSAGE AND ADMINISTRATION**
The recommended adult oral dosage of Cilnidipine is 5-10 mg once daily. The dosage can be increased up to 20 mg, if needed.
Starting dose 5 to 10 mg per day depending on individual case.
Maintaining dose- physician will titrate the dose as per patient's symptoms.
Maximum dose 20 mg per day.

**DOSAGE FORMS AND STRENGTHS**
Each film coated tablet contains:
Cilnidipine …….20 mg
Excipients ……q. s.

**CONTRAINDICATIONS**
Aortic stenosis, advanced.
Hypersensitivity to Cilnidipine or other calcium channel antagonists.

**WARNINGS AND PRECAUTIONS**
Angina
Chronic renal insufficiency
Congestive heart failure
Hypotension
Liver dysfunction, or elevated liver enzymes
Peripheral edema (confounding physical findings in congestive failure)

**ADVERSE REACTIONS**
Dizziness, headache, peripheral edema, flushing, rash and gingival hyperplasia are the most common adverse events seen with the dihydropyridine derivative calcium channel antagonists. Headache, Flushing was reported in 3.7 & 4.5% of 764 subjects receiving cilnidipine respectively.

**DRUG INTERACTIONS**
Cilnidipine can interact with aldesleukin, quinidine, phenytoin, rifampicin, erythromycin, other anti-hypertensive drugs and anti-psychotic drugs.

**USE IN SPECIFIC POPULATIONS**
***Pregnancy-***
There are no human clinical or animal data concerning the safety of cilnidipine during pregnancy. Until data are available, administration of cilnidipine during pregnancy should be avoided.
***Lactation-***
Nursing mothers should consult a physician before taking Cilnidipine.
***Renal impairment-***
Dose adjustment is not needed in patients with impaired renal function. Cilnidipine at a dose of 10 mg once a day for 7 days in patients with impaired renal function caused no differences in the pharmacokinetic profile compared with that in patients with normal renal function.
***Hepatic impairment-***
Dosage recommendations have not been established in patients with mild to moderate hepatic impairment; therefore dose selection should be cautious and should start at the lower end of the dosing range. Transient and generally clinically insignificant elevations in SGOT, SGPT, alkaline phosphatase, and serum bilirubin have been reported during calcium

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antagonist therapy in less than 1% of patients.

**OVERDOSAGE**
None known.

**CLINICAL PHARMACOLOGY**
**PHARMACODYNAMICS**
Cilnidipine is a third generation dihydropyridine calcium antagonist with a slow onset and long duration of action. Calcium antagonists inhibit influx of extracellular calcium ions into the cells, resulting in decreased vascular smooth muscle tone and vasodilation, leading to a reduction in blood pressure.
In vitro and animal studies suggest that cilnidipine blocks both the L and N type calcium channels. Cilnidipine inhibits the pressor to cold stress by suppressing sympathetic nerve activity in spontaneously hypertensive rats. It does not induce tachycardia caused by hypotensive baroreflexes. In vitro, cilnidipine inhibits norepinephrine release in electrically stimulated rabbit mesenteric arteries.
In human studies, cilnidipine had weak inotropic effects and suppressed cardiac sympathetic overactivity. Therefore it may decrease the risk and mortality from long term cardiovascular complications. Once-daily cilnidipine was associated with less reflex tachycardia and had fewer effect on the autonomic nervous system in hypertensive patients. In contrast to other long acting calcium channel blockers, cilnidipine and amlodipine did not increase plasma renin activity, thus they may decrease the risk of cardiovascular complications due to metabolic imbalances. Cilnidipine may inhibit norepinephrine and dopamine production, therby improving insulin resistance in patients with diabetes. It also had beneficial effects on lipid profiles in hypertensive patients by decreasing total cholesterol, triglyceride, and very low density lipoprotein cholesterol level, and increasing high density lipoprotein cholesterol and the ratio of high density lipoprotein cholesterol to total cholesterol.

**PHARMACOKINETICS**
Cilnidipine has a slow onset and long duration of action of 24 hours, partly explained by its high lipophilicity.
Cilnidipine has a half-life of 2 – 8 hrs. after administration of 5 – 20 mg.

**NONCLINICAL TOXICOLOGY**
No data available.

**STORAGE**
Store below 30°C & Protect from light.

**SHELF LIFE**
3 Years

**PRESENTATION**
Blister strip of 10 Tablets.

Manufactured by:
**UNIQUE PHARMACEUTICAL LABORATORIES**
(A Div. Of J. B. Chemicals & Pharmaceuticals Ltd.)
Plot No. 215 - 219, GIDC Industrial Area, Panoli, 394 116, Gujarat State, India.
* Trade Mark

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