

Composition:

Each tablet contains

Cilnidipine 5/10/20 mg

Description:

Generic name: Cilnidipine

Chemical name: 3-(E)-3-Phenyl-2-propenyl 5-2-methoxyethyl 2,6-dimethyl-4-(m-nitrophenyl)-1,4-

dihydropyridine-3,5-dicarboxylate

Molecular mass: 492.52 g/mol

Structural formula:

Empirical formula: C27H28N2O7

Pharmacokinetic properties:

A PK analysis study with 51 subjects was planned. The mean plasma concentration—time profiles of Cilnidipine after a single oral administration at 10 mg did not significantly differ when it was administered alone and when it was coadministered with valsartan 160 mg. For example, the total exposure to cilnidipine was comparable, ie, the GMR (90% confidence interval [CI]) of Cmax and AUClast for cilnidipine with and without valsartan was 0.91 (0.83–1.00) and 1.04 (0.98–1.10), respectively, although cilnidipine was absorbed slightly slower when it was coadministered with valsartan than when it was administered alone (median tmax: 2.0 vs 2.5 hours for cilnidipine alone and in combination, respectively)

Mechanism of Action



Cilnidipine is a novel dihydropyridine calcium antagonist and its calcium antagonistic activity is lasting longer than those of Nifedipine and Nicardipine. Cilnidipine has been used for the treatment of hypertension and hypertensiveassociated vascular disorders. Its adult dose is about 40 to 80 mg once daily. Cilnidipine has a very low solubility (BCS Class-II drug Low solubility high permeability) and compliance to the medication is always very poor.

Cilnidipine acts on the L-type calcium channels of blood vessels by blocking the incoming calcium and suppressing the contraction of blood vessels, thereby reducing blood pressure. Cilnidipine also works on the N-type calcium channel located at the end of the sympathetic nerve, inhibiting the emission of norepinephrine and suppressing the increase in stress blood pressure.

Other pharmacodynamic properties:

A pharmacodynamic assessment study showed, all treatment groups, both SBP and DBP were decreased after a single administration of cilnidipine or valsartan alone and in combination. The greatest decreases in both SBP and DBP were seen at approximately 6 hours after study drug administration, when coadministered cilnidipine and valsartan resulted in a 2.9-fold significantly larger decrease in SBP (14.7 vs 5.0 mmHg for SBP) and a 2.1-fold significantly larger decrease in DBP than did cilnidipine alone (16.3 vs 7.9 mmHg for DBP) (P<0.001, RM-ANOVA test).

Indication:

Hypertension Management for End Organ Protection

Contraindication:

Cilnidipine is contraindicated in patients with known hypersensitivity (e.g., anaphylaxis or angioedema) to Cilnidipine or any other component of this product

Drug Interaction:

Cilnidipine can interact with aldesleukin, quinidine, phenytoin, rifampicin, erythromycin, other antihypertensive drugs and anti-psychotic drugs

Adverse effects:

- Dizziness
- Flushing
- Headache
- Hypotension
- Peripheral oedema
- Tachycardia
- Palpitations
- GI disturbances
- Increased micturition frequency
- Lethargy



Warnings and Precautions:

- Medicine should be used with caution in patients with hypotension, poor cardiac reserve, heart failure.
- Sudden withdrawal may exacerbate angina.
- Discontinue in patients who experience ischemic pain following administration.

Use in special population:

- 1. Pediatric: Not recommended for pediatric population.
- 2. **Geriatric:** No studies are available in elderly patients.
- 3. Liver impairment: Use with caution.
- 4. Renal failure: Use with caution.
- **5. Pregnancy and lactation:** Medicine is not recommended for use if you are pregnant or planning a pregnancy in near future. Not recommended for use in breastfeeding.

Dosage:

The recommended adult oral dosage of Cilnidipine is 5-10 mg once daily. The dosage can be increased up to 20 mg, if needed

Presentation:

Centapres is available in blister pack of 10 tablets.

Storage and handling:

Store in cool and dry place.