

## Composition:

**Cinekar 5:** Each film coated tablet contains Cilnidipine INN 5 mg.

**Cinekar 10:** Each film coated tablet contains Cilnidipine INN 10 mg.

## Clinical Pharmacology:

### 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 hypertensive-associated 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.

## Pharmacokinetics:

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 C<sub>max</sub> and AUC<sub>last</sub> 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 t<sub>max</sub>: 2.0 vs 2.5 hours for cilnidipine alone and in combination, respectively)

## Pharmacodynamics:

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).

## Indications:

Hypertension Management for End Organ Protection

## 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.

## Contraindications:

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

## Warnings and Precautions:

Hypotension, poor cardiac reserve, heart failure. Sudden withdrawal may exacerbate angina. Discontinue in patients who experience ischemic pain following administration.

## Drug Interactions:

Cinekar can interact with aldesleukin, quinidine, phenytoin, rifampicin, erythromycin, other anti-hypertensive drugs and anti-psychotic drugs.

## Use During Pregnancy, Delivery, or Lactation:

Cinekar should not be administered to pregnant women or women having possibilities of being pregnant. [It has been reported that Cinekar prolongs the gestation period and delivery time in animal experiments (in rats).] It is advisable to avoid the administration of Cinekar to nursing mothers. However, if the administration is indispensable, the patient should be instructed to discontinue lactation. \*Transfer of this drug to mother's milk has been reported in animal experiments (in rats).]

## Effects On Ability to Drive And Operate Machine:

The symptoms, such as dizziness may occur because of the hypotensive action from this drug. Give warning against engaging in hazardous activities requiring alertness, such as working at a height, operating machinery or driving motor vehicles.

## Adverse Reactions:

Adverse reactions, including abnormalities in laboratory data, Hepatic function disorder and jaundice accompanied with increased AST (GOT), ALT (GPT) and  $\gamma$ -GTP may occur. Therefore, close observation should be made, and if any abnormality is observed, appropriate measures, such as discontinuation of Cinekar, should be taken.

## Overdoses and Treatment:

Overdosage of Cinekar may cause excessive reduction in blood pressure. If reduction in blood pressure is remarkable, appropriate measures such as lifting lower extremities, fluid therapy and administration of vasopressors should be taken. Hemodialytical removal of the drug is not effective because of its high rate of protein binding.

## Storage Condition:

Store in a cool and dry place below 30° C, protect from light. Keep out of the reach of children.

## Presentation:

**Cinekar 5:** A box contains 3 blisters pouch x 10 tablets.

**Cinekar 10:** A box contains 3 blisters pouch x 10 tablets.

Manufactured by:

**Jenphar Bangladesh Ltd.**

Sreepur, Gazipur, Bangladesh.