

#### Presentation

Darven 5 Tablet: Each film coated tablet contains Cilnidipine INN 5 mg.

Darven 10 Tablet: Each film coated tablet contains Cilnidipine INN 10 mg.

#### Pharmacodynamics 4 1

Cilnidipine is a dihydropyridine calcium-channel blocker with dual L & N-type Ca<sup>2+</sup> channel blocking action. The L-type calcium blockage by Cilnidipine affects predominantly vascular smooth muscle, thereby producing vasodilation of peripheral resistance vessels and coronary arteries. The blockade of N-type Ca<sup>2+</sup> channels effectively suppresses neurohormonal regulation in the cardiovascular system, including sympathetic nervous system and renin-angiotensin-aldosterone system. Thus, Cilnidipine is expected to be favourable for various types of complications of hypertension as well as cardiovascular diseases.

#### **Pharmacokinetics**

Cilnidipine has a good oral absorption and long duration of action. After oral administration, drug concentration reaches peak level at 1.8 to 2.2 hours. Cilnidipine shows a long half-life of 7.5 hours. Cilnidipine rapidly metabolized in human liver microsomes and dehydrogenation of dihydropyridine ring of Cilnidipine is crucial for the elimination of Cilnidipine. Cytochrome P450 3A(CYP3A) is the major human CYP involved in the dehydrogenation of a dihydropyridine ring of Cilnidipine.

#### Indications

Cilnidipine is indicated for the treatment of hypertension.

### Dosage & Administration

Adults: 5-10 mg once daily after breakfast. Maximum dose 20 mg once daily.

The safety of Cilnidipine in paediatric patients has not been established.

Use in the elderly: Since the elderly may be more susceptible to hypotension, therapy should be initiated with the lowest possible dose of 5 mg.

#### Contraindications

Cilnidipine is contraindicated in patients with known sensitivity to Cilnidipine or any of the excipients or patients having cardiogenic shock, recent MI or acute unstable angina and severe aortic stenosis.

#### Precautions

Cilnidipine should be administered with care in the following patients: Patients with serious hepatic dysfunction, patients with a history of serious adverse reactions to calcium antagonists. During the discontinuation, the dosage should be gradually decreased under close observation.

## Side effects

The most common side effects of Cilnidipine are dizziness, flushing, headache, hypotension, peripheral oedema, palpitations, GI disturbances, increased micturition frequency, lethargy, eve pain and depression.

# **Drug interactions**

Other anti-hypertensive, anti-psychotics that cause hypotension, Quinidine, Carbamazepine, Phenytoin, Rifampicin, Cimetidine, Erythromycin.

#### Use in Pregnancy and Lactation

Cilnidipine should not be administered in pregnant woman or woman having possibilities of being pregnant. It is also advisable to avoid the administration of Cilnidipine to nursing mothers. However, if the administration is indispensable, the patient should be instructed to discontinue lactation.

## Storage

Store  $\bar{\rm in}$  a cool (below 30°C) and dry place, away from light. Keep out of the reach of children.

### **Packing**

Darven 5 Tablet: Each box contains 3 blister packs with each blister of 10 tablets. Darven 10 Tablet: Each box contains 3 blister packs with each blister of 10 tablets.

Manufactured by:

