For the use of a Registered Medical Practitioner only

1.GENERIC NAME & BRAND NAME

Cilnidipine Tablets I.P. 5mg
CILADUO™ 5

Cilnidipine Tablets I.P. 10mg
CILADUO™ 10

2.QUALITATIVE AND QUANTITATIVE COMPOSITION

CILADUO™ 5
Each film coated tablet contains:
Cilnidipine I.P. 5mg
Excipients q.s.
Colour: Titanium Dioxide I.P.

CILADUO™ 10
Each film coated tablet contains:
Cilnidipine I.P. 10mg
Excipients q.s.
Colour: Titanium Dioxide I.P.

3.DOSAGE FORM AND STRENGTH
Refer section 1 & 2

4. CLINICAL PARTICULARS
4.1THERAPEUTIC INDICATION
For the treatment of mild to moderate hypertension.

4.2POSOLOGY AND METHOD OF ADMINISTRATION
In adult patients
Treatment should be individualized on the basis of both effectiveness and tolerance, while not exceeding the maximum recommended daily dose for Cilnidipine.
One tablet once a day administered. Treatment can be initiated with 5-10 mg first, increase to 20 mg daily if necessary.
Dosage can vary based on patient's condition, age, weight, health, in addition patients progress on any medication he/she has already been taking.

4.3 CONTRAINDICATIONS
Cilnidipine is contraindicated in patients with

- Cardiogenic shock
- Recent history of acute unstable angina or MI
- Severe aortic stenosis
- Hypersensitivity to cilnidipine or any excipient product
- Heart failure
- Hypotension

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Keep out of reach of children.

1. Hypotension
2. Poor cardiac reserve
3. heart failure
4. Sudden withdrawal may exacerbate angina
5. Discontinue in patients who experience ischemic pain following administration- Pregnancy, lactation.

Use in special population: (Geriatric, Pediatric, Renal Insufficiency, Hepatic Insufficiency): Data not available for the use of this product in Geriatric/Pediatric population and patient with Renal/Hepatic Insufficiency Usual Precaution for calcium channel blockers in these categories of patients and physician's discretion is advised.

Pregnancy: There is no clinical experience with cilnidipine in pregnant women, discretion is advised.

Nursing Mothers/Lactation: Cilnidipine should not be given.

4.5 DRUG INTERACTIONS

Other anti-hypertensives; aldesleukin; antipsychotics that cause hypotension; may modify insulin and glucose responses; quinidine; carbamazepine; phenytoin; rifampicin; cimetidine; erythromycin.

4.6 USE IN SPECIAL POPULATIONS (SUCH AS PREGNANT WOMEN, LACTATING WOMEN, PAEDIATRIC PATIENTS, GERIATRIC PATIENTS ETC.)

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 antagonist therapy in less than 1% of patients.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Patients should be advised to avoid operating automobiles and machinery or engaging in other tasks requiring alertness until the patient's response to therapy with cilnidipine tablets has been determined.

4.8 UNDESIRABLE EFFECTS Adverse events which occurred with the use of Cilnidipine are as follows:
Nervous system: Dizziness, headache, depression, cerebral ischemia
General: Flushing, peripheral edema, lethargy, tremors, impotence
Cardiovascular: Hypotension, tachycardia, palpitations**,** myocardial ischemia
Gastrointestinal: Gingival hyperplasia**,** GI disturbances, abnormal liver function
Special senses: Eye pain
Other: Myalgia, Transient blindness, Rashes

4.9 OVERDOSAGE
Overdose of cilnidipine 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.

5.0 PHARMACOLOGIC PROPERTIES
5.1 MECHANISM OF ACTION
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.

5.2 PHARMACODYNAMIC PROPERTIES
Cilnidipine is a dihydropyridine calcium-channel blocker. Dihydropyridine derivative selective calcium-channel blockers with mainly vascular effects. Cilnidipine is a N-type and L-type calcium channel blocker. The effects of cilnidipine on N-type channels give it unique organ-protective properties via the suppression of hyperactivity in the sympathetic nervous system (SNS) and renin-angiotensin-aldosterone system (RAAS). Vasodilatation is caused by Cilnidipine because it inhibits cellular influx of calcium. It has greater selectivity for vascular smooth muscle.

It has little or no action at the SA or AV nodes and negative inotropic activity is rarely seen at therapeutic doses.

5.3 PHARMACOKINETIC PROPERTIES
Cilnidipine has been clarified to exert antisympathetic actions in various examinations from cell to human levels, in contrast to classical Ca (2+) channel blockers.
After oral administration of cilnidipine it takes 3 hours to reach the peak concentration.
Cilnidipine is rapidly metabolized in human liver microsomes and dehydrogenation of dihydropyridine ring of cilnidipine is crucial for the elimination of cilnidipine. Cytochrome P 4503A (CYP3A) is the major human CYP involved in the dehydrogenation of dihydropyridine ring of cilnidipine.
After oral administration, large amount of the drug could be detected in the gallbladder, bladder, liver and kidney. The α-phase half-life is 1.1 hour.

6. NONCLINICAL PROPERTIES

6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

No data available.

7. DESCRIPTION

CILADUO 5 :

CILADUO 5 is supplied for oral administration, as a film coated tablet of Cilnidipine. Each film coated tablet of CILADUO 5 contains Cilnidipine 5mg.

CILADUO 10 :

CILADUO 10 is supplied for oral administration, as a film coated tablet of Cilnidipine. Each film coated tablet of CILADUO 10 contains Cilnidipine 10mg.

8. PHARMACEUTICAL PARTICULARS

8.1 INCOMPATIBILITIES

Not Applicable

8.2 SHELF-LIFE

Refer pack

8.3 PACKAGING INFORMATION

Refer pack

8.4 STORAGE AND HANDING INSTRUCTIONS

Refer pack

9. PATIENT COUNSELLING INFORMATION

Swallow the whole tablet. Do not crush, chew or break it.
Try to take it at the same day every day.
Avoid operating automobiles and machinery or engaging in other tasks requiring alertness until your response to therapy with cilnidipine tablets has been determined

10. DETAILS OF MANUFACTURER

Refer Pack for Manufacturer details

Marketed By:
Abbott Healthcare Pvt. Ltd.
Angel Space, Bldg. D-4, Gala No. 1 to 3 &
11 to 13 Ground Floor, 101 to 106 &
111 to 116 First Floor, 201 to 206 & 211 to 216
2nd Floor, Pimplas, Dist. Thane, Bhiwandi - 421 302,
Maharashtra, India.

11. DETAILS OF PERMISSION OR LICENCE NUMBER

Refer Pack for Permission/License details.

12. DATE OF REVISION

Version 5.0 Dated 28th August 2025

Version 5.0; Dated 28th August 2025
Replaces Version 4.0; Dated 06th September 2023

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For Product Complaints/Adverse events or Queries please write to
webmasterindia@abbott.com