	ATOZ Pharmaceuticals Pvt. Ltd. **Chennai – India.**
Product Name	**CILNEED 20 CT** (Cilnidipine 20mg and Chlorthalidone 12.5mg Tablets)
Composition	Each film coated tablet contains: Cilnidipine 20mg Chlorthalidone USP 12.5mg
SUMMARY OF PRODUCT CHARACTERISTICS	

1. Name of the medicinal product

Cilnidipine 20mg and Chlorthalidone 12.5mg Tablets

2. Qualitative and quantitative composition

Each film coated tablet contains:

Cilnidipine 20mg

Chlorthalidone USP 12.5mg

S. No.	Wt. / tablet (mg)	Ingredient	Spec	Overages	Std. Qty for 100,000 tablets (in kg)
1.	20.00	Cilnidipine	IHS	Nil	2.000
2.	12.50	Chlorthalidone	USP	Nil	1.250
3.	20.00	Croscarmellose Sodium	BP	Nil	2.000
4.	40.00	Maize Starch	BP	Nil	4.000
5.	22.40	Microcrystalline Cellulose	BP	Nil	2.240
6.	69.70	Lactose	BP	Nil	6.970
7.	6.60	Povidone K30	BP	Nil	0.660
8.	---	* Isopropyl Alcohol	BP	Nil	q.s
	Lubrication				
9.	4.40	Colloidal Anhydrous Silica	BP	Nil	0.440
10.	4.40	Magnesium Stearate	BP	Nil	0.440
	Coating				
11.	4.00	Hypromellose E15	BP	Nil	0.400
12.	0.50	Titanium Dioxide	BP	Nil	0.050
13.	0.50	Iron Oxide of Yellow	IHS	Nil	0.050

14.	---	* Isopropyl Alcohol	BP	Nil	q.s
15.	---	* Dichloromethane	BP	Nil	q.s

USP – United States Pharmacopoeia, BP – British Pharmacopoeia, IHS-In-House Specification.

3. Pharmaceutical form

Tablet: A yellow color circular shape biconvexed film coated tablet, plain on both the sides.

4. Clinical particulars

4.1 Therapeutic indications

CILNEED 20 CT is indicated for the management of Hypertension. Cilnidipine is a calcium channel blocker which relaxes blood vessels and makes the heart more efficient at pumping blood throughout the body. Chlorthalidone is a diuretic which removes extra water and certain electrolytes from the body by increasing the amount of urine produced.

4.2 Posology and method of administration

A single dose is recommended or as directed by physician.

Method of administration: Oral.

Not recommended for children below 18 years.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed. Cilnidipine and Chlorthalidone tablets are contraindicated in patients with severe aortic stenosis, cardiogenic shock, recent history of unstable angina or MI, heart failure and hypotension. Anuria, severe renal failure (creatinine clearance lower than 30 mL/min), and severe hepatic failure.

4.4 Special warnings and precautions for use

Cilnidipine should be used with caution in patients with hypotension (low blood pressure), heart failure and poor cardiac reserve. Chlorthalidone should be used with caution in patients with impaired hepatic

function or progressive liver disease since minor changes in the fluid and electrolyte balance due to thiazide diuretics may precipitate hepatic coma, especially in patients with liver cirrhosis.

4.5 Interaction with other medicinal products and other forms of interaction

The metabolism of Cilnidipine can be decreased when combined with (R)-warfarin. The risk or severity of hypoglycemia can be increased when Cilnidipine is combined with 2,4-thiazolidinedione. The metabolism of 4-hydroxycoumarin can be decreased when combined with Cilnidipine. The metabolism of Cilnidipine can be decreased when combined with 6-Deoxyerythronolide. Chlorthalidone with Diuretics may reduce lithium excretion and thus increase its plasma levels.

4.6 Pregnancy and lactation

CILNEED 20 CT is contraindicated for hypertension in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Caution is recommended, during driving or operating dangerous or poor precision machines as well as performing other activities requiring concentration.

4.8 Undesirable effects

Fever, rashes, GERD, increased urination, edema, flushing, myalgia, impotence, ischemic chest pain, serious hypotension, abnormal liver function, depression, eye pain, cerebral or myocardial ischemia and tremors.

4.9 Overdose

Dizziness, nausea, somnolence, hypovolaemia, hypotension, and electrolyte disturbances associated with cardiac arrhythmias and muscle spasms.

Treatment: There is no specific antidote. Induction of vomiting or gastric lavage and administration of activated charcoal should be employed to reduce absorption if the patient is conscious.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Cilnidipine decreases blood pressure safely and effectively without excessive blood pressure reduction or tachycardia. 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. Chlorthalidone is a long-acting oral diuretic with antihypertensive activity. Its diuretic action commences a mean of 2-6 hours after dosing and continues for up to 72 hours. The drug produces diuresis with increased excretion of sodium and chloride.

5.2 Pharmacokinetic properties

Absorption: Cilnidipine presents a very rapid absorption with a maximum peaked concentration after 2 hours. The bioavailability of an oral chlorthalidone is approximately 64%, peak blood concentrations being attained after 8-12 hours.

Distribution: Drugs on the group of dihydropyridines such as cilnidipine tend to have a large volume of distribution. In blood, only a small fraction of chlorthalidone is free, due to extensive accumulation in erythrocytes and binding to plasma proteins.

Metabolism: Cilnidipine is metabolized by both liver and kidney. It is rapidly metabolized by liver microsomes by a dehydrogenation process. Chlorthalidone Metabolism and hepatic excretion into bile constitute a minor pathway of elimination.

Elimination: Cilnidipine gets eliminated through the urine in a proportion of 20% of the administered dose and 80% is eliminated by the feces. Chlorthalidone is eliminated from whole blood and plasma with an elimination half-life averaging 50 hours.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber.

6. Pharmaceutical Particulars

6.1 List of excipients

Croscarmellose Sodium

Maize Starch Microcrystalline Cellulose Lactose Povidone K30 Colloidal Anhydrous Silica Magnesium Stearate Hypromellose E15 Titanium Dioxide Iron Oxide of Yellow
6.2 Incompatibilities
None known.
6.3 Shelf life
24 Months
6.4 Special precautions for storage
Store below 30°C. Protect from light & moisture.
6.5 Nature and contents of container
Commercial Presentation: 4's, 10's, 20's, 30's & 100's 3 x 10's (10 tablets are packed in one Alu-Alu blister and 3 such Alu-Alu blisters are kept in one carton along with package insert).
6.6 Special precautions for disposal and other handling
Not applicable.
7. Marketing authorisation holder

	ATOZ Pharmaceuticals Pvt. Ltd. **Chennai – India.**
Product Name	**CILNEED 20 CT** (Cilnidipine 20mg and Chlorthalidone 12.5mg Tablets)
Composition	Each film coated tablet contains: Cilnidipine 20mg Chlorthalidone USP 12.5mg
SUMMARY OF PRODUCT CHARACTERISTICS	

Company name:	INNOCIA LIFESCIENCES PVT. LTD.,
Address:	Block A, No.12, Balaji Nagar, Ambattur, Chennai-600 053
Country:	INDIA.
8. Marketing authorisation number(s)	
Telephone:	044 26585811, 26585855
Telefax:	-
E-Mail:	ah@innocialife.com