For PPB use only	
1.17	**Product Information**
1.17.1	**Summary Product Characteristics (SPC)**

1. Name of the medicinal product

Cilnidipine 20mg, Telmisartan 80mg and Chlorthalidone 12.5mg Tablets

2. Qualitative and quantitative composition

Each film coated tablet contains:

Cilnidipine 20mg

Telmisartan USP 80mg

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.	80.00	Telmisartan	USP	Nil	8.000
3.	12.50	Chlorthalidone	USP	Nil	1.250
4.	10.00	Croscarmellose Sodium	BP	Nil	1.000
5.	20.00	Maize Starch	BP	Nil	2.000
6.	12.40	Microcrystalline Cellulose	BP	Nil	1.240
7.	29.70	Lactose	BP	Nil	2.970
8.	6.60	Povidone K30	BP	Nil	0.660
9.	---	* Isopropyl Alcohol	BP	Nil	q.s
	Lubrication				
10.	4.40	Colloidal Anhydrous Silica	BP	Nil	0.440
11.	4.40	Magnesium Stearate	BP	Nil	0.440
	Coating				
12.	4.00	Hypromellose E15	BP	Nil	0.400
13.	0.50	Titanium Dioxide	BP	Nil	0.050
14.	0.50	Iron Oxide of Red	IHS	Nil	0.050
15.	---	* Isopropyl Alcohol	BP	Nil	q.s
16.	---	* Dichloromethane	BP	Nil	q.s

*Represents solvents will not be present in finished product.

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

3. Pharmaceutical form

Tablet: A light red colour circular shape biconvexed film coated tablet, plain on both the sides.

4. Clinical particulars

4.1 Therapeutic indications

Cilnitel CT is indicated for the management of hypertension, indicated for Arterial hypertension, essential or nephrogenic or isolated systolic.

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. Cilnitel CT is 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. The concomitant use of telmisartan with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment.

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. Telmisartan is not to be given to patients with cholestasis, biliary obstructive disorders or severe hepatic impairmen.

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. When telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49%) and in trough concentration (20%) were observed.

4.6 Fertility, Pregnancy and lactation

Cilnitel 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. Thiazide and thiazide-like diuretics act primarily on the distal renal tubule (early convoluted part), inhibiting NaCl reabsorption (by antagonising the Na+-Cl- cotransporter) and promoting Ca++ reabsorption. Telmisartan is an orally active and specific angiotensin II receptor (type AT1) antagonist. Telmisartan displaces angiotensin II with very high affinity from its binding site at the AT1 receptor subtype, which is responsible for the known actions of angiotensin II.

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. Absorption of telmisartan is rapid although the amount absorbed varies. The mean absolute bioavailability for telmisartan is about 50 %

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. Telmisartan is largely bound to plasma protein (>99.5 %), mainly albumin and alpha-1 acid glycoprotein

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. Telmisartan is metabolised by conjugation to the glucuronide of the parent compound. No pharmacological activity has been shown for the conjugate

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. Telmisartan is characterised by biexponential decay pharmacokinetics with a terminal elimination half-life of >20 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 Red

6.2 Incompatibilities

Not applicable.

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 and Manufacturing Site Address

Marketing authorisation holder:

Company name: INNOCIA LIFESCIENCES PVT. LTD.,

Address: Block A, No.12, Balaji Nagar, Ambattur, Chennai-600 053

Country: INDIA.

Manufacturing Site:

ATOZ Pharmaceutials Pvt.Ltd.,

No.12, Balaji Nagar, Ambattur, Chennai-600053,

India.

8. Marketing authorisation number(s)

Telephone: 044 26585811, 26585855

Telefax: -

E-Mail: ah@innocialife.com

9. Date of first registration / Renewal of the registration

Date of first Authorization: Not Applicable

Date of Latest Renewal: Not Applicable

10. Date of revision of the text: Not Applicable

11. Dosimetry (If Applicable): Not Applicable

12. Instructions for preparation of radiopharmaceuticals (If Applicable): Not Applicable