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

1. Name of the medicinal product

Cilnidipine 20mg and Telmisartan 80mg Tablets

2. Qualitative and quantitative composition

Each film coated tablet contains:

Cilnidipine 20mg

Telmisartan USP 80mg

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.	15.00	Croscarmellose Sodium	BP	Nil	1.500
4.	25.00	Maize Starch	BP	Nil	2.500
5.	14.60	Microcrystalline Cellulose	BP	Nil	1.460
6.	30.00	Lactose	BP	Nil	3.000
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	Erythrosine Lake	IHS	Nil	0.050
14.	---	* Isopropyl Alcohol	BP	Nil	q.s
15.	---	* 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 pink colour circular shape biconvexed film coated tablet, plain on both the sides.

4. Clinical particulars

4.1 Therapeutic indications

Hypertension: Treatment of essential hypertension in adults.Cilnidipine and Telmisartan, which lowers blood pressure effectively. Cilnidipine is a calcium channel blocker (CCB) and Telmisartan is an angiotensin receptor blocker (ARB). They work by relaxing the blood vessels and making the heart more efficient at pumping blood throughout the body.

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 20/80 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. 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. 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

Cilnidipine and Telmisartan Tablet 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. 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. 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. 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. 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
Erythrosine Lake

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: 03.12.2020

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