



ATOZ Pharmaceuticals Pvt. Ltd.
Chennai – India.

Product Name	CILNITEL 10/80 (Cilnidipine 10mg and Telmisartan 80mg Tablets)
Composition	Each film coated tablet contains: Cilnidipine 10mg Telmisartan USP 80mg

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product																																																																																																												
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SUMMARY OF PRODUCT CHARACTERISTICS

Tablet: A yellow color circular shape biconvex film coated tablet, plain on both the sides.
Clinical particulars
4. 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.
4.1 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.
4.2 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed. Cilnitel 10/40 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.
4.3 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



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disorders or severe hepatic impairment.

4.4 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.

4.5 Fertility, Pregnancy and lactation

Cilnidipine and Telmisartan Tablet is contraindicated for hypertension in pregnancy and lactation.

4.6 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.

4.7 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.

4.8 Overdose



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<p>Dizziness, nausea, somnolence, hypovolaemia, hypotension, and electrolyte disturbances associated with cardiac arrhythmias and muscle spasms.</p> <p>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.</p>
5. Pharmacological properties
5.1 Pharmacodynamic properties
<p>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.</p>
5.2 Pharmacokinetic properties
<p>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 %</p> <p>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</p> <p>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</p>



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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
- Quinoline Yellow

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months



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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	
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