SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

CILNITEL 10/40 TABLETS

Cilnidipine 20mg and Telmisartan 40mg Tablets

2. Qualitative and quantitative composition

Each film coated tablet contains:

Cilnidipine……...20mg

Telmisartan USP ……..40mg

Excipients with known effect

Each tablet contains lactose monohydrate equivalent to 40.00 mg lactose.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablet:

An orange 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 impairment.

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 coadministered with digoxin, median increases in digoxin peak plasma concentration (49%) and in trough concentration (20%) were observed.

4.6 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 metabolized 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 characterized 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
Sunset Yellow

6.2 Incompatibilities

None known.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C. Protect from heat, 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 authorization holder

Innocia Lifesciences Pvt. Ltd.,
Block A, No.12, Balaji Nagar, Ambattur,
Chennai-600 053 INDIA.

8. Marketing authorization number(s)

H2022/CTD6682/2458ER

9. Date of first authorization/renewal of the authorization

2022 December 01

10. Date of revision of the text

2022 December 01