

Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Amlodipine 10mg, Telmisartan 40mg and Chlorthalidone 12.5mg Tablets

2. Qualitative and quantitative composition

Each film coated tablet contains:

Amlodipine Besilate BP

Eq. to Amlodipine.....	10mg
Telmisartan USP.....	40mg
Chlorthalidone USP.....	12.5mg

For full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablet: A pink colour circular shape biconvex film coated tablet, plain on both the sides.

4. Clinical particulars

4.1 Therapeutic indications

Amlodipine, Telmisartan and Chlorthalidone 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

Amlodipine tablets are contraindicated in patients with severe hypotension, obstruction of the outflow tract of the left ventricle (e.g., high grade aortic stenosis). Hypersensitivity to the active substance or to any of the excipients listed. 'Telmisartan and Chlorthalidone Tablet' 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

The half-life of amlodipine is prolonged and AUC values are higher in patients with impaired liver function. Amlodipine should therefore be initiated at the lower end of the dosing range and caution should be used, both on initial treatment and when increasing the dose. 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 impairment.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of amlodipine with strong or moderate CYP3A4 inhibitors (protease inhibitors, azole antifungals, macrolides like erythromycin or clarithromycin, verapamil or diltiazem) may give rise to significant increase in amlodipine exposure resulting in an increased risk of hypotension. 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

'Amlodipine, Telmisartan and Chlorthalidone 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.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions to report any suspected adverse reactions to the National Regulatory Authority.

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

Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle. Telmisartan is an orally active and specific angiotensin II receptor (type AT1) antagonist. Chlorthalidone reduce extra salt and water in the body caused by conditions such as heart failure, liver disease, and kidney disease.

5.2 Pharmacokinetic properties

Absorption: Oral administration of therapeutic doses, amlodipine is well absorbed with peak blood levels between 6-12 hours post dose. Absolute bioavailability has been estimated to be between 64 and 80%. 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: The volume of distribution Amlodipine is approximately 21 l/kg. 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: Invitro studies have shown that approximately 97.5% of circulating amlodipine is bound to plasma proteins. The bioavailability of amlodipine is not affected by food intake. 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: The terminal plasma elimination half life for Amlodipine is about 35-50 hours and is consistent with once daily dosing. 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

Maize Starch
Microcrystalline
Cellulose

Crospovidone
Povidone K30
Croscarmellose
Sodium
Colloidal Anhydrous
Silica Magnesium
Stearate
Hypromellose E15
Purified Talc
Titanium
Dioxide
Ponceau 4R
Isopropyl
Alcohol
Dichloromethane
e

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

Company name: INNOCIA LIFESCIENCES PVT. LTD.,

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

Country: INDIA.

8. Marketing Authorisation Number

H2022/CTD8968/20709

9. Date of first registration / Renewal of the authorization

August 24,2022.

10. Date of revision of the text

August 24,2022.