1. Name of the medicinal product

Amlodipine 10mg and Telmisartan 40mg Tablets

2. Qualitative and quantitative composition

Each film coated tablet contains:
Amlodipine Besilate BP Equivalent to
Amlodipine 10mg Telmisartan USP 40mg

For the full list of excipients, see section 6.1.

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

Amlodipine and Telmisartan 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 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. 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. 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 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.

Reporting suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the Pharmacy and Poisons Board (PPB) through the Pharmacovigilance Electronic Reporting System (PvERS) at https://pv.pharmacyboardkenya.org/ or by using the approved PPB ADR reporting forms.

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.

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%. 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. 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. 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. 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

Microcrystalline Cellulose
Maize Starch
Crospovidone
Povidone K30
Purified Talc
Croscarmellose
Sodium Colloidal
Anhydrous Silica
Magnesium Stearate
Hypromellose E15
Titanium Dioxide
Erythrosine Lake
Isopropyl Alcohol
Dichloromethane

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

M/s. Innocia Lifesciences Pvt. Ltd
M/s. Innocia Lifesciences Pvt. Ltd. 12 Balaji nagar Ambattur Chennai 53 Tamilnadu India.

Manufacturing Site:
ATOZ Pharmaceutials Pvt.Ltd.,
No.12, Balaji Nagar, Ambattur, Chennai-600053, India.

8. Marketing authorisation number(s)

CTD8970

9. Date of first registration / Renewal of the registration
2022 March 21

10. Date of revision of the text
2022 March 21