	ATOZ Pharmaceuticals Pvt. Ltd. **Chennai – India.**
Product Name	**BP-TEL 10/40 ACT** (**Amlodipine 10mg, Telmisartan 40mg and Chlorthallidone 12.5mg Tablets**)
Composition	Each film coated tablet contains: Amlodipine Besilate BP Equivalent to Amlodipine 10mg Telmisartan USP 40mg Chlorthalidone USP 12.5mg

SUMMARY OF PRODUCT CHARACTERISTICS

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 Equivalent to Amlodipine 10mg

Telmisartan USP 40mg

Chlorthalidone USP 12.5mg

S. No.	Wt. / tablet (mg)	Ingredient	Spec	Overages	Std. Qty for 100,000 tablets (in kg)
1.	14.00	Amlodipine Besilate	BP	Nil	1.400
2.	40.00	Telmisartan	USP	Nil	4.000
3.	12.50	Chlorthalidone	USP	Nil	1.250
4.	59.50	Maize Starch	BP	Nil	5.950
5.	33.00	Microcrystalline Cellulose	BP	Nil	3.300
6.	10.00	Crospovidone	BP	Nil	1.000
7.	6.00	Povidone K30	BP	Nil	0.600
8.	---	*Dichloromethane	BP	Nil	q.s
	Lubrication				
9.	10.00	Maize Starch	BP	Nil	1.000
10.	10.00	Croscarmellose Sodium	BP	Nil	1.000
11.	2.50	Colloidal Anhydrous Silica	BP	Nil	0.250
12.	2.50	Magnesium Stearate	BP	Nil	0.250
	Coating				
13.	3.00	Hypromellose E15	BP	Nil	0.300
14.	1.00	Purified Talc	BP	Nil	0.100
15.	0.50	Titanium Dioxide	BP	Nil	0.050
16.	0.50	Ponceau 4R	IHS	Nil	0.050
17.	--	*Isopropyl Alcohol	BP	Nil	q.s
18.	--	*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.

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3. Pharmaceutical form

Tablet: A pink color circular shape biconvexed 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 impairmen.

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.

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C. Protect from heat, light & moisture.

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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