	ATOZ Pharmaceuticals Pvt. Ltd. **Chennai – India.**
Product Name	**BP-TEL 5/80 AM** (**Amlodipine 5mg and Telmisartan 80mg Tablets**)
Composition	Each film coated tablet contains: Amlodipine Besilate BP Equivalent to Amlodipine 5mg Telmisartan USP 80mg

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Amlodipine 5mg and Telmisartan 80mg Tablets.

2. Qualitative and quantitative composition

Each film coated tablet contains:

Amlodipine Besilate BP Equivalent to Amlodipine 5mg

Telmisartan USP 80mg

S. No.	Wt. / tablet (mg)	Ingredient	Spec	Overages	Std. Qty for 100,000 tablets (in kg)
1.	7.00	Amlodipine Besilate	BP	Nil	0.700
2.	80.00	Telmisartan	USP	Nil	8.000
3.	25.50	Microcrystalline Cellulose	BP	Nil	2.550
4.	18.50	Maize Starch	BP	Nil	1.850
5.	23.00	Crospovidone	BP	Nil	2.300
6.	6.00	Povidone K30	BP	Nil	0.600
7.	---	*Dichloromethane	BP	Nil	q.s
	Lubrication				
8.	10.00	Maize Starch	BP	Nil	1.000
9.	2.50	Purified Talc	BP	Nil	0.250
10.	20.00	Croscarmellose Sodium	BP	Nil	2.000
11.	2.50	Colloidal Anhydrous Silica	BP	Nil	0.250
12.	5.00	Magnesium Stearate	BP	Nil	0.500
	Coating				
13.	2.97	Hypromellose E15	BP	Nil	0.297
14.	1.00	Titanium Dioxide	BP	Nil	0.100
15.	1.00	Purified Talc	BP	Nil	0.100
16.	0.03	Sunset Yellow	IHS	Nil	0.003
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.

3. Pharmaceutical form

Tablet: An Orange color 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.

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

Sunset Yellow

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.
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