Size : 3 x 7 Inch

Telmisartan and Amlodipine Besilate Tablets

POM

# AMTEL 80/5

**Composition**

Each film coated tablet contains:

| | |
|---|---|
| Telmisartan BP | 80.0 mg |
| Amlodipine Besilate BP | |
| Equivalent to Amlodipine | 5.0 mg |
| Excipients | Q.S |
| Colour: Titanium Dioxide BP | |

**Pharmacological Classification**

Agents acting on the renin-angiotensin system, angiotensin II antagonists and calcium channel blockers.

**Pharmacological Action**

**Mode of Action**

Amtel 80/5 combines two antihypertensive compounds with complementary mechanisms to control blood pressure in patients with essential hypertension: an angiotensin II receptor antagonist, telmisartan, and a dihydropyridinic calcium channel blocker, amlodipine. The combination of these substances has an additive antihypertensive effect, reducing blood pressure to a greater degree than either component alone. Amtel 80/5 once daily produces effective and consistent reductions in blood pressure across the 24-hour therapeutic dose range.

**Pharmacokinetics**

**Absorption**

Absorption of telmisartan is rapid although the amount absorbed varies. The mean absolute bioavailability for telmisartan is about 50%. By 3 hours after administration, plasma concentrations are similar whether telmisartan is taken fasting or with food. After 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 %. Amlodipine bioavailability is not affected by food ingestion.

**Distribution**

Telmisartan is largely bound to plasma protein (>99.5 %), mainly albumin and alpha-1 acid glycoprotein. The mean steady state apparent volume of distribution ($Vd_{ss}$) is approximately 500 l. The volume of distribution of amlodipine is approximately 21 l/kg.

**Biotransformation**

Telmisartan is metabolised by conjugation to the glucuronide of the parent compound. No pharmacological activity has been shown for the conjugate. Amlodipine is extensively (approximately 90 %) metabolised by the liver to inactive metabolites

**Elimination**

After oral administration, telmisartan is nearly exclusively excreted with the faeces, mainly as unchanged compound. Amlodipine elimination from plasma is biphasic, with a terminal elimination half-life of approximately 30 to 50 hours consistent with once daily dosing. Steady-state plasma levels are reached after continuous administration for 7-8 days. 10 % of original amlodipine and 60 % of amlodipine metabolites are excreted in urine.

**Indications**

Treatment of essential hypertension in adults

**Add on therapy**

It is indicated in adults whose blood pressure is not adequately controlled on amlodipine.

**Replacement therapy**

Adult patients receiving Telmisartan and amlodipine from separate tablets can instead receive tablets of Amtel 80/5 containing the same component doses.

**Dosage and Directions for Use**

**Posology**

The recommended dose is one tablet per day. It is indicated for long term treatment. Administration of amlodipine with grapefruit or grapefruit juice is not recommended as bioavailability may be increased in some patients resulting in increased blood pressure lowering effects

**Add on therapy**

Amtel 80/5 may be administered in patients whose blood pressure is not adequately controlled.

**Special population**

Elderly patients

No dose adjustment is necessary for elderly patients.

Patients with renal impairment

No posology adjustment is required for patients with mild to moderate renal impairment

**Method of administration**

It can be taken with or without food. It is recommended to take with some liquid

**Contra-Indications**

Hypersensitivity to the active substances, to dihydropyridine derivatives, or to any of the excipients, second and third trimesters of pregnancy, biliary obstructive disorders and severe hepatic impairment, shock, severe hypotension, obstruction of the outflow tract of the left ventricle, haemodynamically unstable heart failure after acute myocardial infarction

**Warnings**

**Pregnancy**

Angiotensin II receptor antagonists should not be initiated during pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.

**Hepatic impairment**

Telmisartan is mostly eliminated in the bile. Patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance. Furthermore as with all calcium antagonists, amlodipine half-life is prolonged in patients with impaired liver function and dose recommendations have not been established. It should therefore be used with caution in these patients.

**Dual blockade of the renin-angiotensin-aldosterone system**

Dual blockade of the renin-angiotensin-aldosterone system is not recommended, close monitoring of renal function is advisable if co-administration is considered necessary.

**Primary aldosteronism**

Patients with primary aldosteronism generally will not respond to antihypertensive medicinal products acting through inhibition of the renin-angiotensin system. Therefore, the use of telmisartan is not recommended.

**Diabetic patients treated with insulin or antidiabetics**

In these patients hypoglycaemia may occur under telmisartan treatment. Therefore, in these patients an appropriate blood glucose monitoring should be considered; a dose adjustment of insulin or antidiabetics may be required when indicated.

**Drug Interactions**

Some drugs that increase the potassium level in the blood may interact with amtel 80/10. Hence caution is advised while taking these drugs

**Side-Effects:** The most common adverse reactions include dizziness and peripheral oedema.

**Overdosage and its Treatment**

**Symptoms**

The most prominent manifestations of telmisartan overdose are expected to be hypotension and tachycardia; bradycardia, dizziness, increase in serum creatinine, and acute renal failure. Overdose with amlodipine may result in excessive peripheral vasodilatation and possibly reflex tachycardia.

**Treatment**

The patient should be closely monitored, and the treatment should be symptomatic and supportive. Activated charcoal may be useful in the treatment of overdose of both telmisartan and amlodipine. Serum electrolytes and creatinine should be monitored frequently. If hypotension occurs, the patient should be placed in a supine position with elevation of extremities, with salt and volume replacement given quickly. Supportive treatment should be instituted. Telmisartan and Amlodipine are not removed by haemodialysis.

**Storage Condition**: Store below 30 °C. Protect from light and moisture

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

**Shelf Life:** 24 months

**Presentation:** 3 Strips of 10 Tablets in one printed carton with pack insert.

Physician Sample: 1 strip of 10 tablets in one printed carton with pack insert.

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