Telmacal®

Telmisartan and Amlodipine

Tablet

Description

Telmacal® is the combination of Telmisartan and Amlodipine. Telmisartan is an angiotensin II receptor antagonist. Telmisartan keeps blood vessels from narrowing, which lowers blood pressure and improves blood flow. Amlodipine is a Dihydropyridine calcium channel blocker. Amlodipine relaxes (widens) blood vessels and improves blood flow.

Indications

Telmacal® (Telmisartan and Amlodipine combination) is indicated for the treatment of hypertension alone or with other antihypertensive agents to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. This tablet is also indicated for initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.

Dosage and Administration

Telmisartan is an effective treatment of hypertension in once daily doses of 20-80 mg while Amlodipine is effective in doses of 2.5-10 mg.

Dosage must be individualized and may be increased after at least 2 weeks. Most of the antihypertensive effect is apparent within 2 weeks and maximal reduction is generally attained after 4 weeks.

Initial Therapy:

A patient may be initiated on Telmacal tablets if it is unlikely that control of blood pressure would be achieved with a single agent. The usual starting dose of Telmacal® is 5/40 mg once daily. Patients requiring larger blood pressure reduction may be started on Telmacal 5/80 tablet once daily.

Initial therapy with Telmacal® is not recommended in patient's ≥75 years old or with hepatic impairment. Correct imbalances of intravascular volume or salt-depletion, before initiating therapy with Telmacal tablets.

Add-on Therapy for patients with Hypertension Not Adequately Controlled on Antihypertensive Monotherapy:

Telmacal® tablet may be used to provide additional blood pressure lowering for patients not adequately controlled with amlodipine (or another dihydropyridine calcium channel blocker) alone or with Telmisartan (or another angiotensin receptor blocker) alone.

Patients treated with 10 mg amlodipine who experience any dose limiting adverse reactions such as edema, may be switched to Telmacal® 5/40 tablets once daily, reducing the dose of Amlodipine without reducing the overall expected antihypertensive response.

Replacement Therapy:

Patients receiving amlodipine and Telmisartan from separate tablets may instead receive Telmacal® tablet containing the same component doses once daily. When substituting for individual components, increase the dose of Telmacal® if blood pressure control has not been satisfactory.

Renal Impairment:

No initial dosage adjustment is required for patients with mild or moderate renal impairment. Titrate slowly in patients with severe renal impairment.

Hepatic Impairment:

In most patients, initiate amlodipine therapy at 2.5 mg. Titrate slowly in patients with hepatic impairment.

Patients 75 Years of Age and Older:

In most patients, initiate amlodipine therapy at 2.5 mg. Titrate slowly in patients 75 years of age and older.

Method of Administration:

Telmacal may be taken orally with or without food.

Use in Specific Populations

Paediatric Use:

Safety and effectiveness of Telmisartan and Amlodipine in pediatric patients have not been established.

***Pregnancy** (Pregnancy Category D):*

Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy can cause fetal and neonatal morbidity and death. When pregnancy is detected, discontinue Telmisartan and Amlodipine as soon as possible.

Nursing Mothers:

Telmisartan: It is not known whether Telmisartan is excreted in human milk, but Telmisartan was shown to be present in the milk of lactating rats. Because of the potential for adverse effects on the nursing infant, decide whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Amlodipine: It is not known whether amlodipine is excreted in human milk. In the absence of this information, it is recommended to discontinue nursing while amlodipine is administered.

Warning and Precautions

Hypotension

Telmisartan: In patients with an activated renin-angiotensin system, such as volume or salt-depleted patients (e.g., those being treated with high doses of diuretics), symptomatic hypotension may occur after initiation of therapy with Telmacal®. Either correct this condition prior to administration of Telmacal® tablet, or start treatment under close medical supervision with a reduced dose. If hypotension does occur, the patient should be placed in the supine position and, if necessary, given an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further treatment, which usually can be continued without difficulty once the blood pressure has stabilized.

Amlodipine: Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. Because of the gradual onset of action, acute hypotension is unlikely.

Impaired Hepatic Function

Not recommended in hepatically impaired patients for initial therapy.

Impaired Renal Function

Telmisartan: In patients whose renal function may depend on the activity of the renin-angiotensin-aldosterone system (e.g., patients with severe congestive heart failure or renal dysfunction), treatment with angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor antagonists has been associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure and/or death. Similar results may be anticipated in patients treated with Telmisartan.

Heart Failure

Closely monitor patients with heart failure.

Side Effects

Common side effects include peripheral edema, dizziness, drowsiness, tired feeling, flushing (warmth, redness, or tingly feeling), back pain, nausea, diarrhea, stomach pain. Swelling hands/ankles/feet or flushing may also occur.

Contraindications

Telmisartan and Amlodipine tablets are contraindicated in patients with known hypersensitivity (e.g. anaphylaxis or angioedema) to Telmisartan, Amlodipine, or any other component of this product. Do not co-administer Aliskiren with Telmisartan and Amlodipine in patients with diabetes.

Drug Interactions

Some medicines and Telmacal® tablet may interfere with each other. These include: aliskiren, diuretics, ACE inhibitors, potassium supplements or potassium containing salt substitutes, lithium, medicines used to treat certain types of depression or mental illness, non-steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors (medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis), anticonvulsant agents (such as carbamazepine, phenobarbital, phenytoin, primidone), some antibiotics (such as rifampicin), some antifungals, (such as ketoconazole or itraconazole), antiproteases, medicines used to treat HIV infection (such as ritonavir, simvastatin), immunosuppressants (such as ciclosporin or tacrolimus that used to prevent organ rejection after transplantation). These medicines may be affected by Telmacal® tablet or may affect how well it works.

Overdose

If you take too much Telmacal® tablet, you may feel dizzy, light-headed or you may faint. Your heartbeat may be faster or slower than usual. You may experience rapid, shallow breathing or cold, clammy skin. This is because your blood pressure is too low. You may need urgent medical attention even if there are no signs of discomfort or poisoning.

Pharmaceutical Precautions

Keep in a dry place, below 30° C. Protect from light. Keep out of the reach of children.

Commercial Pack

Telmacal® 5/40 Tablet: Box containing 30 tablets in 3 x 10's Alu-Alu form packs. Each film coated tablet contains Telmisartan USP 40 mg & Amlodipine Besilate BP equivalent to Amlodipine 5 mg.

Telmacal® 5/80 Tablet: Box containing 30 tablets in 3 x 10's Alu-Alu form packs. Each film coated tablet contains Telmisartan USP 80 mg & Amlodipine Besilate BP equivalent to Amlodipine 5 mg.

BEXIMCO PHARMA

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