

Package leaflet: Information for the user

TELMI TAB – 40 AMH

TELMISARTAN 40 MG, AMLODIPINE 5 MG AND HYDROCHLOROTHIAZIDE 12.5 MG
TABLETS

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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2. What you need to know before you take **TELMI TAB- 40 AMH**
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1. What TELMI TAB- 40 AMH is and what it is used for

TELMI TAB belongs to a group of medicines used to treatment of essential hypertension.

2. What you need to know before you take TELMI TAB- 40 AMH

Do not take TELMI TAB- 40 AMH

If you are Hypersensitivity to Telmisartan and Hydrochlorothiazide.

Hypersensitivity to Amlodipine Besylate or other Calcium channel blockers.

Patients with anuria, pregnant and lactating females and hereditary or idiopathic angioedema.

Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

Warnings and Precautions

Fetal Toxicity

WARNING: FETAL TOXICITY When pregnancy is detected, discontinue TELMI TAB AMH as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When pregnancy is detected, discontinue Telmi Tab AMH as soon as possible. Thiazides cross the placental barrier and appear in cord blood. Adverse reactions include fetal or neonatal jaundice, thrombocytopenia.

Hypotension 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 initialization of treatment with Telmi Tab AMH. Correct volume or salt depletion prior to administration of Telmi Tab AMH. **Amlodipine** Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. Because of the gradual onset of action, acute hypotension is unlikely. **Impaired Renal Function** Changes in renal function including acute renal failure can be caused by drugs that inhibit the renin-angiotensin system and by diuretics. Patients whose renal function may depend in part on the activity of the renin-angiotensin system (e.g., patients with renal artery stenosis, chronic kidney disease, severe congestive heart failure, or volume depletion) may be at particular risk of developing oliguria, progressive azotemia, or acute renal failure on Telmi Tab AMH. Monitor renal function periodically in these patients. Consider withholding or discontinuing therapy in patients who develop a clinically significant decrease in renal function on Telmi Tab AMH.

Patients with Hepatic Failure Telmi Tab AMH is not recommended in hepatically impaired patients. **Dual Blockade of the Renin-Angiotensin-Aldosterone System and Changes in Renal Function** Dual blockade of the renin-angiotensin-aldosterone system (RAS) with angiotensin blockers, ACE inhibitors, or aliskiren is associated with increased risks of hypotension, hyperkalemia, and renal impairment. In general, avoid combined use of RAS inhibitors. Closely monitor blood pressure, renal function and electrolytes in patients on Telmi Tab AMH and other agents that affect the RAS. Do not co-administer aliskiren with Telmi Tab AMH in patients with diabetes. Avoid concomitant use of aliskiren with Telmi Tab AMH in patients with renal impairment (GFR <60 mL/min/1.73 m²)

Electrolytes and Metabolic Disorders

Drugs, including telmisartan, that inhibit the renin-angiotensin system can cause hyperkalemia, particularly in patients with renal insufficiency, diabetes, or combination use with other angiotensin receptor blockers or ACE inhibitors and the concomitant use of other drugs that raise serum potassium levels. Hydrochlorothiazide can cause hypokalemia and hyponatremia. Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia. Hypomagnesemia can result in hypokalemia which may be difficult to treat despite potassium repletion. Monitor serum electrolytes periodically. Hydrochlorothiazide decreases urinary calcium excretion and may cause elevations of serum calcium.

Hydrochlorothiazide may alter glucose tolerance and raise serum levels of cholesterol and triglycerides. Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy. Because telmisartan decreases uric acid, telmisartan in combination with hydrochlorothiazide attenuates the diuretic-induced hyperuricemia.

Hypersensitivity Reaction Hydrochlorothiazide Hypersensitivity reactions to hydrochlorothiazide may occur in patients with or without a history of allergy or bronchial asthma, but are more likely in patients with such a history. **Acute Myopia and Secondary Angle-Closure Glaucoma** Hydrochlorothiazide, a sulfonamide, can cause an idiosyncratic reaction, resulting in acute transient myopia and acute angle-closure glaucoma. Symptoms include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of drug initiation. Untreated angle-closure glaucoma can lead to permanent vision loss. The primary treatment is to discontinue hydrochlorothiazide as rapidly as possible. Prompt medical or surgical treatments may need to be considered if the intraocular pressure remains uncontrolled. Risk factors for developing acute angle-closure glaucoma may include a history of sulfonamide or penicillin allergy. **Systemic Lupus Erythematosus** Thiazide diuretics have been reported to cause exacerbation or activation of systemic lupus erythematosus. **Postsympathectomy Patients** The antihypertensive effects of hydrochlorothiazide may be enhanced in the postsympathectomy patient.

Increased Angina or Myocardial Infarction Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of amlodipine, particularly in patients with severe obstructive coronary artery disease.

Heart Failure Closely monitor patients with heart failure.

Other medicines and TELMI TAB- 40 AMH

Telmisartan and Hydrochlorothiazide Agents Increasing Serum Potassium Co-administration of telmisartan with other drugs that raise serum potassium levels may result in hyperkalemia. Monitor serum potassium in such patients. **Lithium** Increases in serum lithium concentrations and lithium toxicity have been reported with concomitant use of thiazide diuretics or angiotensin II receptor antagonists, including telmisartan. Monitor lithium levels in patients receiving Telmi Tab AMH and lithium. **Digoxin** When telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49%) and in trough concentration (20%) were observed. Monitor digoxin levels in patients taking concomitant Telmi Tab AMH and digoxin. **Aliskiren** Do not co-administer aliskiren with Telmi Tab AMH in patients with diabetes. Avoid use of aliskiren with Telmi Tab AMH in patients with renal impairment.

Non-Steroidal Anti-Inflammatory Agents including Selective Cyclooxygenase-2 Inhibitors (COX-2 Inhibitors): **Telmisartan Non-Steroidal Anti-Inflammatory Agents including Selective Cyclooxygenase-2 Inhibitors (COX2 Inhibitors):** In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, co-administration of NSAIDs, including selective COX-2 inhibitors, with ARBs, including telmisartan, may result in deterioration of renal function, including possible acute renal failure. These effects are usually reversible. The antihypertensive effect of ARBs may be attenuated by NSAIDs. Therefore, monitor renal function periodically in patients receiving Telmi Tab AMH and NSAIDs.

Hydrochlorothiazide Administration of a non-steroidal anti-inflammatory agent, including a selective COX-2 inhibitor, can reduce the diuretic, natriuretic, and antihypertensive effects of diuretics.

Therefore, when Telmi Tab AMH and nonsteroidal anti-inflammatory agents including selective COX-2 inhibitors are used concomitantly, observe closely to determine if the desired effect of the diuretic is obtained.

Antidiabetic drugs (oral agents and insulin) Dosage adjustment of the antidiabetic drug may be required when co-administered with hydrochlorothiazide.

Cholestyramine and Colestipol resins

Absorption of hydrochlorothiazide is impaired in the presence of anionic exchange resins. Stagger the dosage of hydrochlorothiazide and the resin such that hydrochlorothiazide is administered at least 4 hours before or 4 to 6 hours after the administration of the resin.

Amlodipine CYP3A4 Inhibitors Co-administration with CYP3A inhibitors (moderate and strong) results in increased systemic exposure to amlodipine and may require dose reduction. Monitor for symptoms of hypotension and edema when amlodipine is co-administered with CYP3A4 inhibitors to determine the need for dose adjustment. CYP3A4 Inducers No information is available on the quantitative effects of CYP3A4 inducers on amlodipine. Blood pressure should be closely monitored when amlodipine is coadministered with CYP3A4 inducers. Sildenafil Monitor for hypotension when sildenafil is co-administered with amlodipine. Simvastatin Co-administration of simvastatin with amlodipine increases the systemic exposure of simvastatin. Limit the dose of simvastatin in patients on amlodipine to 20 mg daily. Immunosuppressants Amlodipine may increase the systemic exposure of cyclosporine or tacrolimus when coadministered. Frequent monitoring of trough blood levels of cyclosporine and tacrolimus is recommended and adjust the dose when appropriate.

TELMI TAB- 40 AMH with food, drink and alcohol

You are recommended not to consume alcohol along with TELMI TAB- 40 AMH to avoid unpleasant side-effects.

Pregnancy and breast-feeding

TELMI TAB- 40 AMH is not recommended during pregnancy unless your doctor considers it essential. Your doctor will weigh the benefits and any potential risks before prescribing it to you. It is not recommended during breast-feeding. However, your doctor may prescribe it for you during breast-feeding if he/she feels that the benefit to you outweighs the risk. You should not take TELMI TAB- 40 AMH without doctor's advice.

Driving and using machines

This medicinal product has moderate influence on the ability to drive and use machines. Patients should be advised that they may experience adverse reactions such as syncope, somnolence, dizziness, or vertigo during treatment. Therefore, caution should be recommended when driving a car or using machines.

If patients experience these adverse reactions, they should avoid potentially hazardous tasks such as driving or using machines

3. How to take TELMI TAB- 40 AMH

Dose once daily. Telmi Tab AMH may be substituted for its individually titrated components for patients on telmisartan, amlodipine, and hydrochlorothiazide. Telmi Tab AMH may be used as add-on/switch therapy to provide additional blood pressure lowering for patients not adequately controlled on agents from two of the following antihypertensive classes: angiotensin receptor blockers, calcium channel blockers, and diuretics at their maximally tolerated, labeled, or usual dose.

Special Populations:

Pediatric Use Safety and effectiveness in paediatric patients has not been established
Geriatric Use Telmisartan and Hydrochlorothiazide In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant diseases or other drug therapy
Amlodipine Elderly patients have decreased clearance of amlodipine with a resulting increase of AUC of approximately 40–60%, and a lower initial dose may be required. Patients with Renal Impairment Safety and effectiveness in patients with severe renal impairment (CrCl \leq 30 mL/min) have not been established. Not recommended in patients with severe renal impairment. No dose adjustment is required in patients with mild (CrCl 60 to 90 mL/min) or moderate (CrCl 30 to 60 mL/min) renal impairment. Patients with Hepatic Impairment Telmisartan As the majority of telmisartan is eliminated by biliary excretion, patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance and higher blood levels. Hydrochlorothiazide Minor alterations of fluid and electrolyte balance may precipitate hepatic coma in patients with impaired hepatic function or progressive liver disease. Amlodipine Amlodipine is extensively metabolized by the liver and the plasma elimination half-life ($t_{1/2}$) is 56 hours in patients with impaired hepatic function. Since patients with hepatic impairment have decreased clearance of amlodipine, start amlodipine or add amlodipine at 2.5mg. Since the dose of Telmi Tab AMH is 40/5/12.5mg, Telmi Tab AMH is not recommended in hepatically impaired patients.

If you take more TELMI TAB- 40 AMH than you should

Telmisartan Limited data are available with regard to overdosage in humans. The most likely manifestations of overdosage with telmisartan would be hypotension, dizziness and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted. Telmisartan is not removed by hemodialysis.
Hydrochlorothiazide The most common signs and symptoms observed in patients are those caused by electrolyte depletion (hypokalemia, hypochloremia, hyponatremia) and dehydration resulting from excessive diuresis. If digitalis has also been administered, hypokalemia may accentuate cardiac arrhythmias. The degree to which hydrochlorothiazide is removed by hemodialysis has not been established. The oral LD50 of hydrochlorothiazide is greater than 10 g/kg in both mice and rats.

Amlodipine

Overdosage might be expected to cause excessive peripheral vasodilation with marked hypotension and possibly a reflex tachycardia. In humans, experience with intentional overdosage of amlodipine is limited. If massive overdose should occur, initiate active cardiac and respiratory monitoring. Frequent blood pressure measurements are essential. Should hypotension occur, provide cardiovascular support including elevation of the extremities and the judicious administration of fluids. If hypotension remains unresponsive to these conservative measures, consider administration of vasopressors (such as phenylephrine) with attention to circulating volume and urine output. As amlodipine is highly protein bound, hemodialysis is not likely to be of benefit.

If you forget to take TELMI TAB- 40 AMH

It is important to take your TELMI TAB- 40 AMH capsules regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking TELMI TAB- 40 AMH

Do not stop taking TELMI TAB- 40 AMH unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week.

4. Possible side effects

The combination of Telmisartan/ Hydrochlorothiazide/ Amlodipine is generally well tolerated. The most frequent clinical adverse effects in patients treated with this combination are fatigue, dizziness, diarrhea, nausea, back pain, dyspepsia, vomiting, hypokalemia, bronchitis, rash and postural hypotension. Other rare events included paresthesias, anorexia, sexual dysfunction, nocturia.

5. How to store TELMI TAB- 40 AMH

Keep all medicines away from the reach of children. Store in cool, dark & dry place at a temperature below 30°C.

Protected from moisture

6. Contents of the pack and other information What TELMI TAB- 40 AMH contains

TELMISARTAN 40 MG, AMLODIPINE 5 MG AND HYDROCHLOROTHIAZIDE 12.5 MG TABLETS

Contents of the pack and other information

ALU- ALU Blister pack of 3 x 10 Tablets

ALU- ALU Blister pack of 1 x 10 Tablets

Not all pack sizes may be marketed.

Further Information :

Composition:

Each film coated tablet contains:

Telmisartan USP 40 mg

Amlodipine Besylate USP Equivalent to Amlodipine 5 mg

Hydrochlorothiazide USP 12.5 mg

Sunset Yellow

Excipients Q. S.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Galaxy Pharmaceuticals.

Arihant Complex, Building No. 37,

Gala No. 1, Kopar, Purna Village.

Bhiwandi, Dist. Thane - 421302

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Manufacturer:

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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