

Brand Name: Gertel-AM

Generic Name: Telmisartan + Amlodipine Combination

Dosage Form: Oral Tablet

Strength of Gertel-AM: Telmisartan: 40 mg + Amlodipine: 5 mg

Gertel-AM is the combination of Telmisartan (an Angiotensin II Receptor Blocker, ARB) and Amlodipine (a Calcium Channel Blocker, CCB) that works synergistically to treat hypertension and cardiovascular diseases. Each medication targets different mechanisms in the body to help lower blood pressure and reduce the risk of cardiovascular events. Here's the mechanism of action (MOA) of each drug and how they work together:

1. Telmisartan in Gertel-AM (Angiotensin II Receptor Blocker, ARB):

- **MOA: Telmisartan selectively and competitively blocks the angiotensin II type 1 (AT1) receptor. Angiotensin II is a potent vasoconstrictor that causes blood vessels to narrow and increases blood pressure. It also promotes the release of aldosterone, which leads to salt and water retention and further increases blood pressure.**
 - **By blocking the AT1 receptor, telmisartan prevents vasoconstriction and reduces aldosterone release, leading to vasodilation (widening of blood vessels) and reduced blood pressure.**
 - **Telmisartan also helps protect the kidneys, especially in conditions like diabetic nephropathy and chronic kidney disease.**

2. Amlodipine in Gertel-AM (Calcium Channel Blocker, CCB):

- **MOA: Amlodipine works by inhibiting the entry of calcium ions into vascular smooth muscle cells and cardiac muscle cells through L-type calcium channels. Calcium is essential for muscle contraction, so blocking its entry causes:**
 - **Vasodilation: Amlodipine primarily causes the relaxation of vascular smooth muscles, leading to the widening of blood vessels and reduced vascular resistance. This lowers blood pressure.**
 - **Reduced cardiac workload: Amlodipine also has mild effects on the heart, reducing the force of contraction and heart rate, which decreases the heart's demand for oxygen and helps in managing conditions like angina.**
- **Effect on the Heart and Blood Vessels: Amlodipine has a long-lasting effect on the blood vessels, providing significant control over systemic vascular resistance, especially in patients with chronic hypertension.**

Combined Mechanism of Action of Telmisartan + Amlodipine:

When used together, these two medications complement each other to more effectively manage high blood pressure

- **Telmisartan:**
 - **Blocks the effects of angiotensin II by inhibiting the AT1 receptor, which causes vasodilation, reduces aldosterone secretion and helps lower blood pressure.**
 - **Protects the kidneys and can improve outcomes in patients with heart failure or chronic kidney disease.**
- **Amlodipine:**
 - **Blocks calcium influx into vascular smooth muscle and heart cells, causing vasodilation and a reduction in vascular resistance.**
 - **Reduces heart workload, helping prevent angina and improving cardiovascular function.**

Synergistic Effects:

- **The combination of these two drugs provides comprehensive control of blood pressure through different mechanisms:**
 - **Telmisartan acts by blocking the angiotensin II receptor, leading to blood vessel relaxation and sodium balance regulation.**
 - **Amlodipine works by reducing calcium influx, causing further vasodilation and lowering blood pressure through a different pathway.**
- **Together, these medications help control both systolic and diastolic blood pressure effectively while providing additional cardiovascular protection, particularly in patients with hypertension, angina, or heart failure.**

Summary:

- **Telmisartan blocks the angiotensin II receptor to cause vasodilation and reduce aldosterone secretion, lowering blood pressure.**
- **Amlodipine blocks calcium channels, causing vasodilation and reducing vascular resistance and cardiac workload.**
- **Together, these drugs provide synergistic blood pressure reduction, improving outcomes in patients with hypertension and other cardiovascular conditions.**

1. Indications

- **Hypertension (High Blood Pressure):** This combination is used to treat **hypertension** in patients who are not adequately controlled with either medication alone or as initial therapy when blood pressure is not adequately controlled by one agent.
- **Hypertensive Patients with Comorbid Conditions:** It may also be prescribed to patients with additional cardiovascular risk factors, such as diabetes or a history of heart disease.

2. Dosage and Administration of Gertel-AM

- **Recommended Dose:**
 - **Initial Dose:** Typically, **1 tablet** (containing 40 mg of Telmisartan and 5 mg of Amlodipine) once daily.
 - The dose can be adjusted based on the individual's response to therapy. The maximum recommended dose is **80 mg** of Telmisartan and **10 mg** of Amlodipine once daily.
- **Renal Impairment:** In patients with renal impairment, the dosage may need to be adjusted, particularly in those with severe renal dysfunction.
- **Hepatic Impairment:** Dose adjustment is required in patients with hepatic impairment, especially for Telmisartan.
- **Missed Dose:** If a dose is missed, it should be taken as soon as remembered unless it is close to the time for the next dose. **Do not take two doses at once.**

3. Contraindications of Gertel-AM

- **Hypersensitivity:** Contraindicated in patients with a known hypersensitivity to Telmisartan, Amlodipine, or any component of the formulation.
- **Pregnancy:** Contraindicated during pregnancy, especially in the second and third trimesters, due to the risk of fetal harm.
- **Severe Renal Impairment:** Contraindicated in patients with severe renal impairment or those with a creatinine clearance of < 30 mL/min.
- **Severe Hepatic Impairment:** Contraindicated in patients with severe hepatic impairment (e.g., cirrhosis).
- **Hypotension:** Not recommended in patients with severe hypotension or shock.
- **Aortic Stenosis:** Amlodipine should not be used in patients with severe aortic stenosis.

4. Warnings and Precautions

- **Hypotension:** The combination may cause a **drop in blood pressure** upon initial dosing, particularly in volume-depleted patients (e.g., those on diuretics). Blood pressure should be monitored.
- **Renal Impairment:** Use with caution in patients with renal dysfunction. Regular monitoring of renal function is recommended.
- **Electrolyte Imbalance:** Monitor serum potassium and sodium levels as Telmisartan can increase potassium, and Amlodipine may cause fluid retention.
- **Angina or Heart Failure:** In patients with severe coronary artery disease, use with caution as Amlodipine may cause reflex tachycardia, leading to angina or worsening heart failure.
- **Liver Disease:** Caution in patients with hepatic impairment. Telmisartan should be used with care in these patients, and Amlodipine requires dosage adjustments.

5. Adverse Reactions

- **Common Side Effects:**

- Dizziness
- Headache
- Fatigue
- Swelling (oedema), especially in the ankles or legs
- Flushing
- Palpitations (heart pounding)
- **Serious Side Effects:**
 - **Hypotension** (especially after the first dose)
 - **Angioedema** (swelling of the skin, lips, tongue, or throat)
 - **Liver dysfunction**
 - **Elevated potassium levels** (hyperkalemia)
 - **Severe allergic reactions**
 - **Tachycardia** (rapid heartbeat, mainly due to Amlodipine)
 - **Chest pain or heart attack** (due to exacerbation of heart failure or angina)

6. Drug Interactions

- **Diuretics:** Concurrent use of diuretics (especially those causing potassium loss) can increase the risk of low blood pressure, dehydration, and electrolyte imbalances.
- **ACE Inhibitors:** Concomitant use of ACE inhibitors, especially in patients with renal artery stenosis, can increase the risk of renal impairment and hyperkalemia.
- **Lithium:** The combination may increase serum lithium levels, requiring careful monitoring.
- **NSAIDs:** NSAIDs may reduce the effectiveness of Telmisartan and increase the risk of renal impairment.
- **CYP3A4 Inhibitors (e.g., Ketoconazole, Grapefruit Juice):** These may increase the plasma concentration of Amlodipine, increasing the risk of side effects like swelling and dizziness.

7. Use in Specific Populations

- **Pregnancy:** This medication is **contraindicated** during pregnancy. It may cause harm to the fetus, particularly in the second and third trimesters.
- **Lactation:** It is not known whether Telmisartan and Amlodipine are excreted in human milk. Caution is recommended when used during breastfeeding.
- **Pediatrics:** Safety and efficacy in pediatric patients have not been established.
- **Geriatrics:** No specific dose adjustment for elderly patients, but they are more likely to have renal and hepatic impairment, so close monitoring is recommended.

8. Overdose

- **Symptoms of Overdose:** Hypotension, dizziness, lightheadedness, tachycardia (from Amlodipine), and bradycardia (from Telmisartan) may occur.
- **Management:** In the case of overdose, symptomatic treatment should be initiated. If blood pressure drops significantly, the patient should be placed in a supine position and monitored. If necessary, blood pressure can be supported with intravenous fluids and vasopressors. Dialysis is not expected to be helpful as Telmisartan is highly protein-bound and Amlodipine is not significantly dialyzable.

9. Pharmacology

- **Telmisartan:** Telmisartan is an angiotensin II receptor blocker (ARB) that works by inhibiting the effects of angiotensin II, a hormone that constricts blood vessels, resulting in lower blood pressure.
- **Amlodipine:** Amlodipine is a calcium channel blocker that relaxes the blood vessels and reduces the heart's workload by blocking calcium entry into muscle cells, thereby helping to lower blood pressure.

10. Storage

- Store at room temperature (between 15°C and 30°C) in a dry place.
- Keep out of the reach of children.

11. Packaging:

- Each Alu-Alu strip of Gertel-AM contains 10 tablets.
- Each box of Gertel-AM contains 10 strips.

Note: This summary provides general prescribing information.