

IMPORTANT SAFETY INFORMATION

KATERZIA®(amlodipine) Oral Suspension, 1 mg/mL

INDICATIONS

KATERZIA is a calcium channel blocker and may be used alone or in combination with other antihypertensive and antianginal agents for the treatment of:

- Hypertension in adults and children 6 years of age and older to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.
- Coronary Artery Disease:
 - Chronic stable angina.
 - Vasospastic angina (Prinzmetal's or Variant Angina).
 - Angiographically documented Coronary Artery Disease in patients without heart failure or an ejection fraction < 40%.

*A calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. A household teaspoon or tablespoon is not an adequate measuring device. Ask your pharmacist or doctor for assistance in selecting a measuring device. **Shake well before using.***

ADDITIONAL IMPORTANT SAFETY INFORMATION

Do not use KATERZIA if you are allergic to amlodipine.

What is the most important information I should know about KATERZIA?

KATERZIA may cause serious side effects, including:

- **Low blood pressure:** Symptoms of low blood pressure (hypotension) are possible, particularly in patients with serious heart valve disease (severe aortic stenosis). However, acute low blood pressure is unlikely.
- **Increased chest pain or heart attack:** Worsening chest pain called angina, and heart attack (acute myocardial infarction) can develop after starting or increasing the dose of Katerzia, particularly in patients with severe obstructive coronary artery disease.
- **Patients with severe liver disease:** Patients with severe liver disease may need to start with a lower initial dose of Katerzia.

Before taking KATERZIA, tell your healthcare provider about all your medical conditions, including if you:

- ever had heart disease
- ever had liver problems
- are pregnant or plan to become pregnant. Your doctor will decide if KATERZIA is the best treatment for you.
- are breastfeeding. Do not breastfeed while taking KATERZIA. You can stop breastfeeding or take a different medicine.

Tell your healthcare provider about all your medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Tell your doctor if you are talking simvastatin, cyclosporine, or tacrolimus. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

The most common side effect of KATERZIA is swelling (edema), which occurs in a dose-related manner. Other adverse experiences not dose-related but reported with an incidence >1.0 % are tiredness, nausea, abdominal pain, and sleepiness.

Store KATERZIA at refrigerated temperature (2°C to 8°C/36°F to 46°F). Avoid freezing and excessive heat. Protect from light.

The Important Safety Information does not include all the information needed to use KATERZIA safely and effectively. Please talk to your healthcare provider and see the complete Prescribing Information for KATERZIA.

To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449 or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

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