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%.

ADDITIONAL IMPORTANT SAFETY INFORMATION:

Contraindications:
KATERZIA is contraindicated in patients with known sensitivity to amlodipine.

Warnings and Precautions:
Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. Because of the gradual onset of action, acute hypotension is unlikely.
Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of KATERZIA, particularly in patients with severe obstructive coronary artery disease.
Because KATERZIA is extensively metabolized by the liver, and the plasma elimination half-life is 56 hours in patients with impaired hepatic function, titrate slowly when administering KATERZIA to patients with severe hepatic impairment.

Adverse Reactions: *See Full Prescribing Information for additional Adverse Reactions (6).*
The most common dose-related adverse reaction to amlodipine is edema.
Incidents of dose-related dizziness, flushing, and palpitation also have been observed.
For several reported adverse experiences that appear to be drug and dose related (edema, flushing, palpitations), there was a greater incidence in women than in men associated with amlodipine treatment.
Other adverse experiences not dose-related but reported are fatigue, nausea, abdominal pain, and somnolence.

Drug Interactions:

Impact of Other Drugs on Amlodipine
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 CYP3A inhibitors to determine the need for dose adjustment. Blood pressure should be closely monitored when amlodipine is co-administered with CYP3A inducers.

Impact of Amlodipine on Other Drugs:
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.
Amlodipine may increase the systemic exposure of cyclosporine or tacrolimus when co-administered. Frequent monitoring of trough blood levels of cyclosporine and tacrolimus is recommended and adjust the dose when appropriate.

Use in Specific Populations: *See Full Prescribing Information for Additional Information (8).*

Pregnancy
Limited data on post-marketing use of amlodipine in pregnant women are not sufficient to inform a drug-associated risk for major birth defects or miscarriages. There are risks to the mother and fetus associated with poorly controlled hypertension during pregnancy.

Lactation
Limited available data from a published clinical lactation study reports that amlodipine is present in human milk. No adverse effects of amlodipine on the breastfed infant have been observed.

Pediatric Use
Amlodipine (2.5 to 5 mg daily) is effective in lowering blood pressure in patients 6 to 17 years. The effect of amlodipine on blood pressure in patients less than 6 years of age is not known.

Geriatric Use
In general, dose selection for elderly patients should be cautious, usually starting with a lower initial dose.

Hepatic Impairment
A lower initial dose may be required for patients with hepatic insufficiency.

This Important Safety Information does not include all the information needed to use KATERZIA safely and effectively. Visit KATERZIA.com for Full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-855-379-0383, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

FDA-4