Important Safety Information

Indications and Usage

DURLAZA (aspirin) Extended-Release Capsules 162.5 mg is indicated:

- to reduce the risk of death and myocardial infarction (MI) in patients with chronic coronary artery disease, such as patients with a history of MI or unstable angina pectoris or with chronic stable angina;
- to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack.

Limitation of Use: Use immediate-release aspirin, not DURLAZA in situations where a rapid onset of action is required (such as acute treatment of myocardial infarction or before percutaneous coronary intervention).

Important Safety Information

Contraindications: DURLAZA is contraindicated in patients with a hypersensitivity to nonsteroidal anti-inflammatory drugs (NSAIDs) and in patients with the syndrome of asthma, rhinitis, and nasal polyps. DURLAZA may cause severe urticaria, angioedema, or bronchospasm.

Warnings and precautions:

- DURLAZA increases the risk of bleeding. Risk factors for bleeding include the use of other drugs that increase the risk for bleeding.
- DURLAZA may cause gastric ulceration and bleeding. Avoid DURLAZA in patients with active peptic ulcer disease.
- DURLAZA can cause fetal harm when administered to a pregnant woman, including low birth weight, increased incidence for intracranial hemorrhage in premature infants, stillbirths and neonatal death. Avoid DURLAZA in the third trimester of pregnancy.

Adverse reactions: The following adverse reactions have been reported for products containing low dose aspirin:

- Central Nervous System: Agitation, cerebral edema, coma, confusion, dizziness, headache, lethargy, seizures;
- Fluid and Electrolyte: Hyperkalemia, metabolic acidosis, respiratory alkalosis;
- Gastrointestinal: Dyspepsia, hepatic enzyme elevation, hepatitis, Reye's Syndrome;
- Renal: Interstitial nephritis, papillary necrosis, proteinuria, renal insufficiency and failure.

Drug interactions:

- Alcohol: Do not take DURLAZA 2 hours before or 1 hour after consuming alcohol.
- Dual inhibition of the renin-angiotensin system: Increased risk of renal impairment, hypotension and hyperkalemia.
- Anticoagulant and antiplatelets: Increased risk of bleeding.
- Anticonvulsants: Decreased phenytoin concentration and increased serum valproic acid levels.
- Methotrexate: Increased risk of bone marrow toxicity.
- NSAIDs: Increased risk of bleeding. Nonselective NSAIDs may interfere with the antiplatelet effect of DURLAZA.

Use in specific populations:

- Pregnancy: Avoid use during the third trimester.
- Hepatic Impairment: Avoid use in patients with severe impairment.
- Renal Impairment: Avoid use in patients with GFR <10mL/min.

Please see full Prescribing Information for DURLAZA.