Yosprala™ (aspirin/omeprazole) – New Drug Approval

- On September 14, 2016, the FDA approved Aralez Pharmaceutical's Yosprala (aspirin/omeprazole) delayed-release tablets, for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers.
    - Yosprala is not for use as the initial dose of aspirin therapy during onset of acute coronary syndrome, acute myocardial infarction (MI) or before percutaneous coronary intervention, for which immediate-release aspirin therapy is appropriate.
    - Yosprala has not been shown to reduce the risk of gastrointestinal (GI) bleeding due to aspirin.
    - Yosprala is not interchangeable with the individual components of aspirin and omeprazole.
- Yosprala is a combination product containing aspirin and omeprazole.
    - The aspirin component of Yosprala is for reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli, reducing the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris, reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris, and use in patients who have undergone revascularization procedures (Coronary Artery Bypass Graft or Percutaneous Transluminal Coronary Angioplasty) when there is a pre-existing condition for which aspirin is already indicated.
    - The omeprazole component of Yosprala is indicated for decreasing the risk of developing aspirin-associated gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers due to age (≥ 55) or documented history of gastric ulcers.
- The FDA approval of Yosprala was based on two clinical trials that compared Yosprala 325 mg/40 mg against enteric-coated aspirin 325 mg.
    - Each study achieved its individual primary endpoint with patients in the Yosprala arm experiencing significantly fewer endoscopic gastric ulcers compared to those taking enteric-coated aspirin alone.
    - In addition, significantly fewer patients treated with Yosprala discontinued therapy because of pre-specified upper GI adverse events compared to patients in the enteric-coated aspirin arm.
- Yosprala is contraindicated in patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs); pediatric patients with suspected viral infections, with or without fever, because of the risk of Reye's Syndrome; known hypersensitivity to aspirin, omeprazole, substituted benzimidazoles or to any of the excipients of Yosprala; and patients receiving rilpivirine-containing products.
- Warnings and precautions of Yosprala include coagulation abnormalities, GI adverse reactions, bleeding risk with use of alcohol, interaction with clopidogrel, interaction with ticagrelor, renal failure, presence of gastric malignancy, acute interstitial nephritis, *Clostridium difficile*-associated diarrhea, bone fracture, cutaneous and systemic lupus erythematosus, hepatic impairment, cyanocobalamin deficiency, hypomagnesemia, reduced effect of omeprazole with St. John's Wort or rifampin, interactions with diagnostic investigations for neuroendocrine tumors, interaction with methotrexate, premature closure of fetal ductus arteriosus, and abnormal laboratory tests.

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- The most common adverse events (≥ 2%) with Yosprala use were gastritis, nausea, diarrhea, gastric polyps, and non-cardiac chest pain.
- The recommended oral dose of Yosprala is one tablet daily at least 60 minutes before a meal.
- Aralez plans to launch Yosprala in early October 2016. Yosprala will be available as delayed-release tablets containing aspirin (81 mg or 325 mg) in combination with omeprazole (40 mg).