FDA Updates

Recent FDA Boxed Warnings

The FDA's MedWatch program safety labeling changes for boxed warnings are compiled quarterly for drugs and therapeutic biologics where important changes have been made to the safety information. You can search these and other label changes in the Drug Safety Labeling Changes (SLC) database, where data are available to the public in downloadable and searchable formats. Boxed warnings are ordinarily used to highlight either adverse reactions so serious in proportion to the potential benefit from the drug that it is essential that it be considered in assessing the risks and benefits of using the drug; or serious adverse reactions that can be prevented/reduced in frequency or severity by appropriate use of the drug; or FDA approved the drug with restrictions to ensure safe use because FDA concluded that the drug can be safely used only if distribution or use is restricted.

NONSTEROIDAL ANTI-INFLAMMATORY DRUGS:

Updated Warning May 2016

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.
- NSAID is contraindicated in the setting of coronary artery bypass graft surgery.

Gastrointestinal Bleeding, Ulceration, and Perforation

NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

JUXTAPID (lomitapide) capsules:

Added section to warning May 2016

Prescribe Juxtapid only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH). The safety and effectiveness of Juxtapid have not been established in patients with hypercholesterolemia who do not have HoFH.

KADCYLA (ado-trastuzumab emtansine) injection, for intravenous:

Edited and updated warning April 2016

Embryo-Fetal Toxicity: Exposure to Kadcyla during pregnancy can result in embryo-fetal harm. Advise patients of these risks and the need for effective contraception.

KYNAMRO (mipomersen sodium) solution for subcutaneous injection:

Added section to warning May 2016

Prescribe Kynamro only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH). The safety and effectiveness of Kynamro have not been established in patients with hypercholesterolemia who do not have HoFH.