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. These and other label changes are searchable 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.

IMODIUM (LOPERAMIDE HYDROCHLORIDE):

New warning December 2016

WARNING: TORSADES DE POINTES AND SUDDEN DEATH

Cases of Torsades de Pointes, cardiac arrest, and death have been reported with the use of a higher than recommended dosages of Imodium (see WARNINGS and OVERDOSAGE).

Imodium is contraindicated in pediatric patients less than 2 years of age (see CONTRANIDICATIONS).

Avoid Imodium dosages higher than recommended in adults and pediatric patients 2 years of age and older due to the risk of serious cardiac adverse reactions (see DOSAGE AND ADMINISTRATION).

AUBAGIO (TERIFLUNOMIDE) TABLETS:

Edited and updated warning December 2016

Risk of Teratogenicity

Aubagio is contraindicated for use in pregnant women and in women of reproductive potential who are not using effective contraception because of the potential for fetal harm. Teratogenicity and embryolethality occurred in animals at plasma teriflunomide exposures lower than that in humans. Exclude pregnancy before the start of treatment with Aubagio in females of reproductive potential. Advise females of reproductive potential to use effective contraception during Aubagio treatment and during an accelerated drug elimination procedure after Aubagio treatment. Stop Aubagio and use an accelerated drug elimination procedure if the patient becomes pregnant.

PROMACTA (ELTROMBOPAG) TABLETS, FOR ORAL USE AND ORAL SUSPENSION:

Edited and updated warning December 2016

Chronic Hepatitis C

Promacta may increase the risk of severe and potentially life-threatening hepatotoxicity. Monitor hepatic function and discontinue dosing as recommended.

ICLUSIG (PONATINIB HYDROCHLORIDE):

Edited and updated warning December 2016

WARNING: ARTERIAL OCCLUSION, VENOUS THROMBOEMBOLISM, HEART FAILURE, and HEPATOTOXICITY

Arterial Occlusion

Arterial occlusions have occurred in at least 35% of Iclusig-treated patients. Some patients experienced more than 1 type of event. Events observed included fatal myocardial infarction, stroke, stenosis of large arterial vessels of the brain, severe peripheral vascular disease, and the need for urgent revascularization procedures. Patients with and without cardiovascular risk factors, including patients age 50 years or younger, experienced these events. Monitor for evidence of arterial occlusion. Interrupt or stop Iclusig immediately for arterial occlusion.

Venous Thromboembolism

Venous occlusive events have occurred in 6% of Iclusig-treated patients. Monitor for evidence of venous thromboembolism. Consider dose modification or discontinuation of Iclusig in patients who develop serious venous thromboembolism.

Heart Failure

Heart failure, including fatalities, occurred in 9% of Iclusig-treated patients.