Current FDA-Related Drug Information

Summaries of Safety Labeling Changes Approved by the FDA: Boxed Warnings Highlights October - December 2016

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. Search of Drug Safety Labeling Changes (SLC) database was conducted on December 31, 2016 for date range "10/1/2016-12/31/2016", labeling section "Boxed Warning". 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. (Drug Safety Labeling Changes are available at: http://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/?source=govdelivery&utm_medium=email&utm_source=govdelivery.) 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) capsules
<i>New Imodium Boxed Warning</i>
<p>WARNING: TORSADES DE POINTES AND SUDDEN DEATH</p> <ul style="list-style-type: none"> • 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 CONTRINDICATIONS). • 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).
Iclusig (ponatinib hydrochloride)
Updated Iclusig Boxed Warning (<i>additions and/or revisions are underlined</i>)
<p>WARNING: ARTERIAL OCCLUSION, VENOUS THROMBOEMBOLISM, HEART FAILURE, and HEPATOTOXICITY</p> <p>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...</p> <p>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.</p> <p>Heart Failure: Heart failure, including fatalities, occurred in 9% of Iclusig-treated patients...</p>

Aubagio (teriflunomide) tablets
Updated Aubagio Boxed Warning (<i>additions and/or revisions are underlined</i>)
<p>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.</p>
Promacta (eltrombopag) tablets, for oral use and oral suspension
Updated Promacta Boxed Warning (<i>addition underlined</i>)
<p>CHRONIC HEPATITIS C PROMACTA may increase the risk of severe and potentially life-threatening hepatotoxicity. Monitor hepatic function and discontinue dosing as recommended.</p>
Chantix (varenicline) tablets
Removed Chantix Boxed Warning
<p>The <i>Boxed Warning</i> for serious mental health side effects has been removed from the Chantix drug label. The existing warning section in the label has been updated that describes the side effects on mood, behavior, or thinking to include the results from the clinical trial. FDA has determined the risk of serious side effects on mood, behavior, or thinking with Chantix (varenicline) is lower than previously suspected. The risk of these mental health side effects is still present, especially in those currently being treated for mental illnesses such as depression, anxiety disorders, or schizophrenia, or who have been treated for mental illnesses in the past. However, most people who had these side effects did not have serious consequences such as hospitalization. The results of the trial confirm that the benefits of stopping smoking outweigh the risks of taking Chantix. http://www.fda.gov/Drugs/DrugSafety/ucm532221.htm</p>

MedWatch-FDA's safety alerts for medical products and monthly Drug Safety Labeling Changes are available at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/default.htm>

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