



Drug Information Newsletter- February 2011

FDA Reviews Safety of Lantus

In July of 2009, the FDA issued an early safety communication of a possible link between patients using Lantus, a long-acting insulin used in Type 1 and Type 2 diabetics, and the occurrence of cancer. After analysis of four trials, the FDA concluded that the evidence presented in these studies was inconclusive due to limitations of the studies. The FDA continues to work with the manufacturer for further evaluation of risk. Until further information is available, the FDA recommends that healthcare professionals continue to follow the recommendations in the drug label when prescribing Lantus.

Multaq Linked to Two Cases of Liver Damage

Multaq (dronedarone), a drug used for the treatment of abnormal heart rhythms, has been linked to two cases of liver damage. Both cases resulted in liver transplants being performed on the affected patients. Current advice includes advising health care professionals and patients to be aware of the signs of liver damage, especially during the first 6 months of treatment. The FDA suggests monitoring for “anorexia, nausea, vomiting, fever, malaise, fatigue, right upper quadrant pain, jaundice, dark urine, or itching.” If these symptoms do present, forward the patient to a physician for further treatment.

Abnormal Heart Rhythms Associated with Anzemet Use.

Injectable Anzemet (dolasetron mesylate), which is utilized in oncology for the management of nausea has been associated with prolongation of the QT, QRS and PR intervals and torsade de pointes. As a result, the FDA has stated that this drug should no longer be used to prevent nausea and vomiting associated with cancer chemotherapy in pediatric and adult patients. A contraindication against such use is being added to the product label for the injection form of Anzemet. Anzemet **tablets** may still be used to prevent CINV because the risk of developing an abnormal heart rhythm with the oral form of this drug is less than that seen with the injection form. However, a stronger warning about this potential risk is being added to the *Warnings* and *Precautions* sections of the Anzemet tablet label. Please refer to the package insert for complete prescribing information, which includes direction on which populations of patients Anzemet use should be avoided.

Tessalon (Benzonatate) Capsules Pose Risk to Pediatric Population

With cold season quickly approaching us, we are now seeing increased prescribing of Tessalon capsules to calm chronic coughs. Tessalon, approved for use in patients older than 10 years of age, has been linked to accidental ingestion and overdose, and in some cases death in children younger than 10 years of age. The drug is often described as having a “candy-like” appearance, therefore it may be attractive to children. Signs of benzonatate overdose can appear in approximately 15 to 20 minutes of ingestion and include: restlessness, tremors, convulsions, coma, and cardiac arrest. Please counsel all patients taking Tessalon at home to store it in a safe location with child proof lids. If accidental ingestion occurs, the poison control center may be called at 1-800-222-1222.

Meridia Voluntarily Withdrawn By Manufacturer

Meridia (sibutramine), a weight loss drug approved in 1997, was voluntarily withdrawn from the market in early November. The Sibutramine Cardiovascular OUTcomes (SCOUT) trial demonstrated a 16% increase in risk of major adverse cardiovascular events when compared to placebo. The FDA currently recommends that all providers should discontinue prescribing Meridia and consider use of alternative weight loss options.

All Products Containing Propoxyphene Withdrawn from Market

Products containing propoxyphene commonly known as Darvocet or Darvon were found to cause “serious toxicity to the heart” and the manufacturer withdrew their product at the request of the FDA. When used at therapeutic doses, propoxyphene changed electrical conduction in the heart, which could result in serious abnormal heart rhythms and death. Patients who are still in possession of propoxyphene containing products should be instructed to discard their remaining supply as follows: 1. mix the tablets or capsule with coffee grounds, kitty litter or another undesirable substance. 2. Seal the mixture in a plastic bag so that no drug may leak out and discard into the trash. 3. Please take note that propoxyphene should not be flushed into the water system.

Citations

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