

NEW INDICATION

Rituxan Approved for New Indication

The FDA has approved Genentech's and Biogen Idec's *Rituxan* (rituximab) for use in the first-line treatment of patients with diffuse large B-cell, CD20-positive, non-Hodgkin lymphoma, in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) or other anthracycline-based chemotherapy regimens. *Rituxan* has previously been approved as a single agent for use in relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin lymphoma. (http://www.gene.com/gene/products/information/oncology/rituxan/rituxan_pi.pdf)

FDA STATUS

New-Onset Type 1 Diabetes Treatment Granted Orphan Drug Status

The FDA has granted orphan drug status to TolerRx's TRX4 for the treatment of new-onset type 1 diabetes mellitus. TRX4, a monoclonal antibody, has been shown to preserve the function of insulin-producing beta cells in the pancreas and reduce the amount of required exogenous insulin for at least 18 months.

Black Box Warning Added for Nimodipine

Bayer Healthcare is notifying health care professionals of changes to the prescribing information for nimodipine (*Nimotop*), indicated for oral administration to improve neurological outcome after subarachnoid hemorrhage. These changes include a Black Box Warning alerting prescribers about medication administration errors. The administration of nimodipine parenterally can lead to serious adverse events, including cardiac arrest, cardiovascular collapse, hypotension, bradycardia, and even death. The notification emphasizes that nimodipine must not be administered intravenously or by any other parenteral route.

Gaucher Disease Treatment Granted Orphan Drug Status

The FDA has granted orphan drug status to Amicus Therapeutics' AT2101, an experimental oral therapy for the treatment of Gaucher disease. The condition is a lysosomal storage disorder resulting from an enzyme deficiency that can cause damage to the liver, spleen, bone marrow, and, in some cases, the central nervous system. The therapy is expected to enter clinical studies in the first half of this year.

FDA Tentatively Approves Adenosine Injection

The FDA has granted tentative approval for Teva Pharmaceutical Industries Ltd.'s ANDA for adenosine 3 mg/mL injection. Once approved, the medication will be the generic equivalent of *Adenoscan* injection by Astellas Pharma, indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately.

NEWS SCANS

FDA Advisory Committee Recommends Stronger Labeling for ADHD Drugs

The FDA's Drug Safety and Risk Management Advisory Committee voted 15 to 0 that Medication Guides be available for attention deficit/hyperactivity drugs (ADHD) warning of possible cardiovascular risks with this class of stimulant agents. The committee's votes were split 8 to 7 on recommending that a Black Box Warning be added to the labeling of stimulants used to treat ADHD. The FDA conducted an analysis of adverse event rates for the following ADHD drugs: amphetamine/dextroamphetamine (*Adderall*, *Adderall XR*, *Dextrostat*, *Dexedrine*, and *Dexedrine Spansules*), methylphenidate (*Concerta*, *Ritalin*, *Ritalin SR*, *Ritalin LA*, *Methylin*, *Methylin ER*, *Metadate ER*, and *Metadate CD*), methamphetamine (*Desoxyn*), and dexamethylphenidate (*Focalin*). Results of the study found higher rates of serious cardiovascular events and sudden death for amphetamine than methylphenidate in both children and adults, with more events observed in adults rather than children.

Public Health Advisory Issued for Benzocaine Spray

The FDA has issued a public health advisory regarding benzocaine spray used for locally numbing mouth and throat mucous membranes for minor surgical procedures or for the insertion of a tube into the stomach or airways. However, use of benzocaine spray has occasionally been associated with methemoglobinemia. The condition has also resulted from medication errors caused by incorrect use, such as longer duration or more frequent sprays than recommended. The Veterans Health Administration has decided to stop using benzocaine sprays for the cited purposes, believing that other topical anesthetics are less likely to cause methemoglobinemia and because the minor surgical procedures themselves might cause similar signs, suggesting that methemoglobinemia may occur but be unrecognized in some cases. The FDA noted that this advisory applies only to benzocaine sprays used in the mouth and throat, not other benzocaine products or benzocaine sprays applied to exterior skin. (<http://www.fda.gov/cder/drug/advisory/benzocaine.htm>)

FDA Requests Recall of *Balanced Salt Solution* Irrigant

The FDA is requesting a recall of all brands and sizes of *Balanced Salt Solution* (BSS) manufactured by Cytosol Laboratories, including *AMO Endosol*, *Cytosol Ophthalmics*, and *Akorn*. BSS is used by health professionals to irrigate a patient's eyes, ears, nose, and/or throat during a variety of surgical procedures. The recall was requested following the discovery of elevated endotoxin levels in some product lots, which can cause a wide variety of serious reactions, including fever, shock, and changes in blood pressure and other circulatory functions. The agency has received reports of a serious and potentially

irreversible eye injury, Toxic Anterior Segment Syndrome, which occurs when a contaminant such as endotoxin enters the anterior segment of the eye during surgery and causes an inflammatory reaction. The FDA has received complaints related to injuries in over 300 patients who were given *BSS* manufactured by Cytosol. The FDA is requesting that Cytosol take immediate action to retrieve all product inventories. Hospitals, physicians, and consumers are being asked to immediately stop the use of any of these products, quarantine any remaining product, and destroy the product if no return instructions are received from Cytosol. An estimated 1 million units of *BSS* products were distributed between December 2003 and December 2005.



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