PRODUCT UPDATE

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Mitoxantrone Receives Final Approval

Mitoxantrone hydrochloride (Mayne Pharma, Paramus, NJ), the generic equivalent of Novantrone® injection (Serono, Inc., Rockland, MA), has been approved by the U.S. Food and Drug Administration (FDA) after the December 2004 submission of an abbreviated new drug application. The drug has been determined safe and effective with its present labeling. The patent held by Serono has expired, and Mayne Pharma now markets mitoxantrone as a generic equivalent.

Oral Cancer Drug Is Approved for Testing

Reata Pharmaceuticals, Inc., in Dallas, TX, has received clearance from the FDA to begin testing on RTA 402, an oral agent that has shown excellent anticancer activity and has been noted to protect normal tissue from toxic side effects.

RTA 402 (also known as CDDO-Me) is a targeted therapy that takes advantage of the physiologic differences between cancer cells and normal cells by modulating the oxidative stress pathway. By doing this, the drug is toxic to cancer cells but activates an anti-inflammatory and protective antioxidant response in normal cells. Phase I clinical trials are under way in patients with lymphoma, myeloma, and solid tumors at the University of Texas M.D. Anderson Cancer Center in Houston. For more information, visit www.reatapharma.com/rta401_2.asp.

Lymphoma Treatment Receives Labeling Change

Ligand Pharmaceuticals in San Diego, CA, and the FDA notified healthcare professionals of changes to the warnings section of the prescribing information for Ontak® (denileukin difitox), indicated for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma. Loss of visual acuity, usually with loss of color vision, has been reported following administration of Ontak. Although some of the affected patients recovered, most patients reported persistent visual impairment. Cutaneous T-cell lymphoma is a rare, slow-growing form of non-Hodgkin lymphoma.

Anesthetic Spray May Cause Oxygenation Problems

The FDA issued a public health advisory to notify healthcare professionals and patients about adverse events, including methemoglobinemia, associated with the use of benzocaine sprays used in the mouth and throat. The FDA is aware of the reported adverse events and is reviewing all available safety data, but at this time, it is not planning to remove the drugs from the market.

Methemoglobinemia is a condition where too much of the hemoglobin in red blood cells becomes unable to bind to and carry oxygen. Although treatment is available, until the condition is reversed, oxygen is not effectively delivered throughout a patient's body. Patients with methemoglobinemia can experience effects ranging from headache to cyanosis that can be life threatening in the most severe cases. Patients with underlying breathing problems such as asthma or emphysema, patients with heart disease, and those who smoke may be more susceptible to the problems from methemoglobinemia and may experience negative effects from the condition earlier than healthy individuals.

Docetaxel Is Approved to Treat Stomach Cancer

Docetaxel (Taxotere® injection, Sanofi-Aventis, Bridgewater, NJ) was approved by the FDA for use in combination with cisplatin and fluorouracil for the treatment of patients with advanced gastric carcinoma, including carcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease. Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions, and contraindications, is available at www.fda.gov/cder/foi/label/2006/020449s035lbl.pdf.

New Form of Immunoglobulin Is Injected Subcutaneously

The FDA has approved a new immunoglobulin product that is injected subcutaneously. The product, called Vivaglobin®, is made by the German company ZLB Behring in King of Prussia, PA. Until now, immunoglobulin products have been administered either via IV or intramuscularly.

The approval of Vivaglobin provides a new way to administer antibody replacement therapy to patients with primary immune deficiency disease. This may be especially beneficial in patients who do not easily tolerate IV immunoglobulin administration because of poor venous access or serious side effects. Because Vivaglobin is injected on a weekly basis using an infusion pump, patients can self-administer the product at home. For more information, visit www.vivaglobin.com.

Hydroxyurea Label Change Includes Additional Warnings and Adverse Reactions

Bristol-Myers Squibb in New York, NY, has revised the warnings and adverse reactions sections of hydroxyurea's prescribing information to describe cutaneous vasculitic toxicities, including vasculitic ulcerations and gangrene, in patients with myeloproliferative disorders. The conditions most often are reported in patients with a history of or currently receiving interferon therapy. Label changes for geriatric use were as follows.

- Older adults may be more sensitive to the effects of hydroxyurea and may require a lower dose regimen.
- This drug is known to be excreted by the kidneys, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because older adults are more likely to have decreased renal function, care should be taken in dose selection and monitoring renal function may be useful.

Cetuximab Helps Treat Head and Neck Cancer

The FDA has granted approval to cetuximab (Erbitux®, ImClone Systems, Inc., New York, NY) for use in combination with radiation therapy for the treatment of locally or regionally advanced squamous cell carcinoma of the head and neck or as a single agent for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck for whom prior platinum-based therapy has failed.

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