

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/2006/020449s0351bl.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 (Erbix®), 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.

Mention of specific products and opinions related to those products do not indicate or imply endorsement by the Oncology Nursing Forum or the Oncology Nursing Society.

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NEW PRODUCTS

Screening Test Is Highly Accurate for Breast Cancer

BioCurex Inc. in Richmond, Canada, has announced that its RECAF receptor blood test for cancer is highly accurate in detecting early-stage breast cancer. RECAF is a tumor marker that appears on the surface and inside the cytoplasm of most cancers and leukemias. A blinded study showed that the RECAF test was able to identify breast cancer cells accurately and with high specificity. The test has the potential to detect cancer cells early, aiding in timely detection, which is known to increase the odds for favorable outcomes after treatment of disease. The specificity of a test indicates the number of times a test will give false-positive or -negative results, and sensitivity indicates how often a test will detect cancer. Sensitivity and specificity are determined by comparing the screening results with those of a definitive diagnostic test. The test has the potential to become a screening tool for many cancers, based on the studies done by BioCurex to date, and may lead to better outcomes because of earlier diagnosis.

New Imaging Device Provides Fast Results



Imaging3™ Inc. in Burbank, CA, has developed a breakthrough imaging device called the Dominion™, which captures a three-dimensional image of nearly any part of the human body in real time, resulting in immediate pictures. Real-time technology provides practitioners with the ability to perform invasive procedures with instant imaging available. Dominion is a portable machine that uses a standard wall outlet; it uses low-output x-ray radiation with photofluoroscopy. Unlike computed tomography or magnetic resonance imaging technologies, which may take time to produce usable images, Dominion will provide usable images immediately. For more information about Imaging3 and Dominion, visit www.imaging3.com.

Device Makes Collecting Specimens Easier



Tru-Catch® (Cherie Enterprises LLC, Nokesville, VA) is a new, unique apparatus for obtaining urine or stool samples. Especially convenient for women, the reusable, washable two-piece unit is designed for use on a commode. The

Tru-Catch bowl, with or without a sterile cup, is placed on the commode frame, and it can be moved forward to catch a midstream urine specimen. The Tru-Catch bowl can be placed horizontally or vertically along the commode for easier positioning. For more information, visit www.tru-catch.com.

Body-Length Water Bottle Provides Comfort and Symptom Relief



The World's Longest Water Bottle (World's Longest Water Bottle LLC, Hasbrouk Heights, NJ) is a body-length water bottle for use with warm or cold water. This unique water bottle can be used to alleviate symptoms from injuries, joint pain, or cramps or to cool off from hot flashes. The water bottle is 4 feet long and 11 inches wide and, when empty, folds in to an 11-inch square. The bottle has unique air chambers that make it lightweight when filled. For more information, visit www.longhotwater.com.

Test Helps Diagnose Blood Cancer

Quest Diagnostics Inc. in Lyndhurst, NJ, has introduced a unique new blood test, called Leumeta™, that will help diagnose leukemia and lymphoma. Leumeta provides the same diagnostic information as a bone marrow biopsy but is much less invasive. Quest Diagnostics developed Leumeta to identify and analyze genetic components of leukemia and lymphoma tumors using blood plasma instead of bone marrow. The assays are designed to measure tumor load, or the amount of cancer in a patient; detect certain blood cancer markers; and assist the physician in monitoring the impact of treatment. They are the first diagnostic assays available to doctors that directly measure tumor load, identify markers in blood plasma, and can allow for personalization of treatment regimens based on individual genetic specifics. For more information, visit www.questdiagnostics.com.

New Product Alleviates Dry Mouth



Laclede Inc. in Rancho Dominguez, CA, has introduced Oral Balance® Dry Mouth Moisturizing liquid. This new, long-lasting oral lubricant features Biotene's unique salivary antibacterial enzyme system to quickly and effectively soothe and moisten dry mouth while protecting dry oral tissue. The liquid formulation makes application easy and convenient. Oral Balance contains five moisturizers, eight amino acids, and milk protein to recreate the natural protection

found in the mouth. For more information, call 800-922-5856 or visit www.biotene.com.

RECALL ALERTS

Insulin Syringe Is Recalled

Boca Medical Products, Inc., of Coral Springs, FL, is initiating a recall of 3,984 boxes of Ultilet® insulin syringe 30 g, 0.5 cc product with the lot number 5GEXI displayed on the inner case. The product is being recalled because of possible bacterial presence of *Bacillus cereus* and *Staphylococcus intermedius*, which may present a risk of local infection after soft tissue injection with a contaminated syringe as well as a risk of introducing a contaminating organism into a previously sterile vial. The introduced contamination may degrade the insulin, which could lead to problems maintaining insulin levels. Boca Medical is continuing to evaluate possible risks. For questions, call Boca Medical at 800-354-8460.

Antibiotic Is Recalled

Hanford Pharmaceuticals in Syracuse, NY, and the FDA notified healthcare professionals about the recall of four lots (379,975 vials) of cefazolin for injection USP, 1 g/10 ml vials, an antibiotic used in hospital environments to treat skin and skin structure, respiratory, and other infections. The product was distributed by Sandoz, Inc., of Broomfield, CO, and Watson Pharmaceuticals, Inc., of Corona, CA. Certain lots of the active ingredient used to manufacture the product have contained microbial contamination (*Bacillus pumilus*, *Staphylococcus hominis*, *Propionibacterium acnes*, or *Micrococcus luteus*), which may pose a serious or life-threatening risk for some patients. Healthcare providers should stop using the affected lots immediately.

NOTEWORTHY

Web Site Provides Products and Information

One in Seven™ (San Clemente, CA) recognizes that one of every seven women will be diagnosed with breast cancer. This is the message of www.oneinsevenwomen.org's Mission-Driven Merchandise™, which supports the Orange County, CA, affiliate of the Susan G. Komen Breast Cancer Foundation. The Web site features merchandise geared to educating and promoting breast cancer awareness. The company contributes 50% of the net profits from the sale of the products to the fight against breast cancer.