PRODUCT UPDATE

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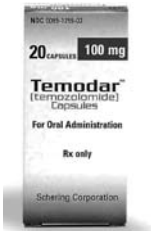
Generic Available for Antinausea Drug

Teva Pharmaceuticals has unveiled granisetron hydrochloride tablets, bioequivalent to Kytril® (Roche Laboratories, Inc.).

The U.S. Food and Drug Administration (FDA) rates all generic drugs AA or AB, with AB drugs determined to be bioequivalent to the brand name original through human bioavailability study and AA drugs considered inherently unlikely to have bioavailability issues. Granisetron hydrochloride tablets have been rated AB and are available in 1 mg tablets.

Glioblastoma Treatment Shows Promise



According to Swiss researchers, more patients with glioblastoma are living longer when the oral alkylating agent temozolomide (Temodar®, Schering-Plough Corp.) is combined with radiation therapy. According to the researchers, patients' four-year survival rates were four times higher than patients treated with radiation alone, with a rate higher still among patients with good performance status or favorable genetics. Temozolomide was granted accelerated approval by the FDA in 1999 for anaplastic astrocytoma in relapse. Approved in 2005 for glioblastoma after European and Canadian researchers showed that the drug significantly improved short-term survival, long-term results from the randomized trial of temozolomide and radiation now show a clear benefit for the combined therapy at two, three, and four years.

NEW PRODUCTS

First Aid Kit Talks to Users

The Intelligent First Aid™ (DLH, Inc.) talking kit is a revolutionary first aid tool that includes individually labeled, color-coded injury packs that supply the user with easy-to-follow instructions for managing a specific injury. The audio module in each injury pack delivers step-by-step instructions, pausing and repeating when necessary to provide guidance. Each kit includes nine injury-specific packs: breathing, bleeding, shock, head and spine, bone, eye, burns, bites and stings, and basics, and comes complete with easy-to-follow, color-coded instruction cards and supplies. Intelligent First Aid kits also allow companies to meet Occupational Safety and Health Administration standards for providing on-site care in the workplace. For more information, visit http://www.intelligentfirstaid.com/catalog/index.php/cPath/5_6.

Ginger Root Relieves Pain

ZingiberRX™ (HealthSonix, Inc.) is a natural product made from ginger that is bringing relief to people suffering from aches and pain related to arthritis, sore muscles, and injured or inflamed tendons and ligaments. ZingiberRx contains the essential oil and powder from the rhizome of the zingiber cassumunar plant. HealthSonix uses a distillation process to extract oil from the rhizome and formulate it as a fast-absorbing, deep-penetrating topical cream. Unlike most over-the-counter creams, ZingiberRx is not a counter-irritant; it does not create a hot sensation like capsaicin or a cooling effect like menthol. For more information, visit www.healthsonix.com or call +1-877-622-2121 (North America) or +1-905-212-7711 (international).

Through-Wave Ultrasound Unveiled

Advanced Imaging Technologies has introduced ARIA Breast Imaging System (BIS), a real-time, through-wave ultrasound imaging system that uses the diffractive properties of sound combined with holography to create highly detailed three-dimensional images of breast tissue. The system also is equipped for image-guided biopsy.

ARIA BIS has been clinically proven to provide quality views of breast tissue, particularly dense tissue, and deliver comprehensive data for enhanced diagnostic decision making. ARIA BIS is automated with whole-breast presentation capabilities, and provides high spatial and contrast resolution. In addition, the system allows for retrieval of prior comparative studies for quick comparison. ARIA BIS is FDA approved for breast imaging and image-guided breast biopsy. For more information, visit www.aitimaging.com.

Radiation Therapy Educational Resources Available

The National Cancer Institute announced the availability of easy-to-use radiation therapy educational resources that include 11 fact sheets (in English and Spanish) and various booklets for patients.

The resources provide straightforward information to help patients understand how radiation therapy works and how to best manage side effects. Patient-centered publications encourage individuals to fully participate in their care by providing personalized tips and answering key questions.

For more information, call the National Cancer Institute at +1-800-422-6237, or visit www.cancer.gov/publications or www.cancer.gov/cancertopics/wtk/index.

Recombinant Clotting Solution Wins FDA Approval

The FDA has approved Recothrom™ (ZymoGenetics, Inc.), a clotting solution derived from ovarian cells harvested from hamsters to help control bleeding during surgery. Recothrom is the first clotting solution manufactured using recombinant DNA technology. The hamster cells were genetically modified to produce human thrombin.

In a clinical trial of surgical patients (N = 411), Recothrom controlled bleeding within 10 minutes when used topically. Recothrom also demonstrated noninferiority to an approved topical thrombin derived from cattle plasma. The hamster cells are free from known infectious agents and undergo an additional viral inactivation process.

Drug-Resistant *Staphylococcus Aureus* Test Gains Clearance

The FDA has cleared for marketing GeneOhm StaphSR Assay (Beckton, Dickinson, and Co.), the first rapid blood test for the drug-resistant bacterium known as methicillin-resistant *Staphylococcus aureus* (MRSA), which can cause potentially deadly infections. Methicillin is an antibiotic that successfully treated infections from the *S. aureus* bacterium. However, over the years, the bacterium mutated and spawned MRSA, a strain resistant to methicillin with a higher rate of fatalities. The GeneOhm StaphSR Assay uses molecular methods to identify whether a blood sample has genetic material from MRSA or a more common and less dangerous bacterium that can still be treated with methicillin. For more information, visit www.bd.com/geneohm/english/products/idi_mrsa.asp.

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RECALLS AND ALERTS

Fatal Errors Associated With Labeling

The FDA has notified healthcare professionals and patients about important safety information concerning cases where children and adults have died when they were mistakenly given edetate disodium instead of edetate calcium disodium, or when edetate disodium was used for chelation therapies and other uses that are not approved by the FDA. Edetate disodium was approved as an emergency treatment for certain patients with hypercalcemia (very high levels of calcium in the blood) or certain patients with heart rhythm issues as a result of very high amounts of digitalis in the blood. Edetate calcium disodium was approved to reduce dangerously high lead levels in the blood (severe lead poisoning). The two drugs have very similar names and are commonly referred to as EDTA. As a result, the products are easily mistaken for each other when prescribing, dispensing, and administering. Edetate disodium and edetate calcium disodium work by binding heavy metals or minerals in the body, allowing them to be passed out of the body through the urine. The FDA also recommended that

- Hospitals that determine they have no need to stock edetate disodium should remove the drug from their pharmacy supplies.
- Edetate disodium and edetate calcium disodium should not be used to remove heavy metals and toxins from the body, to treat coronary artery disease, or for other uses not described in the product labeling.
- Physicians and other healthcare providers should use the full product name instead of the EDTA abbreviation.
- The prescribing order should include the product's indicated use.

For the complete 2008 MedWatch Safety Summary, including a link to the FDA Public Health Advisory, visit www.fda.gov/medwatch/safety/2008/safety08.htm#Edetate.

Fatal Skin Reactions Related to Provigil® Use

Cephalon, Inc. has notified healthcare professionals about new safety information for Provigil® (modafinil), a drug used to reduce excessive sleepiness in adult patients with narcolepsy and other sleep disorders. The revised labeling warns that Provigil can cause life-threatening skin reactions, including Stevens-Johnson Syndrome. Although benign rashes also can occur with this drug, Cephalon says that it is not possible to reliably predict which rashes will be serious. Because of this, Provigil should be stopped at the first sign of a rash, unless the rash clearly is not related to the drug. The labeling also warns that Provigil can cause other serious hypersensitivity reactions. If a multiple-organ hypersensitivity reaction is suspected, the drug should be discontinued. Patients should be told to stop taking the drug if they develop signs or symptoms suggesting angioedema or anaphylaxis. Provigil also can cause psychiatric symptoms, including anxiety, mania, hallucinations, and suicidal thoughts. The company advises caution when the drug is given to patients with a history of psychosis, depression, or mania. If psychiatric symptoms develop, discontinue drug use. For the FDA MedWatch Safety Alert, visit www.fda.gov/medwatch/safety/2007/safety07.htm#Provigil.

Bisphosphonates Linked to Bone Pain

The FDA has informed healthcare professionals and patients of the possibility of severe and sometimes incapacitating bone, joint, or muscle pain in patients taking bisphosphonates. Although severe musculoskeletal pain is included in the prescribing information for all bisphosphonates, the association between bisphosphonates and severe musculoskeletal pain may be overlooked by healthcare professionals, causing a delay in diagnosis, prolonging pain or impairment, and necessitating analgesic use. Severe musculoskeletal pain may occur days, months, or years after patients start taking bisphosphonates. Some patients have reported complete relief of symptoms after discontinuing drug use, whereas others have reported slow or incomplete resolution. The risk factors for and incidence of severe musculoskeletal pain associated with bisphosphonates are unknown. For the MedWatch Safety Summary, including a link to the FDA drug information page, visit www.fda.gov/medwatch/safety/2008/safety08.htm#Bisphosphonates.

NOTEWORTHY

Test Developed for Early Detection, Staging, and Monitoring of Melanoma

DermTech, Inc., a biotechnology company developing molecular diagnostics for the early detection of melanoma and other diseases, has been issued a patent claiming the use of DermTech's tape-stripping technology to detect, determine the stage of, and monitor melanoma.

Specifically, adhesive tape is placed over a lesion suspected for melanoma and removed to harvest the top layer of skin cells. RNA is extracted from the cells and analyzed to determine the level of a key melanoma marker, interleukin-2 receptor 1. A decrease in interleukin-2 receptor 1 is indicative of early-stage melanoma.

The patent also claims the use of evaluating additional biomarkers based on differences in gene expression, such that a change in messenger RNA is indicative of late-stage melanoma. The ability to detect, stage, and monitor disease is critical for improving clinical outcomes.

FDA Approves Platelet Bacteria Test

The FDA cleared the Platelet Pan Genera Detection Test System (Verax Biomedical, Inc.) for marketing, the first rapid test to detect bacterial contamination in blood platelets before transfusion. Bacterial contamination of platelets is the leading infectious cause of patient deaths after transfusions. To reduce the risk, blood centers typically culture samples of the platelets one day after donation, and then read the cultures within another day to determine whether the units are contaminated. In some cases, however, the number of bacteria present at the time of the culture are so low that they cannot be detected. Using the new test, a sample can be prepared, processed, and read in 30 minutes so the platelets can be retested closer to the time of use. That way, if bacteria are present, they will have multiplied and be easier to detect, providing additional assurance that the platelets are free from contamination. For more information, visit www.fda.gov/bbs/topics/NEWS/2007/NEW01702.html.

Support Organization Provides Cultural Breast Cancer Booklets

Living Beyond Breast Cancer (LBBC) is an education and support organization dedicated to empowering all women affected by breast cancer to live as long as possible with the best quality of life. Programs include a quarterly educational newsletter, a Web site (www.lbbc.org), conferences and teleconferences, a peer support survivors' helpline (+1-888-753-5222), community outreach to medically underserved communities, a young survivors network, and a library and resource center.

LBBC has produced booklets that focus on Latino and African American women who are breast cancer survivors and their loved ones. Both publications can be accessed at http://lbbc.org/programs-consumer.asp.

LBBC also offers educational workshops as an effective tool for healthcare professionals to use when talking to Latino women at risk for or diagnosed with breast cancer. The training includes discussion of the resource's philosophy, themes, and psychosocial nature; identification of the resource's characteristics that make it culturally relevant; and an explanation of how to best use the resource in individual counseling or group education settings.

For more information, contact Eloesa McSorley, education and outreach coordinator, at Living Beyond Breast Cancer, 10 East Athens Avenue, Suite 204, Ardmore, PA 19003 USA; call +1-610-645-4567; or e-mail eloesa@lbbc.org.