PRODUCT UPDATE

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NEW PRODUCTS

Molecular Test Has Been Approved for Node-Positive Cancer

The U.S. Food and Drug Administration (FDA) approval of GeneSearch™ Breast Lymph Node (BLN) Assay (Veridex) marks the first molecularly based technology to determine whether the disease is node-positive while the patient is still in the operating room.

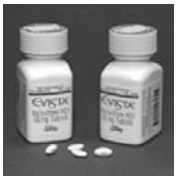
The sentinel node commonly is removed for examination during lumpectomy or mastectomy. In some cases, the node is immediately examined and additional nodes are removed if cancer cells are found. That initial examination is followed by more complete pathology that typically takes one to two days.

For some women, cancer cells are not discovered until the later examination and additional surgery may be needed.

In a clinical trial, the GeneSearch BLN Assay showed strong agreement with results from extensive pathology of the nodes of 416 patients. The test accurately predicted almost 88% of the time that breast cancer had spread in women with metastasis. Patients without metastasis were identified accurately 94% of the time. For more information on the GeneSearch BLN Assay, visit www.veridex.com.

PHARMACY CORNER

Tablets Curb Breast Cancer Risk



The (FDA) approved raloxifene hydrochloride tablets (Evista®, Eli Lilly and Company) to reduce the risk of invasive breast cancer in postmenopausal women with osteoporosis and in postmenopausal women at high risk for invasive breast cancer. Evista, an oral tablet, is a selective estrogen receptor modulator and should not be used by women with a high risk for blood clots. For more information on Evista, visit www.evista.com.

New Dosage Is Available

Sanofi-aventis U.S. launched a new 200 mg single-use vial of its chemotherapy treatment Eloxatin® (oxaliplatin injection) for patients who have adjuvant stage III colon cancer and advanced colorectal cancer. The single-use vial offers convenience, efficiency, and safety during preparation. Eloxatin previously had been available in 50 mg and 100 mg single-use vials. The 200 mg vial is available for order by cancer treatment clinics and hospitals nationwide. For more information, visit www.eloxatin.com.

Drug Targets Breast Cancer

The FDA has approved ixabepilone for injection Ixempra™ (Bristol-Myers Squibb) for the following two indications

- In combination with capecitabine for treatment of patients with metastatic or locally advanced breast cancer resistant to treatment with an anthracycline and a taxane
- Patients with cancer that are taxane resistant and for whom further anthracycline therapy is contraindicated.

Ixempra also is indicated as monotherapy for the treatment of metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine.

Ixempra is a microtubule inhibitor in the epothilone class of antineoplastic agents. Dose reduction is required in patients with elevated aspartate aminotransferase, alanine aminotransferase, or bilirubin levels. Peripheral neuropathy, myelosuppression, and nausea and vomiting are the most common side effects seen after IV Ixempra use. For more information on this drug and to read the full prescribing information, visit www.ixempra.com.

New Drug Fights Alzheimer Disease

The FDA has approved a rivastigmine transdermal patch for mild to moderate Alzheimer disease. The Exelon Patch® (Novartis) is the first transdermal system approved to treat Alzheimer disease. The patch also has been approved for mild to moderate Parkinson disease dementia. Rivastigmine oral formulations already were approved for the Alzheimer indication. In adults, the patch has an initial dose of 4.6 mg, with a gradual increase to a 9.5 mg patch applied daily.

Transdermal patches should be applied immediately after being removed from their outer packaging and should never be cut into smaller pieces. The Exelon Patch should be removed after 24 hours and a new patch should be applied. Application sites should be rotated. Make sure all transdermal patches and medications are disposed of properly and out of reach of children and pets. The most common side effects reported in a trial of Exelon Patch were gastrointestinal symptoms, such as nausea and vomiting, that are typical of all cholinesterase inhibitors. For more information on the Exelon patch, visit www.exelon.com.

Generic Toporol® Is Now Available

KV Pharmaceutical has begun shipment of its 100 mg and 200 mg strengths of metoprolol succinate extended-release tablets, a generic form of Toporol® XL (AstraZeneca). A generic drug is manufactured and distributed without patent protection and must contain the same active ingredients as the original formulation. In most cases, a generic drug is considered bioequivalent to the brand name with respect to pharmacokinetic and pharmacodynamic properties. Generic products are not available until the patent protections afforded to the original developer expire. When generic products become available, the market competition often leads to substantially lower prices for both the brand name and generic. Generic drugs' appearance on the market varies. Drug patents give 20 years of protection, but the applications are submitted prior to clinical trials, so the effective life of a patent tends to be 7–12 years. For more information, visit www.kvpharma.com.

NEW SOFTWARE

Healthcare Program Is Unveiled

SmartDraw.com has launched a software tool to help healthcare professionals create patient handouts, anatomic diagrams, healthcare facility floor plans, case management time lines, schedules, flowcharts, and organizational charts.

The SmartDraw Healthcare Edition 2008 is graphics software for use by hospitals, physicians, nurses, healthcare educators, students, and healthcare administrators. SmartDraw contains thousands of healthcare images and graphics, including more than 3,000 medical images. SmartDraw allows the user to create diagrams, graphics, and charts. For more information on SmartDraw, visit www.smartdraw.com.

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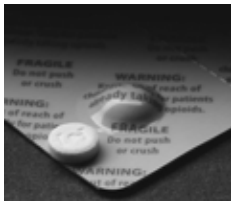
Digital Object Identifier: 10.1188/08.ONF.137-138

RECALLS AND ALERTS

World Health Organization Issues Vincristine Alert

The World Health Organization (WHO) is alerting healthcare professionals that, despite repeated warnings, patient deaths continue to occur when the chemotherapy drug vincristine, which is intended for IV use, is given intrathecally. Patients receiving improper administration of the drug have died slowly and painfully. WHO recommends developing a lock-and-key design for needles, syringes, catheters, tubing, and bags that prevents medications intended for IV use from being administered intrathecally and vice versa. In the absence of a lock-and-key system, WHO recommends diluting IV vincristine and delivering it only in minibags, rather than in syringes. When diluting vincristine, use only normal saline or glucose in water because vincristine is pH-sensitive. For more information on the vincristine safety issue, visit www.accessdata.fda.gov.

Warning Issued in Narcotic Substitution



The FDA has issued a public health advisory and a healthcare professional sheet to alert healthcare professionals and consumers regarding concerns over the use of Fentora® (fentanyl buccal, Cephalon) tablets after recent reports of adverse events including deaths. The deaths were the result of improper patient selection, dosing, or product substitution.

Fentora is indicated only for the management of breakthrough pain in patients with cancer who already are receiving and are tolerant to opioid therapy for underlying persistent pain. Patients considered opioid tolerant are those who take at least 60 mg of oral morphine per day, at least 25 mcg of transdermal fentanyl per hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily, or an equianalgesic dose of another opioid for one week or longer. The FDA warns physicians and other healthcare professionals that the Fentora product labeling must be followed during administration.

According to the FDA, Fentora is dangerous for use with short-term pain, such as headaches or migraines. Fentora should not be used in patients who are not opioid tolerant. In addition, the FDA is concerned about the improper substitution of Fentora for other pain medicines. Fentora is different from other fentanyl products and cannot be substituted for Actiq® (Cephalon).

To read the complete MedWatch 2007 Safety Summary, which includes a link to and more information about the FDA public health advisory and healthcare professional sheet, visit www.fda.gov/medwatch/safety/2007.

Antibiotic Usage Revised

Roche, Inc., and the FDA informed healthcare professionals of revisions to the contraindications, warnings, precautions, adverse reactions, dosage, and administration sections of the prescribing information for Rocephin® for injection. The revisions are based on new information that describes the potential risk associated with concomitant use of Rocephin with calcium or calcium-containing solutions or products. Cases of fatal reactions with calcium-ceftriaxone precipitates in the lungs and kidneys, in term and premature neonates, have been reported. Hyperbilirubinemic neonates, particularly prematures, should not be treated with Rocephin. The drug must not be mixed or administered simultaneously with calcium-containing solutions or products, even via different infusion lines. Additionally, calcium-containing solutions or products must not be administered within 48 hours of the last administration of ceftriaxone. To read the complete MedWatch 2007 Safety Summary, which includes a link to the manufacturer's healthcare letter, visit www.fda.gov/MedWatch/safety/2007/Rocephin_HCP_august2007.pdf.

Saline Flush Is Recalled

B. Braun Medical Inc. issued a recall of normal saline flush syringes with lot numbers ending in SFR because of an increase in customer complaints of particulate matter in the saline. Introduction of particular matter into the bloodstream may result in phlebitis or damage to vital organs, such as the brain, kidneys, heart, and lungs. To date, B. Braun has received no reports of patient injury associated with this issue.

This voluntary recall affects normal saline 3 ml in 12 ml syringes designated by product code 513584, and normal saline 10 ml in 12 ml syringes designated by product code 513587. From June 11–July 18, 2007, B. Braun distributed approximately 33,000 units of product code 513584 and 1.2 million units of product code 513587 of lot numbers ending in SFR to hospitals and distributors. The product code identified as REF and lot number identified as LOT can be found on the syringe label below the product description. Customers who have the affected product may contact the B. Braun customer support department at 800-227-2862, 8 am–7 pm EST, Monday–Friday, on instructions for handling the product and to arrange for a replacement.

Read the complete MedWatch 2007 Safety Summary, which also includes a link to the manufacturer's press release, at www.fda.gov/medwatch/safety/2007.htm.

NOTEWORTHY

Health Records Held Electronically With New FDA Tool

The FDA has developed a tool called My Medicine Record to help patients track the medicines they use and easily share the information with their healthcare providers. The record can be completed by hand or via computer. If patients keep the record updated and take it with them every time they visit a doctor's office or pharmacy, the pharmacist or physician can quickly review the list of medicines and dietary supplements and troubleshoot any potential issues. The record also can be sent to the pharmacy or doctor's office electronically.

For more information on My Medicine Record or to print or download a version, visit www.fda.gov/cder/consumerinfo/my_medicine_record.htm.

Safety Guidelines Are Released for Magnetic Resonance Imaging

Serious and sometimes fatal patient injuries associated with magnetic resonance imaging (MRI) procedures are an ongoing safety concern. Issues might include burns from electrodes and cables during examinations, injuries in patients with implanted neurologic stimulators, burns in patients wearing transdermal patches, or death from being hit by metallic objects that have flown across the room. Many life-threatening or fatal MRI-associated accidents still occur.

To help reduce the risk, the American College of Radiology (ACR) has issued a comprehensive update in 2007 to its 2004 white paper on MRI safety, the "ACR Guidance Document for Safe MR Practices." The article was authored by Kanal et al. and published in *The American Journal of Roentgenology,* vol. 188, issue 6, pages 1447–1474. The document covers every aspect of MRI safety, from the design of the suite and the qualifications of personnel to screening patients and what to do in an emergency.

Personnel who work in or near MRI facilities should read the ACR document. It contains information that may be useful for nonradiology personnel who prepare patients for MRI procedures, including managing the potential risks of aneurysm clips, pacemakers, dermal drug delivery patches, and gadolinium-based contrast agents.

For more information about ACR and MRI safety, visit http://www.acr.org/SecondaryMainMenuCategories/quality_safety/MRSafety.aspx.