PRODUCT UPDATE

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PHARMACY CORNER

Capecitabine Is Approved for Adjuvant Treatment of Colon Cancer

Capecitabine, previously used as a treatment for patients with metastatic breast cancer, now can be used by patients with colon cancer. The new indication allows for the use of Xeloda® (capecitabine, Roche Laboratories, Inc., Nutley, NJ) oral tablets as a single agent for adjuvant treatment in patients with Dukes C colon cancer who have undergone complete resection of the primary tumor. The approved use of this oral chemotherapeutic agent provides patients with colon cancer the opportunity for a convenient new treatment option with an easy method of administration. For complete drug information, visit www.xeloda.com.

Colorectal Cancer Treatment Dosage Changes Based on Genetic Information

Camptosar® (irinotecan hydrochloride injection, Pharmacia Corporation, Peapack, NJ) is indicated as part of first-line therapy with 5-fluorouracil and leucovorin for patients with metastatic colon cancer or cancer of the rectum. Camptosar is also a treatment for patients with colon or rectal cancer that has recurred or progressed after initial therapy.

The active form of Camptosar, SN-38, is metabolized by the polymorphic enzyme UGT1A1. UGT1A1 activity is reduced in individuals with genetic polymorphisms (genetic change seen across a population) that lead to decreased enzyme activity such as the UGT1A1*28 polymorphism. Approximately 10% of people in North America are homozygous for the UGT1A1*28 allele. This means they are unable to metabolize Camptosar at the usual rate. Patients with reduced UGT1A1 activity are at increased risk for neutropenia when treated with Camptosar because the drug will have a longer half-life, which increases patients' exposure to the drug.

A reduced initial dose should be considered for patients known to be homozygous for the UGT1A1*28 allele. Heterozygous patients (carriers of one variant allele and one wild-type allele which results in intermediate UGT1A1 activity) also may be at increased risk for neutropenia.

New labeling for Camptosar indicates recommendations for a lower starting dose for patients who are homozygous for UGT1A1*28 allele and indicates an increased risk for neutropenia for patients with reduced UGT1A1 activity. Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions, and contraindications, is available at www.fda.gov/cder/foi/label/2005/020571s024,027,028lbl.pdf.

Manufacturer Changes Gefitinib Labeling

The U.S. Food and Drug Administration (FDA) has approved new labeling for gefitinib (Iressa®, AstraZeneca Pharmaceuticals LP, Wilmington, DE) that limits the indication for usage to patients who currently are benefiting or previously have benefited from gefitinib treatment. The drug will be distributed only to patients currently receiving and benefiting from Iressa, patients who have previously benefited from Iressa therapy, and those enrolled in clinical trials approved before June 17, 2005.

Iressa was approved in 2003 under an accelerated approval regulation that allows products to get to market quickly while still being studied. No significant survival benefit has been seen in the trials required as part of the accelerated approval process. The FDA said that it is not considering withdrawing gefitinib at this time. New clinical trials are in development, and other ongoing trials are being completed; results from these trials will determine the future role of gefitinib treatment. For more information about drug advisories, visit the FDA's Center for Drug Evaluation and Research at www.fda.gov/cder.

Company Discontinues Insulin Products

Eli Lilly and Company (Indianapolis, IN) is discontinuing the production of Humulin® L Lente® and Humulin® U Ultralente® insulins. Use of these longer-acting insulins has been declining because of newer insulin therapies that increase treatment options. Lilly is committed to helping patients transition as smoothly as possible. For more information, call 800-LillyRx (545-5979) Monday–Friday, 9 am–5 pm (ET).

New Drug for Type 2 Diabetes Is Available

Exenatide (Byetta™, Amylin Pharmaceuticals, Inc., San Diego, CA) is a glucagon-like peptide-1 receptor agonist that recently was approved for treating type 2 diabetes. This drug adds another option for patients with diabetes and is used as an adjuvant to oral antihyperglycemic agents. Byetta is indicated as adjuvant therapy to improve glycemic control in patients with type 2 diabetes mellitus who are taking metformin, a sulfonylurea, or a combination of metformin and a sulfonylurea but have not achieved adequate glycemic control. Byetta is recommended to be administered via a subcutaneous injection on a twice-daily fixed dosing schedule. For more information on this new drug, visit www.byetta.com

NEW PRODUCTS

Safety Kit for Pain Lozenges Is Available

Cephalon, Inc., manufacturer of ACTIQ® (oral transmucosal fentanyl citrate, Salt Lake City, UT) will provide a safety kit at no charge to patients who use ACTIQ transmucosal lozenges. ACTIQ resembles a lollipop, which may be attractive to a child but can be fatal if ingested by a child. This welcome kit provides tools and instructions to minimize the risk of accidental exposure to the drug by children. The kit ensures safe storage and disposal of the ACTIQ lozenges. It includes a locking fanny pack for ready availability and security,

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child-resistant storage containers for partially used doses, and patient education materials. ACTIQ contains an oral form of fentanyl, which is used to treat moderate to severe breakthrough cancer pain. ACTIQ is dispensed as an oral lozenge attached to a stick and is administered by rubbing the lozenge along the buccal mucosa. Patients can order a kit online at www.actiq.com or by calling Cephalon toll free at 800-505-4421.

Washable Keyboard Cover Minimizes Germ Transmission

Unotron (Hong Kong and Shenzhen, China), manufacturer of SpillSeal® washable computer keyboards, is finding a way to combat a significant source of germ contamination in healthcare centers. Unotron designs and manufactures washable data input and security devices that can be cleaned and disinfected easily. Infectious disease practitioners have begun to discuss the potential risk of pathogen transmission via computer keyboards in the healthcare setting. The SpillSeal technology protects the keyboard from liquid or airborne contamination and is completely washable. Patient safety is addressed by using this new device that can be washed thoroughly, minimizing the spread of germs with more complete cleaning options. The keyboard is liquid and dust proof, thus allowing for easy maintenance. For more information on Unotron SpillSeal keyboards, visit www.unotron.com or call 800-381-5817.

RECALL ALERTS

Possible Interaction With Alcohol Causes Narcotic Sale Suspension

The FDA has issued a public health advisory to inform patients and healthcare providers that the sponsor of Palladone® (hydromorphone hydrochloride, extended release capsules, Purdue Pharma LP, Stamford, CT) has agreed to suspend sales and marketing of Palladone because of the potential for severe side effects if the drug is taken with alcohol. Palladone is a time-released prescription of hydromorphone, a potent narcotic. Purdue Pharma provided the FDA data that showed that drinking alcohol while taking Palladone may cause a rapid release of hydromorphone, leading to high drug levels in the body and potentially fatal effects. Patients being treated with Palladone should consult their physicians for appropriate alternative medications.

FDA Looks Into Fentanyl Overdose Reports

The FDA is investigating the reports of death and other serious side effects related to the use of transdermal fentanyl. Until results are available, the FDA recommends the following.

- The lowest dose needed for pain relief should be prescribed.
- Fentanyl transdermal patches should not be used to treat short-term pain, pain that is not constant, or pain after an operation.
- Patients who are using the fentanyl transdermal patch and their caregivers must be fully informed about the directions for safe use of the patch. These directions are provided in the product label and in the patient package insert, available at www.fda.gov/cder/drug/infopage/fentanyl/DuragesicPPI.pdf.

The FDA presently is looking into whether these deaths are associated with misuse of the product or a quality issue. Patients and their families need to be aware of dangers inherent with potent narcotic use and should be educated regarding their safe and effective use.

NOTEWORTHY

Web Site Increases Awareness of Stem Cell Research

U.S. BioDefense, Inc., is the sponsor of 1-800-STEM-CELLS.com, a Web site designed to increase awareness of cord blood banking, which also is committed to the advancement of stem cell research. This is the Web site of the Stem Cell Industry Council and is designed to provide toll-free and online directory service for regional cord blood banks and physicians. U.S. BioDefense, Inc., is a Department of Defense central contractor and is committed to the research and development of biotechnology. The Stem Cell Industry Council is a nonprofit organization consisting of a consortium of industry members for advancing the stem cell industry. To learn more about this Web site, visit www.1-800-STEM-CELL.com.

National Institutes of Health Offers Free Online Continuing Education

The National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health is offering a new online continuing education series on complementary and alternative medicine (CAM). CAM is treatment that is not considered a part of conventional medicine. It can include services or products such as dietary supplements, massage therapy, acupuncture, and other mind-body practices.

Healthcare professionals can earn continuing education credits by viewing videos of lectures and taking an online test. Use of CAM therapies is increasing across the United States, and healthcare workers need to be informed of what is available to the public. This knowledge will help providers assist patients in making appropriate decisions about their care. Visit the NCCAM Web site at www.nccam.nih.gov.