PRODUCT UPDATE

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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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