PRODUCT UPDATE

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Rasburicase Approved for Pediatric Patients With Cancer

Elitek™ (rasburicase, Sanofi-Synthelabo, Malvern, PA) is a highly potent uricolytic (i.e., causing the breakdown of uric acid) agent that converts uric acid into allantoin, a soluble byproduct eliminated by the kidneys. Uric acid is formed as a result of the sequential oxidation of hypoxanthine to xanthine by xanthine oxidase. Renal insufficiency develops when urine become supersaturated with uric acid and urate crystals form in the renal tubules, potentially leading to acute renal failure.

Elitek is indicated for the initial management of plasma uric acid levels in pediatric patients with leukemia, lymphoma, and solid tumor malignancies who are receiving anticancer therapy expected to result in tumor lysis and subsequent elevation of plasma uric acid. Elitek will be most useful in patients with malignant hematologic diseases with high tumor burden. Children with rapidly proliferating acute leukemias who are treated with aggressive chemotherapy are at very high risk for tumor lysis syndrome.

Elitek is the only recombinant uricolytic agent. It is indicated for the prevention and treatment of elevated uric acid levels. Allopurinol, the current standard treatment, takes two to three days to block the formation of uric acid. During this time, preexisting uric acid must be excreted unchanged by the kidneys. Elitek is significantly faster acting and more effective than allopurinol. In a comparative trial, Elitek reduced uric acid levels by 86% at four hours after the first dose, compared with a 12% reduction with allopurinol.

Based on in vitro studies and preclinical in vivo studies, no metabolic-based drug interactions are anticipated with Elitek, but no studies of drug interactions have been done in humans. The most serious adverse effects are allergic reactions including anaphylaxis (< 1%), rash (1%), hemolysis (< 1%), and methemoglobinemia (< 1%). The most common adverse reactions are vomiting, fever, nausea, headache, abdominal pain, constipation, diarrhea, mucositis, and rash.

For more information, contact Sanofi-Synthelabo at 212-551-4000 or visit www.sanofi-synthelabous.com.

Fulvestrant Injection Approved for Treating Women With Disease Progression After Antiestrogen Therapy

The U.S. Food and Drug Administration (FDA) has granted approval to AstraZeneca (Wilmington, DE) for its new breast cancer drug Faslodex® (fulvestrant) Injection for treatment of hormone receptor-positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy, such as tamoxifen. Faslodex is an estrogen receptor antagonist without known agonist effects. It is the only estrogen receptor antagonist to be proven effective after tamoxifen failure.

Currently, patients with advanced breast cancer whose tumors have been shown to depend on hormones to grow may be given drugs like tamoxifen that act by blocking the estrogen receptor or aromatase inhibitors that decrease the amount of estrogen in women's bodies. Faslodex is a hormonal therapy that works by binding, blocking, and degrading the estrogen receptor and does not cause the type of side effects commonly associated with cytotoxic chemotherapy. It is administered as a once-monthly intramuscular injection, which may assist healthcare professionals in monitoring compliance and also may make treatment more convenient for some patients.

The FDA approval was based on data from two phase III, randomized, multicenter studies (one in North America and one predominantly in Europe) comparing Faslodex 250 mg once-monthly injection to daily 1 mg oral Arimidex® (anastrozole, AstraZeneca) tablets, the most commonly prescribed aromatase inhibitor. The women in the trials (N = 851) were postmenopausal with a variety of involved sites (including liver and lung) and had been treated with one prior hormonal therapy, in almost all cases tamoxifen. The effectiveness of Faslodex was established by comparison to the selective aromatase inhibitor Arimidex as measured by objective response rate and time to progression (TTP). Objective response rate in the North American trial was 17% with Faslodex versus 17% with Arimidex; in the European trial, the response was 20% with Faslodex versus 15% with Arimidex. The reported TTP for Faslodex versus Arimidex was 5.5 months versus 3.5 months in the North American trial and 5.5 months versus 5.2 months in the European trial.

Faslodex can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised not to become pregnant while receiving Faslodex.

The most commonly reported adverse events with Faslodex versus anastrozole treatment, regardless of the investigator's assessment of causality, were gastrointestinal symptoms (nausea 26.0% versus 25.3%, vomiting 13.0% versus 11.8%, constipation 12.5% versus 10.6%, diarrhea 12.3% versus 12.8%, abdominal pain 11.8% versus 11.6%, headache 15.4% versus 16.8%, back pain 14.4% versus 13.2%, hot flashes 17.7% versus 17.3%, and pharyngitis 16.1% versus 11.6%). Injection site reactions with mild, transient pain and inflammation were reported in 7% of patients (1% of treatments) given single 5 ml and 27% of patients (4.6% of treatments) given 2 x 2.5 ml injections of Faslodex.

For more information, visit www.astrazeneca-us.com.

NEW PRODUCTS

Sealed Safety System for Preparing Chemotherapy Available

A new safety system now is available for healthcare professionals to use in preparing and administering cytotoxic drugs. The system, called PhaSeal® (Carmel Pharma, Shelton, CT), uses a double membrane mechanism to ensure leak-free transfers of drugs. A built-in, pressure-equalization technique ensures that chemotherapy drugs cannot leak out of the system, making mixing of chemotherapy safer. The PhaSeal system has an expansion chamber that prevents overpressure or vacuum from occurring when adding a dilutent or withdrawing the drug from vials, which effectively prevents any leakage.

The staff members most likely to be at risk for exposure to chemotherapy are pharmacy

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staff and oncology nurses. These personnel no longer need to wear gowns, facemasks and gloves, as PhaSeal completely encapsulates the chemotherapy drugs.

PhaSeal's double membrane system ensures leak-free transfer of drugs. Each element is sealed off with a membrane cover, and transfer of the chemotherapy drugs is made via a specially cut injection cannula. The membranes act as tight seals and prevent leakage when the elements are separated after transfer. The combination of the membrane system and the pressure-equalization expansion chamber ensures that drugs have no contact with the atmosphere, and, therefore, no release of aerosols or vapor occurs.

Preclinical studies performed at Eastern Hospital in Gothenburg, Sweden, and the Swedish National Institute for Working Life have showed that the use of PhaSeal lowered the levels of contamination by three to four times. The studies also indicated that drug leakage was undetectable even when inexperienced personnel prepared or administered the cytotoxic agents.

Clinical testing was performed at Ängelholm Hospital in Sweden, the University of Texas MD Anderson Cancer Center in Houston, and the University Hospital in Gent, Belgium. PhaSeal was tested for one year at Ängelholm Hospital. No safety cabinet was used during preparation of the drugs, and, after testing, no cytotoxic drugs were found in the environment.

Over a period of six months, the pharmacy at the University of Texas MD Anderson Cancer Center compared standard techniques with the use of PhaSeal. PhaSeal's results were superior, as the levels of cytotoxic drug contamination barely were detectable when PhaSeal was used and high levels of contamination were recorded in the control group throughout the study. Researchers concluded that PhaSeal successfully had contained the drugs and reduced the level of environmental contamination. As a result, the pharmacy is implementing PhaSeal as standard technique for all preparation of hazardous cytotoxic drugs in addition to using biological safety hoods. For more information, visit www.phaseal.com.

Safety Huber Needle Infusion Set Cleared for Use

The LiftLoc™ (Specialized Health Products International, Inc., Bountiful, UT) safety mechanism is designed to reduce the risk of accidental needle sticks, including rebound injuries. LiftLoc's mechanism shields the needle as it is withdrawn from the port, effectively preventing needle-stick injuries. The safety mechanism is activated by common user techniques and does not require staff members to learn a new method of withdrawing needles from ports.

Each LiftLoc set includes a patient comfort pad for optional use, which is designed to make the LiftLoc more comfortable against patients' skin. Additional Patient Comfort Pads can be purchased as an individually packaged accessory.

LiftLoc features a noncoring needle; its "Y" site is adaptable for needleless access devices and its tubing does not contain DEHP. The set is latex free, low profile, and convenient and easy to use.

The LiftLoc Safety Infusion set will be distributed in the hospital market by Bard Access Systems, Inc., a subsidiary of C.R. Bard, Inc. (Murray Hill, NJ). Healthcare professionals can use LiftLoc to infuse IV fluids and drugs in patients with cancer and other patients who need a surgically implanted port. For more information, visit www.SHPI.com or call 801-298-3360.

Bone Marrow Biopsy Needle Easy to Use

Retrieving an intact bone marrow sample never has been easier. The Goldenberg Snarecoil™ Bone Marrow Needle (Kendall Diagnostic Products, Mansfield, MA) has a unique coil feature at the needle tip that tightens around the marrow specimen to efficiently harvest a viable, nonfragmented sample and deliver intact pathologic material. A lever mechanism allows for specimen capture without redirection of the needle. The trocar tip stylet ensures adequate sharpness for cortical bone penetration, and a probe guide reduces the chance of injury during removal of the specimen from the needle. In addition, an ergonomically designed handle provides a comfortable grip without compromising maximum control.

For more information, contact your Kendall representative, call 800-962-9888, or go to www.mysnarecoil.com.