PRODUCT UPDATE

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Totect™ Approved for Extravasation Treatment

The U.S. Food and Drug Administration's Division of Drug Oncology Products in the Office of Oncology Drug Products approved dexrazoxane hydrochloride for injection (Totect™, TopoTarget) for the treatment of extravasation resulting from IV anthracycline chemotherapy.

Totect is the only FDA-approved drug to treat the often horrific effects of extravasation (accidental leakage into the surrounding tissues) resulting from IV anthracycline chemotherapy doses.

In two studies, patients who received single-agent anthracycline via IV (usually as part of combination chemotherapy) and developed extravasation symptoms of pain, burning, swelling, or redness near the infusion site received Totect to reduce surgical interventions for tissue injury following anthracycline extravasation. Extravasation was confirmed by the presence of fluorescence in tissue biopsies.

The first Totect dose is given as soon as possible, within six hours of extravasation. Treatment is repeated 24 and 48 hours later for a total of three doses. Totect is administered via IV infusion over one to two hours at various venous access locations. The first two doses are 1,000 mg/m^2, with a third dose of 500 mg/m^2. Maximum daily dose on days 1 and 2 is 2,000 mg, dropping to 1,000 mg on day 3.

Extravasation was confirmed in 57 patients. The most common anthracyclines were epirubicin (56%) and doxorubicin (41%). Peripheral sites of extravasation included the forearm (63%), hand (21%), and antecubital area (11%); four patients received anthracycline via a central venous access device. Most presented with swelling (83%), redness (78%), or pain (43%).

Only one of the patients required surgery after Totect treatment. Thirteen had late sequelae at the event site, such as pain, fibrosis, atrophy, and local sensory disturbance; all were considered mild except in the one patient who required surgery. None of the four patients with central venous access devices required surgery.

Totect is a cytotoxic drug. When administered to patients receiving anthracycline-containing cytotoxic therapy, additive cytotoxicity may occur. Totect treatment is associated with leukopenia, neutropenia, and thrombocytopenia. Reversible elevations of liver enzymes may occur. Renal excretion is the primary metabolic pathway. Dimethylsulfoxide should not be used in patients who are receiving dexrazoxane to treat anthracycline-induced extravasation.

Full prescribing information, including clinical trial data, safety and dosing recommendations, drug interactions, and contraindications, is available at www.fda.gov/cder/foi/label/2007/022025lbl.pdf. Additional information is at www.totect.com/totect.htm.

FDA Issues New Box Warnings for Several Erythropoiesis-Stimulating Agents

The FDA approved new box warnings and other safety-related product-labeling changes for the erythropoiesis-stimulating agents (ESAs) Epogen® (epoetin alfa, Amgen Inc.), Procrit® (epoetin alfa, Ortho Biotech Products), and Aranesp® (darbepoetin alfa, Amgen Inc.).

The revised labeling incorporates advice from an FDA advisory committee and expands on labeling changes made in March 2007.

Clinical trials conducted in patients with cancer have shown decreased overall survival or an increased rate of tumor progression when ESAs are used in advanced breast, head and neck, lymphoid, and non-small cell lung malignancies. Trials were conducted to achieve hemoglobin levels of 12 g/dl or more. The new labeling emphasizes that clinical studies have not been conducted to exclude ESA-associated tumor progression or shortened survival when ESAs are dosed to achieve lower hemoglobin levels.

Prescribers should consider the risks of tumor progression and decreased survival in prescribing ESAs, particularly because the risks have not been excluded with lower hemoglobin levels. Risks should be weighed against the potential need for red cell blood transfusions and their associated risks. The FDA strongly recommends that prescribers discuss risks of ESA-associated tumor progression and shortened survival with patients prior to initiating or continuing ESA therapy.

ESAs should be used in patients with cancer only when treating anemia specifically caused by chemotherapy. ESAs should be discontinued when the patient's planned chemotherapy course has been completed.

New labeling also emphasizes that ESAs have not improved symptoms of anemia, poor quality of life, fatigue, or patient well-being in controlled clinical trials of patients with cancer.

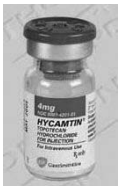
For an FDA healthcare professional sheet and other documents regarding evolving safety issues with ESAs, visit www.fda.gov/cder/drug/infopage/RHE/default.htm.

Prescribing information for Aranesp is available at www.fda.gov/cder/foi/label/2007/103951s5164lbl.pdf, and for Epogen and Procrit at www.fda.gov/cder/foi/label/2007/103234s5158lbl.pdf.

The content of the labels for Epogen and Procrit are the same except for proprietary name.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine or device to the FDA's MedWatch Reporting Program, online at www.fda.gov/medwatch/report.htm; by faxing (+1-800-FDA-0178); by mailing postage-paid Form 3500, available at www.fda.gov/medwatch; or by calling (+1-800-FDA-1088).

Topotecan Approved for Small Cell Lung Cancer



The FDA has approved topotecan (Hycamtin®, GlaxoSmithKline) capsules for the treatment of relapsed small cell lung cancer (SCLC), specifically for patients who demonstrated complete or partial response to first-line chemotherapy and who are at least 45 days from the end of that treatment.

Approval was based on a phase III study comparing topotecan capsules and best supportive care to best supportive care alone in patients with relapsed SCLC who were not suitable candidates for IV therapy.

Approval of an oral agent to treat SCLC provides physicians with an alternative to IV therapy and may allow patients to self-administer chemotherapy.

Common side effects are neutropenia, anemia, and thrombocytopenia, as well as nausea, diarrhea, vomiting, fatigue, and alopecia.

Topotecan belongs to a class of drugs known as topoisomerase I (topo-I) inhibitors.

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