

Infusion Nurses Society References Totect[®] (Dexrazoxane For Injection) as the Only Antidote for the Treatment of Anthracycline Extravasation

Reference cited in Infusion Nursing: An Evidence-Based Approach Third Edition

ROCKAWAY, N.J., Dec. 14 /PRNewswire/ -- The third edition of Infusion Nursing: An Evidence-Based Approach, published by the Infusion Nurses Society (INS), includes Totect[®], the only FDA-approved treatment for anthracycline extravasation.(1) Anthracyclines are a group of chemotherapy medications including daunorubicin, doxorubicin, idarubicin and epirubicin that have been used in the treatment of various types of cancer since the early 1970s.(2)

According to the INS publication: "In September 2007, the FDA approved the first anthracycline extravasation treatment, Totect (dexrazoxane for injection), which has a 98% efficacy in diminishing tissue damage and allows the majority of patients to continue with scheduled chemotherapy."

"In addition to ensuring the availability of Totect in the clinic, all nurses should be aware that it is critical to administer the antidote as soon as possible, and at least within six hours of the anthracycline extravasation," said Linda Person, RN, MSN, AOCN, Advanced Practice Nurse, Ambulatory, USC/Norris Cancer Hospital. "The growing number of Totect citations in the literature is supported by strong clinical data and the absence of Totect in the hospital or clinic could be considered a liability risk."

In addition to this INS citation, ASCO/ONS Chemotherapy Administration Safety Standards, published in 2009 in the *Journal of Clinical Oncology*, defines extravasation management procedures and references the third edition of the Chemotherapy and Biotherapy Guidelines and Recommendations for Practice published by the Oncology Nursing Society, citing Totect[®] as the only FDA-approved treatment for anthracycline extravasation.(3)

During a patient's chemotherapy treatment, whether peripheral or central venous catheter, anthracyclines can leak out of the vein or central line into surrounding healthy tissue causing a serious complication known as extravasation. Anthracycline extravasations cause extreme damage to skin and tissue if left untreated. Approximately 500,000 doses of anthracycline are administered intravenously each year in the U.S.(4)

"We are pleased that the INS, a group of professionals on the front lines of patient care, has clearly and accurately cited Totect[®], the only FDA-approved antidote for anthracycline extravasations," said John L. Parsons, Jr. President of TopoTarget USA, Inc. "This is the third major evidence-based publication to underscore the importance for healthcare institutions providing infusion services to have Totect available on site."

The Infusion Nurses Society, located in Norwood, MA, is a national nonprofit organization founded in 1973. Membership is open to all healthcare professionals from all practice settings who are involved in or interested in the specialty practice of infusion therapy. INS is dedicated to advancing the delivery of quality therapy to patients, enhancing the specialty through stringent standards of practice and professional ethics, and promoting research and education in the infusion nursing practice. Infusion Nursing: An Evidence-Based Approach provides a complete and comprehensive update for infusion nurses to stay informed of the latest advances in equipment, technology, best practices, guidelines, and patient safety. For more information, please visit www.ins1.org.

About Totect

Totect, a product of TopoTarget USA, Inc., is the only U.S. Food and Drug Administration (FDA)-approved patented urgent treatment kit available for anthracycline extravasation. Each kit contains 10 vials of Totect[®] 500 mg and 10 vials of mL diluent, which provides a complete three day treatment.

Totect is available to cancer treatment facilities throughout the U.S. through Cardinal Health Specialty Pharmaceuticals, U.S. Oncology, McKesson Specialty Care Solutions, and ASD Healthcare and Oncology Supply (both AmeriSource Bergen companies). An estimated 5,000 to 6,000 oncology centers and offices in the U.S. could benefit from having a Totect kit available in the event of an anthracycline extravasation. TopoTarget A/S, the parent company, distributes this treatment in Europe under the brand name Savene[®].

Totect is available at two price options to help increase immediate access to Totect for oncology practices, hospitals, infusion centers and clinics. For general information and full prescribing information, including clinical trial information, safety, dosing, drug interactions and contraindications, please visit www.totect.com or call (866) 914-2922. To order Totect, please call (800) 746-6273.

Contraindications: None known **Warnings:** Pregnancy Category D **Precautions:** Totect is a cytotoxic drug. When administered to patients receiving anthracycline containing cytotoxic therapy, additive cytotoxicity may occur. Treatment with Totect is associated with leukopenia, neutropenia, and thrombocytopenia. Hematological monitoring should be performed. Reversible elevations of liver enzymes may occur with dexrazoxane. Patients with Moderate or Severe Renal Insufficiency: Greater exposure to dexrazoxane may occur in patients with compromised renal function. The Totect dose should be reduced by 50% in patients with creatinine clearance values <40mL/min. Dimethylsulfoxide (DMSO) should not be used in patients who are receiving dexrazoxane to treat anthracycline-induced extravasation. **Laboratory Tests:** Blood counts and liver enzymes should be monitored. **Adverse Reactions:** Dexrazoxane has been studied previously as a cytotoxic agent. Adverse reactions of nausea/vomiting, diarrhea, stomatitis, bone marrow suppression (neutropenia, thrombocytopenia), altered liver function (increased AST/ALT), and infusion site burning have been observed. These adverse reactions have been reversible.

About TopoTarget USA, Inc.

TopoTarget USA invests significant resources to educate and raise awareness of anthracycline extravasations, their prevention, early detection and treatment. The company has recruited Regional Business Managers throughout the U.S. geographical regions to support its education/sales programs. The company provides continuing education via live on-site workshops, print materials and online programs. Patient information including patient teaching handouts for those receiving vesicants is available at www.totect.com.

About TopoTarget

TopoTarget (OMX: TOPO) is an international biotech company headquartered in Denmark, dedicated to finding "Answers for Cancer" and developing improved cancer therapies. The company was founded and is run by clinical cancer specialists and combines years of hands-on clinical experience with in-depth understanding of the molecular mechanisms of cancer. TopoTarget has a broad clinical pipeline but is currently focusing on the development of belinostat, which has shown proof of concept as monotherapy in treating haematological malignancies and positive results in solid tumours where it can be used in combination with full doses of chemotherapy, and is in a pivotal trial in PTCL. TopoTarget's expertise in translational research is utilizing its highly predictive in vivo and in vitro cancer models. TopoTarget is directing its efforts on key cancer targets including HDACi, NAD+, mTOR, FasLigand and topoisomerase II inhibitors. The company's first marketed product Savene[®]/Totect[®] was approved by EMEA in 2006 and the FDA in 2007 and is marketed by TopoTarget's own sales force in Europe and the US. For more information, please refer to www.topotarget.com.

- (1) Alexander M., Corrigan A., Gorski L., Hankins J. Perucca R. Infusion Nursing: An Evidence-Based Approach (Third Edition). Infusion Nursing Society: 2009: p. 357- p. 367.
- (2) Schulmeister L. Recent advances in anthracycline extravasation treatment. Hosp Pharm Eur. 2007;34:18-20.
- (3) Polovich M., Whitford J.M., Olsen, M. Chemotherapy and Biotherapy Guidelines and Recommendations for Practice (Third Edition). 2009; ix, 108.
- (4) TopoTarget. Totect now available from TopoTarget: first and only FDA-approved treatment for anthracycline extravasation (press release). Oct. 16, 2007.

CONTACT: John F. Kouten of JFK Communications, Inc., +1-609-514-5117, Mobile: +1-908-227-4714, for TopoTarget USA, Inc.