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Readers Seeks More Information About Extravasation Treatment

I am writing in reference to the article titled, "Totect™: A New Agent for Treating Anthracycline Extravasation" (Vol. 11, pp. 387–395). I was very excited when I read the article and immediately e-mailed our clinical nurse educator, who has been working with a sponsoring physician and our Pharmacy and Therapeutics Committee to have it placed on our formulary in pharmacy.

However, we seem to be unable to confirm that it has been approved by the U.S. Food and Drug Administration (FDA). I understand that it is dexrazoxane "repackaged," but does it have FDA approval in this dosing and for this application? I went to the FDA Web site and could not locate it under the trade name, and the only application for dexrazoxane I found approved was for its cardioprotectant application prior to doxorubicin administration.

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Correction

In the August issue, in an article titled "Port Navigation: Let the Journey Begin" (Vol. 11, pp. 485–488), Figures 2 and 3 and Table 1 incorrectly stated, "If using open-ended catheter that is being used intermittently, flush with an additional 5 ml of heparinized saline and clamp tubing as the last 0.5 ml is instilled to create positive pressure." To clarify, the open-ended catheter is flushed with 20 ml normal saline solution and then 5 ml 100 unit/ml heparin (only once), clamping as the last few milliliters are pushed.

The Author Responds

The article incorrectly stated that Totect (TopoTarget USA, Inc.) had been approved by the U.S. Food and Drug Administration in June 2007 for use as indicated in the article. It was approved after publication of the article, in September 2007.

Here is the link to the FDA announcement: www.ons.org/fda/documents/FDA070906.pdf. Information about Totect also can be found at www.totect.com.

Zinecard® (Pfizer Inc.) and generic dexrazoxane are neither indicated nor FDA approved for anthracycline extravasation treatment. TopoTarget also has a U.S. patent for the use of Totect for extravasation treatment; substitution of any other form of dexrazoxane for Totect anthracycline extravasation treatment constitutes patent infringement.

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