Pfizer Inc.
235 East 42nd St.
New York, NY 10017

February 2018

URGENT: Important Drug Information Update
Availability of Zinecard® (dexrazoxane for injection) 250 mg Single-Dose Vials

Dear Health Care Provider,

In order to alleviate the current drug shortage of **Zinecard® (dexrazoxane for injection)**, Pfizer Inc. (Pfizer) is coordinating with the U.S. Food and Drug Administration (FDA) to increase availability of the drug. Accordingly, Pfizer has released two lots of Zinecard® (dexrazoxane for injection) 250 mg Single-Dose Vials, Lots ADA044 and ADA045A, to address the current critical shortage. These two lots were manufactured using an unapproved supplier of an intermediate for producing the active pharmaceutical ingredient (API). The API and finished drug product were manufactured at approved manufacturing sites.

Although the intermediate supplier has not yet been approved by the FDA, these drug product lots have been fully tested and reviewed by Pfizer. All test results meet the registered specification requirements for the finished drug product. Zinecard® (dexrazoxane for injection) Lot ADA044 and ADA045A met the same product quality standards as previously marketed drug product. Pfizer is working to obtain approval for this intermediate supplier from the FDA, but is releasing these lots in advance with knowledge of FDA in order to make product available to patients.

NDC Number	Product Description	Lot Number
00013-8717-62	Zinecard® (dexrazoxane for injection) 250 mg Single-Dose Vials	ADA044
		ADA045A

This letter is not intended as a complete description of the benefits and risks related to the use of Zinecard® (dexrazoxane for injection). The Full Prescribing Information is available at www.pfizerinjectables.com/products/Zinecard.

Please contact Pfizer Customer Service at 1-844-646-4398 (Mon.-Fri. 8am-7pm ET) or your Pfizer representative for any questions you may have regarding this notification.

To report adverse reactions or quality issues, contact Pfizer at 1-800-438-1985.

Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178)

Important Safety Information

Zinecard® (dexrazoxane for injection) should not be used with non-anthracycline chemotherapy regimens.

ZINECARD may increase the myelosuppressive effects of chemotherapeutic agents. Perform hematological monitoring.

Monitor cardiac function before and periodically during therapy to assess left ventricular ejection fraction (LVEF).

Secondary malignancies such as acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) have been reported in studies of pediatric patients who have received ZINECARD in combination with chemotherapy. ZINECARD is not indicated in pediatric patients. Some adult patients who received ZINECARD in combination with anti-cancer agents known to be carcinogenic have also developed secondary malignancies including AML and MDS.

ZINECARD can cause fetal harm. Advise female patients of reproductive potential of the potential hazard to the fetus.

In clinical studies, ZINECARD was administered to patients also receiving chemotherapeutic agents for cancer. Pain on injection was observed more frequently in patients receiving ZINECARD versus placebo.

Nursing mothers: Discontinue drug or nursing.

Indications

ZINECARD is a cytoprotective agent indicated for reducing the incidence and severity of cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxorubicin dose of 300 mg/m^2 and who will continue to receive doxorubicin therapy to maintain tumor control. Do not use ZINECARD with doxorubicin initiation.

Sincerely,

Eddie G M Power PhD MBA| Lead, US Medical Affairs
Chief Medical Office| Pfizer Essential Health