SAMFORD UNIVERSITY GLOBAL DRUG INFORMATION SERVICE'S

NEW DRUG FAX SHEET

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INCOMPATIBILITY BETWEEN BENDAMUSTINE HYDROCHLORIDE (TREANDA) INJECTIONS AND POLYCARBONATE OR ACRYLONITRILE-BUTADIENE-STYRENE (ABS)

This special issue of *New Drug FAX Sheet* provides information from the FDA regarding a potential interaction between bendamustine hydrochloride and polycarbonate or acrylonitrile-butadiene-styrene. The verbatim safety alert can be found below. If you need further information, please contact the Samford University Global Drug Information Service at (205) 726-2659.

AUDIENCE: Oncology, Pharmacy, Nursing, Risk Manager

ISSUE: FDA is warning health care professionals not to use Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) with closed system transfer devices (CSTD), adapters, and syringes containing polycarbonate or acrylonitrile-butadiene-styrene (ABS). Most marketed CSTDs contain either polycarbonate or ABS and are not compatible with Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution).

N, N-dimethylacetamide (DMA), an ingredient in Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution), is incompatible with polycarbonate or ABS. Devices that contain polycarbonate or ABS dissolve when coming into contact with DMA. This can lead to device failure, possible product contamination, and potential serious adverse health consequences, including skin reactions in health care professionals preparing and administering this product and the risk of small blood vessel blockage in patients.

FDA is requiring label changes for both the solution and the powder formulations of Treanda to reflect safe preparation information.

BACKGROUND: Treanda is available in two formulations, a solution, Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution); and a lyophilized powder, Treanda for Injection (25mg/vial or 100 mg/vial lyophilized powder). Closed system transfer devices are devices that are used to prepare and administer hazardous drugs for intravenous infusion, such as chemotherapy drugs.

RECOMMENDATION: Health care professionals should stop using Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) with CSTDs or vial adapters and syringes containing polycarbonate or ABS. If using Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution):

- If a CSTD would be used with Treanda Injection (45 mg/0.5 mL or 180 mg/2 mLsolution), FDA advises health care professionals to verify with the CSTD manufacturer or Teva U.S. Medical Information (1-800-896-5855) that the CSTD is compatible with Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) prior to preparing the drug.
- FDA recommends health care professionals only use a polypropylene syringe with a metal needle and polypropylene hub to withdraw and transfer Treanda Injection. Polypropylene syringes are translucent in appearance.
- Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.
- Treanda Injection (45 mg/0.5 mL or 180 mg/2 mL solution) must be withdrawn and transferred for dilution in a biosafety cabinet (BSC) or containment isolator and withdrawn and transferred using a polypropylene syringe with a metal needle and a polypropylene hub.

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RECOMMENDATION (continued):

If using Treanda for Injection (25mg/vial or 100 mg/vial lyophilized powder):

- Treanda for Injection (25mg/vial or 100 mg/vial lyophilized powder), must be reconstituted. If a CTSD or adaptor is to be used as supplemental protection during preparation, only use Treanda for Injection (25mg/vial or 100 mg/vial lyophilized powder) and not the solution formulation.
- Do not mix or combine the solution and lyophilized powder formulations of Treanda.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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

Read the MedWatch Safety Alert, including links to the FDA Statement at:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm437626.htm

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