



Pharmaceuticals

November 1, 2017

Teva Administrative Offices:

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IMPORTANT PRESCRIBING INFORMATION

Subject: Supply of TRISENOX[®] (arsenic trioxide) Injection – New Vial Presentation

NOTE Change in total amount from 10 mg to 12 mg per vial

NOTE Change in Concentration from 1 mg/mL to 2 mg/mL

Dear Healthcare Professional:

We are providing an update regarding the supply of TRISENOX[®] (arsenic trioxide) Injection. Teva is now providing a new concentration of TRISENOX supplied in a single-dose vial that contains arsenic trioxide in the same aqueous solution as the ampule formulation. **The vial presentation contains 12 mg of arsenic trioxide in a total volume of 6 mL clear solution at a 2 mg/mL concentration. This represents an increase in the total amount of drug and an increase in the concentration in comparison to the previous ampule presentation.** All other quality attributes of the TRISENOX formulation remain unchanged.

TRISENOX is indicated for the induction of remission and consolidation in patients with acute promyelocytic leukemia (APL) who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression.

Please ensure your staff and any provider in your institution who may be involved in the administration of TRISENOX receives a copy of this letter.

Action for Drug Preparation

The TRISENOX vial presentation contains 12 mg of arsenic trioxide in 6 mL clear solution at a 2 mg/mL concentration which is twice the concentration of the TRISENOX ampule formulation (1 mg/mL). Confirm that the correct volume of TRISENOX is withdrawn from the 2 mg/mL vial during preparation to ensure that the patient receives the correct dose of the product.

Reconstitution

There have been no changes to the labeled reconstitution instructions.

Dilute TRISENOX with 100 to 250 mL 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP, using proper aseptic technique, immediately after withdrawal from the vial. Do not save any unused portions for later administration.



For Further Information

Please see the accompanying Full Prescribing Information for complete safety information before prescribing TRISENOX.

If you have any additional questions about product availability or ordering of TRISENOX Injection, please contact Teva Customer Service at 800-545-8800 (Select Option #3, then # 2).

Reporting Adverse Events

Health care providers and patients should report quality problems and all adverse events in patients taking TRISENOX Injection to Teva Pharmaceuticals at 1-888-483-8279, Option #2.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, or 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.

You also may contact our medical information department at 1-888-483-8279, Option #2 or at USMedInfo@tevapharm.com if you have any questions about the information contained in this letter or the safe and effective use of TRISENOX Injection.

Please see the enclosed full prescribing information, including boxed warning, for TRISENOX.

Sincerely,

Denisa Hurtukova, MD
Vice President, Head of North America Medical Affairs
Teva Pharmaceuticals

Enclosures: Full prescribing information for TRISENOX[®] (arsenic trioxide) Injection