



IMPORTANT DRUG INFORMATION

July 5, 2016

Re: Temporary importation of Bleomycin Sulfate Powder for Injection, 15,000 International Units (IU) to address drug shortage issue

Dear Healthcare Professional,

IMPORTANT NOTE:

Each vial of Amneal Biosciences' product contains 15,000 IU of Bleomycin Sulfate Powder for Injection, which is equivalent to Bleomycin Sulfate USP 15 units (1000 IU of Bleomycin Sulfate Powder for Injection = 1 unit of Bleomycin Sulfate USP). Prescribers and pharmacists must be alert to this difference in labeled units in order to prevent medication errors. Appropriate quality assurance measures should be enacted to reduce the risk of medication errors.

Due to the current critical shortage of Bleomycin Sulfate for Injection, USP, 15 units and 30 units per vial in the United States (U.S.) market, Amneal Biosciences is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of Bleomycin Sulfate for Injection, USP, 15 units per vial.

Amneal Biosciences has initiated temporary importation of a non-FDA approved product, Bleomycin Sulfate Powder for Injection 15,000 IU per vial to the U.S. market: lot numbers GE50604, GE60003, GE60012. The Bleomycin Sulfate Powder for Injection 15,000 IU product being distributed by Amneal Biosciences was manufactured by Cipla Ltd. from its FDA-inspected facility in Verna, Goa, India, for Amneal Pharma Australia Pty Ltd and was sold in Australia under the Willow Pharmaceuticals label.

At this time, no other entity except Amneal Biosciences is authorized by the FDA to import or distribute Amneal Pharma Australia Pty Ltd.'s Bleomycin Sulfate Powder for Injection 15,000 IU product. FDA has not approved the Bleomycin Sulfate Powder for Injection 15,000 IU product being distributed by Amneal Biosciences in the United States.

Amneal Biosciences' Bleomycin Sulfate Powder for Injection 15,000 IU product contains the same active ingredient, bleomycin sulfate, in the same strength as the U.S. FDA-approved Bleomycin Sulfate for Injection, USP, 15 units per vial.

In the U.S., the labeling for Bleomycin Sulfate for Injection includes the following indications: i) squamous cell carcinoma; ii) non-Hodgkin lymphoma; iii) testicular carcinoma; iv) Hodgkin lymphoma; v) malignant pleural effusion.

Bleomycin Sulfate Powder for Injection 15,000 IU product being distributed by Amneal Biosciences is approved in Australia and is dispensed with a Medication Guide. The information on the medication guide differs from the full prescribing information for the current U.S. FDA reference listed drug (RLD). Two key differences between the two package inserts is that the U.S. FDA-approved label uses different units from the Amneal Biosciences label and the Amneal Australia label does not include an indication for malignant pleural effusions. Additionally, the U.S. FDA-approved label provides weight-based dosing information as well as body surface area-based dosage, whereas the imported product label contains only BSA-based dosing information.

This letter is not intended as a complete description of the benefits and risks related to the use of Bleomycin Sulfate Powder for Injection 15,000 IU. Please refer to the package insert for the U.S. FDA-approved Bleomycin Sulfate for Injection, USP for full prescribing information.

Please note that the barcode used for Amneal Biosciences' Bleomycin Sulfate Powder for Injection, 15,000 IU product may not be appropriately recognized by scanning systems used in the United States. Institutions should confirm that barcode systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

The Bleomycin Sulfate Powder for Injection 15,000 IU product distributed by Amneal Biosciences should be handled exactly as you have handled the U.S. FDA-approved Bleomycin Sulfate for Injection, USP. Refrigerate unopened vials at 2°C to 8°C (36°F to 46°F). The Bleomycin Sulfate Powder for Injection 15000IU product distributed by Amneal Biosciences should not be reconstituted or diluted with D5W or other dextrose-containing diluents.

To order Bleomycin Sulfate Powder for Injection, 15,000 IU product distributed by Amneal Biosciences, health care professionals can order the product from their wholesaler/distributor of choice.

To report adverse events or medication errors, or for answers to medical and technical inquiries for patients who have used Amneal Biosciences' Bleomycin Sulfate Powder for Injection, 15,000 IU product, please contact Amneal Biosciences Drug Safety by telephone at 1-855-266-3251 Monday through Friday from 9:00-5:30 EST, or email at biosciencesdrugsafety@amneal.com.

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.

For full U.S. FDA reference listed drug (RLD) prescribing information for Bleomycin Sulfate for Injection, USP, including the BOXED WARNING, please visit:

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b5806c40-12ce-48e3-8abd-9f8997ef4428>

For full prescribing information for Amneal Bioscience's Bleomycin Sulfate Powder for Injection 15,000 IU product, please visit:

http://tga-search.clients.funnelback.com/s/search.html?collection=tga-artg&profile=record&meta_i=157341

Sincerely,



Charles D. Lucarelli
President
Amneal Biosciences LLC




**Amneal Pharm Australia Pty Ltd.
Bleomycin Sulfate Lyophilized Powder for Solution Injection USP 15 unit
Comparison of Carton and Vial Labels (v 1.0)**

| Item | Bleomycin for Injection, USP (Approved RLD Carton and Vial Label Information - Presentius Kabi, USA) | Bleomycin Sulfate Lyophilized Powder for Solution Injection 15,000 I.U. (Proposed Carton and Vial Label Information – Amneal Pharma Australia Pty Ltd.) |
|-----------------|--|---|
| Carton Label | <p>Principal Display: NDC 63323-136-10 103610 BLEOMYCIN FOR INJECTION, USP 15 units per vial For intravenous, intramuscular, subcutaneous, or intrapleural use. Caution: Cytotoxic – Special handling procedures. Rx only Presentius Kabi</p> | <p>Principal Display: PRESCRIPTION ONLY MEDICINE KEEP OUT OF REACH OF CHILDREN BLEO 15K FOR INJECTION For intravenous, intramuscular, subcutaneous or intra arterial injection bleomycin sulfate 15,000 IU 1 vial contains: 15,000 IU powder for reconstitution AUST R 157341</p> <p>Side 2: CAUTION: CYTOTOXIC Each vial contains: bleomycin sulfate 15,000 IU Willow Pharmaceuticals Pty Ltd Level 4, 5 Essex Street The Rocks NSW 2000 Phone 1 800 708 648 Insert Barcode number 9339164000306</p> <p>Side 4: CAUTION: CYTOTOXIC Store at 2 - 8°C Refrigerate. Do not freeze. See package insert for instructions for use. Not to be administered undiluted. Dissolve in Water for Injections, 0.9% Sodium Chloride Intravenous Infusion or Bacteriostatic Water for Injection before use. Contains no antimicrobial preservative. Use in one patient on one occasion only.</p> |

Bleomycin Sulfate Lyophilized Powder for Solution Injection USP 15 unit
 Comparison of Carton and Vial Labels (v 1.0)

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| <p>Item</p> <p>Bleomycin for Injection, USP (Approved RLD Carton and Vial Label Information - Fresenius Kabi, USA)</p> | <p>Bleomycin Sulfate Lyophilized Powder for Solution Injection 15,000 IU. (Proposed Carton and Vial Label Information – Amneal Pharma Australia Pty Ltd.)</p> |
| <p>Carton Label Image</p> <p>For intravenous, intramuscular, subcutaneous, or intrapleural use.</p> <p>Caution: Cytotoxic - Special handling procedures.</p> <p>Rx only</p> <p>FRESENIUS KABI</p> | <p>PRESCRIPTION ONLY MEDICINE KEEP OUT OF REACH OF CHILDREN</p> <p>BLEO 15K</p> <p>FOR INJECTION</p> <p>For intravenous, intramuscular, subcutaneous, or intra arterial injection bleomycin sulfate 15,000 IU</p> |
| <p>Vial Label</p> <p>NDC 63323-136-10 103610 BLEOMYCIN FOR INJECTION, USP 15 units per vial For intravenous, intramuscular, subcutaneous, or intrapleural use.</p> | <p>PRESCRIPTION ONLY MEDICINE KEEP OUT OF REACH OF CHILDREN BLEO 15K FOR INJECTION For intravenous, intramuscular, subcutaneous, or intra arterial injection bleomycin sulfate 15,000 IU</p> |

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| Item | Bleomycin for Injection, USP (Approved RLD Carton and Vial Label Information - Fresenius Kabi, USA) | Bleomycin Sulfate Lyophilized Powder for Solution Injection 15,000 I.U. (Proposed Carton and Vial Label Information – Amneal Pharma Australia Pty Ltd.) |
|-------------------------|---|--|
| | <p>Caution: Cytotoxic – Special handling procedures. Single Use Vial Rx only</p> <p>Read circular for detailed indications, dosage and precautions. Discard unused portion. Store dry powder under refrigeration 2°C to 8°C (36°F to 46°F). Fresenius Kabi USA, LLC Lake Zurich, IL 60047 402161F LOT/EXP Barcode</p> | <p>Store at 2 – 8°C. Refrigerate. Do not freeze. See package insert for instructions for use. Not to be administered undiluted. Willow Pharmaceuticals. Exp:</p> |
| <p>Vial Label Image</p> | <p>NDC 63323-136-10 100610</p> <p>BLEOMYCIN FOR INJECTION, USP</p> <p>15 units per vial</p> <p>For intravenous, intramuscular, subcutaneous or intrarterial use Caution: Cytotoxic - Special handling procedures. Single Use Vial Rx only</p> <p>Read circular for detailed indications, dosage and precautions. Discard unused portion. Store dry powder under refrigeration 2°C to 8°C (36°F to 46°F).</p> <p> Fresenius Kabi USA, LLC Lake Zurich, IL 60047</p> <p>402161F LOT/EXP</p> <p> 3 63323-136-10 9</p> | <p>PRESCRIPTION ONLY MEDICINE KEEP OUT OF REACH OF CHILDREN</p> <p>BLEO 15K FOR INJECTION For intravenous, intramuscular, subcutaneous or intra arterial injection bleomycin sulfate 15,000 IU</p> <p>Store at 2 – 8°C. Refrigerate. Do not freeze. See package insert for instructions for use. Not to be administered undiluted. Willow Pharmaceuticals</p> <p></p> |