COMUNICACIÓN DE ALERTA

Santa Tecla, 16 de Mayo de 2016

LA DIRECCIÓN NACIONAL DE MEDICAMENTOS (DNM) ALERTA SOBRE *PRODUCTO: BICNU (CARMUSTINA INYECTABLE) 100mg*

Nivel de alerta: 1
Nombre del producto: Bicnu (Carmustina Inyectable) 100mg
Presentación/Forma Farmacéutica: Solución Inyectable
Número de registro sanitario: No posee
Laboratorio Fabricante: No se detalla
Lotes: Ver en anexo "Notificación de Alerta"
Fecha de vencimiento: Ver en anexo "Notificación de Alerta"
Entidad emisora de la Alerta: Agencia para Administración de Drogas y Alimentos de los Estados Unidos (FDA, por sus siglas en ingles)
País de Origen: Estados Unidos
Fecha de emisión de la Alerta: 12 de Mayo de 2016

Descripción del problema encontrado: De acuerdo a la alerta emitida por la FDA, el producto antes mencionado está siendo falsificado. De acuerdo a la investigación realizada por la DNM No se encontró registro sanitario activo alguno ni importaciones del producto.

La DNM alerta a toda la población a abstenerse de adquirir y/o suministrar éste producto, en virtud de que su uso representa un riesgo para la salud de la persona que lo consuma. En razón de que el producto Bicnu (Carmustina Inyectable) 100mg NO cumplen con los requerimientos de calidad que avale su seguridad, calidad y eficacia.

La DNM recomienda no adquirir este tipo de producto ya que puede generar un riesgo a la salud. Así mismo recuerda adquirir los medicamentos en lugares autorizados por la DNM. Cualquier duda puede recurrir a ésta Dirección llamando al teléfono gratuito 136.

Se informa que la DNM continuará las acciones de vigilancia, como el aseguramiento de productos, para evitar la venta de los mismos porque representan un riesgo a la población.

ANEXOS

# Heritage Pharmaceuticals Issues Product Safety Warning Due to Reported Sales of Counterfeit Drug Product Labeled as BiCNU® (Carmustine for Injection) 100mg Outside of the United States

NEWS PROVIDED BY
Heritage Pharmaceuticals Inc. →
Apr 29, 2016, 08:00 ET

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EATONTOWN, N.J., April 29, 2016 /PRNewswire/ -- Heritage Pharmaceuticals Inc. ("Heritage") today announced that it recently became aware of the existence of a counterfeit drug product labeled as BiCNU® (Carmustine for Injection) 100mg that has been sold and distributed outside of the United States.

BiCNU® is primarily used for chemotherapy in the treatment of several types of brain cancer, multiple myeloma and lymphoma (Hodgkin's and non-Hodgkin). BiCNU® is also sometimes used for immunosuppression before organ transplantation or hematological stem cell transplantation, a type of bone marrow transplant, in order to reduce the white blood cell count in the recipient.

To the best of Heritage's knowledge, the counterfeit product has only been found in distribution in countries outside the United States - including India, Ireland and Israel. However, because Heritage takes the issue of counterfeiting this BiCNU® product very seriously, Heritage is consulting with the U.S. Food and Drug Administration ("FDA") to aid their evaluations, assist with determining the source of the counterfeit drug, and prevent the further distribution of this product or its introduction into the United States.

Heritage has directly notified all customers of this product along with providing detailed information that will help identify a counterfeit BiCNU® product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of, and return any suspected counterfeit product. Any customers who may have recently distributed the BiCNU® products to its own customers have been requested to convey this information to their customers, healthcare professionals, and any others who use the BiCNU® product, so they will be able to carefully examine all BiCNU® products before use and to identify the characteristics of a suspected counterfeit product.

Anyone who has questions, or needs additional information concerning this matter should contact the Heritage customer call center directly at (866) 901-3784 M-F 9am-5pm EST.

Any health practitioner customers, who determine that they are in possession of a counterfeit product, should contact the FDA through MedWatch, and instructions for such reporting are available at http://www.fda.gov/drugs/drugsafety/ucm170314.htm.

Any end user customers, who believe they may have received a counterfeit drug, should return the product to the pharmacy that dispensed the medicine.

Additional information about this counterfeit product can be found at: www.heritagepharma.com.

SOURCE Heritage Pharmaceuticals Inc.

Related Links
http://www.heritagepharma.com

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# FDA advises health care professionals that counterfeit BiCNU has been discovered in some foreign countries

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**[05/12/2016]** The FDA is informing health care professionals that a counterfeit version of the FDA approved cancer drug, BiCNU (carmustine for injection) 100 mg, has been detected in some foreign countries. There is no indication at this time that counterfeit BiCNU has entered the legitimate U.S. drug supply chain and no indication that any U.S. patients have received counterfeit BiCNU.

The authentic product is approved to treat different types of brain cancer, multiple myeloma, and lymphoma (Hodgkin's and non-Hodgkin's). BiCNU is manufactured by Emcure Pharmaceuticals Ltd. and distributed in the United States by Heritage Pharmaceuticals Inc.

The FDA is advising health care professionals to carefully inspect the BiCNU vial as an added precaution to ensure the product administered to patients is authentic.

BiCNU is available as a vial of BiCNU and dehydrated alcohol co-packaged together. While the NDC on the outer package of the authentic and counterfeit versions might match, the best way to distinguish a counterfeit is to look at the BiCNU vial inside the packaging.

The product may also be counterfeit if the vial displays the following lot numbers, batch numbers, manufacturing dates, and expiration dates. Following is identifying information for the counterfeit lots that have been reported to the FDA to date:

**Comparison of the authentic BiCNU product vial to the counterfeit product vial**

| Authentic BiCNU Vial | Counterfeit Product Vial |
|---|---|
|  |  |



- The authentic product has a **blue** flip top; the counterfeit product has a **gray** flip top
- The NDC number on the authentic product vial **should end with -31, not -41.**

| Product | Exp. | Mfg. | Lot | Batch No. |
|---|---|---|---|---|
| BiCNU | 01/18 | 02/16 | BCEM771322 | EM/BC20161990 |
| Diluent | 01/18 | 02/16 | SBCDA224736 | EM/BCD2220 |
| BiCNU | 12/17 | 01/16 | BCEM771318 | EM/BC20151896 |
| Diluent | 12/17 | 01/16 | SBCDA224732 | EM/BCD2216 |
| BiCNU | 10/17 | 11/15 | BCEM771317 | EM/BC20151895 |
| Diluent | 10/17 | 11/15 | SBCDA224731 | EM/BCD2215 |

The FDA urges health care professionals to purchase drug products only from legitimate suppliers. Health care professionals are encouraged to report sales solicitation of suspect drug products by:

- Calling the FDA's Office of Criminal Investigations (OCI) at 800-551-3989;
- Reporting to OCI; or
- Emailing DrugSupplyChainIntegrity@fda.hhs.gov.

Health care professionals and patients should report adverse events related to the use of any suspect medications to the FDA's MedWatch Adverse Event Reporting program by:

- Completing and submitting the report online at www.fda.gov/medwatch/report.htm; or
- Downloading and completing the form, then submit it via fax at 1-800-FDA-0178.

The FDA is committed to protecting public health by securing the drug supply chain against counterfeit and unapproved medications that enter the United States through fraudulent sources. Visit Know Your Source: Protecting Patients from Unsafe Drugs for information about how to safely purchase prescription drugs for your patients.