COMPANY ANNOUNCEMENT

Teva Initiates Voluntary Nationwide Recall of One Lot of Topotecan Injection 4 mg/4 mL (1 mg/mL) Due to Presence of Particulate Matter

Summary

Company Announcement Date:

June 30, 2021

FDA Publish Date:

July 01, 2021

Product Type:

Drugs

Reason for Announcement:

Presence of particulate matter

Company Name:

Teva Pharmaceuticals

Brand Name:

Teva

Product Description:

Topotecan Injection 4 mg/4 mL (1 mg/mL)

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Teva Pharmaceuticals has initiated a voluntary recall of lot 31328962B of Topotecan Injection 4 mg/4 mL (1 mg/mL), to the retail/institutional level in the United States. This voluntary recall was initiated based on a complaint received from a pharmacy after a single glass particle was observed inside one vial. After further examination of the complaint sample, two other particulates were found and identified as one (1) grey silicone particle and one (1) translucent, colorless cotton fiber.

The administration of an injectable product that contains particulate matter may result in local irritation or swelling in response to the foreign material. If the particulate matter reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death. While the health hazard risk could be severe if particulate matter is infused, Teva's internal health assessment determined that the likelihood of patient exposure to impacted product is remote or unlikely. To date Teva has received no further complaints or reports of illness or injury.

Carton NDC	Vial NDC	Lot#	Exp. Date
0703-4714-01	0703-4714-71	31328962B	04/2022

Topotecan Injection, as a single agent, is indicated for the treatment of patients with metastatic ovarian cancer after disease progression on or after initial or subsequent chemotherapy and for patients with small cell lung cancer (SCLC) platinum-sensitive disease who progressed at least 60 days after initiation of first-line chemotherapy. It is also indicated for treatment of patients with Stage IV-B, recurrent, or persistent cervical cancer which is not amenable to curative treatment, in combination with cisplatin. It is packaged in 4 mg/4 mL single use vials. The affected product information is listed in the table above. Teva distributed the product nationwide to six of its Wholesale customers.

Teva notified its customers on June 18th 2021 and asked that the lot be recalled and to make arrangements for impacted product to be returned. Instructions for returning recalled product and crediting are given in the [**recall letter**] (https://www.tevausa.com/globalassets/us/usa-files---global/topotecan-recall-06-2021-letter-and-srf_18-june-2021.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)released by Teva.

Any consumer who has questions or concerns should first consult with their health care provider(s). To report an Adverse Event or Quality Complaint, or have Medical Related Questions, customers and patients should contact Teva's Medical Information at: 888-838-2872, option 3, then, option 4. Live calls are received: Monday-Friday, 8:30 am - 5:00 pm Eastern Time and voicemail: 24 hrs. /day, 7 days/week or by email at druginfo@tevapharm.com (mailto:druginfo@tevapharm.com).

Adverse reactions 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 (file:///C:/node/360543) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Regular Mail or Fax: Download form (file:///C:/node/360547) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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

This recall was made with the knowledge of the Food and Drug Administration. Teva will continue to partner with, and regularly update, all relevant stakeholders, including regulatory authorities, to resolve this situation.

Company Contact Information

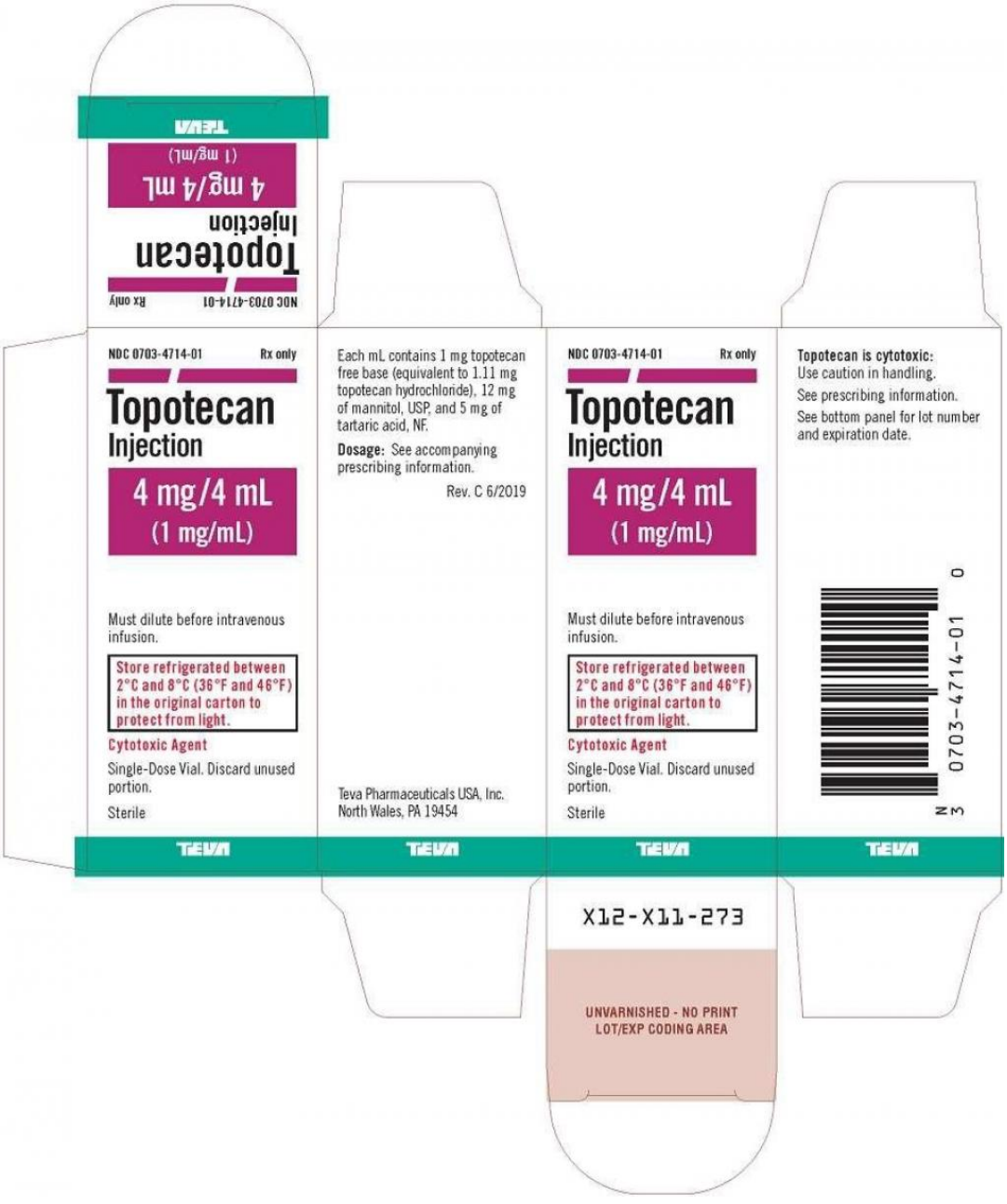
Consumers:

Teva's Medical Information

888-838-2872

druginfo@tevapharm.com (mailto:druginfo@tevapharm.com)

Product Photos



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