

COMPANY ANNOUNCEMENT

Fresenius Kabi Issues Voluntary Nationwide Recall of Two Lots of Fluorouracil Injection Due to the Potential for Glass Particulate

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

July 01, 2019

FDA Publish Date:

July 02, 2019

Product Type:Drugs
Generic Drugs**Reason for Announcement:**

Potential for glass particulate

Company Name:

Fresenius Kabi USA, LLC

Brand Name:

Fresenius Kabi, Novaplus

Product Description:

Fluorouracil Injection

Company Announcement

Fresenius Kabi USA, LLC is voluntarily recalling two lots of Fluorouracil Injection, USP 5g/100mL (50mg/mL), 100mL fill in 100mL vials, to the user level due to the potential for glass particulate. The affected lots, distributed between December 6, 2018 and February 20, 2019, are listed below:

Product Name/Size	NDC Number	Product Code	Lot Number	Expiration Date	First Ship Date	Last Ship Date
Fluorouracil Injection, USP, 5g/100mL (50mg/mL), 100mL fill in a 100mL vial	63323-117-69	NP101761	6120341	04-2020	12/06/2018	12/18/2018
	63323-117-61	101761	6120420	04-2020	12/07/2018	02/20/2019

Products containing glass particulate should not be administered intravenously due to the potential for life-threatening consequences. Reports in the literature suggest that sequelae of thromboembolism, such as pulmonary emboli, phlebitis, granulomas, or fibrosis may occur.

To date, Fresenius Kabi has not received any complaints or reports of adverse events related to this recall.

The company is issuing this notification after finding glass particulate in five vials in retained sample inventory of lot 6120341 during an inspection for a quality investigation. The second lot (6120420) is included in the recall as a precautionary measure as it was produced in the same filling campaign.

Fluorouracil is a chemotherapy drug that is administered intravenously and indicated for the treatment of a variety of cancers.

Fresenius Kabi is notifying its distributors and customers by letter and asking customers and distributors to check their stock immediately and to quarantine and discontinue the use and distribution of any affected product. Distributors should notify their customers and direct them to quarantine and discontinue distributing or dispensing any affected lots, and to return the product to Fresenius Kabi. The recall letter and response form are available at <https://www.fresenius.com> (<https://www.fresenius-kabi.com/us/pharmaceutical-product-updates>) <http://www.fda.gov/about-fda/website-policies/website-disclaimer>)- (<https://www.fresenius-kabi.com/us/pharmaceutical-product-updates>) <http://www.fda.gov/about-fda/website-policies/website-disclaimer>)kabi.com/us/pharmaceutical (<https://www.fresenius-kabi.com/us/pharmaceutical-product-updates>) <http://www.fda.gov/about-fda/website-policies/website-disclaimer>)- (<https://www.fresenius-kabi.com/us/pharmaceutical-product-updates>) <http://www.fda.gov/about-fda/website-policies/website-disclaimer>)product (<https://www.fresenius-kabi.com/us/pharmaceutical-product-updates>) <http://www.fda.gov/about-fda/website-policies/website-disclaimer>)- (<https://www.fresenius-kabi.com/us/pharmaceutical-product-updates>) <http://www.fda.gov/about-fda/website-policies/website-disclaimer>)updates (<https://www.fresenius-kabi.com/us/pharmaceutical-product-updates>)

product-updates) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>).
(<https://www.fresenius-kabi.com/us/pharmaceutical-product-updates>) [↗](#)
(<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

Consumers with questions regarding this recall may contact Fresenius Kabi at 1-800-551-7176 Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. or via email at

productcomplaint.USA@fresenius-kabi.com

(mailto:productcomplaint.USA@fresenius-kabi.com) or

adverse.events.USA@freseniuskabi.com (mailto:adverse.events.USA@freseniuskabi.com)

Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product.

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 \(/node/360543\)](/node/360543)
- Regular Mail or Fax: [Download form \(/node/360547\)](/node/360547) 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 is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Fresenius Kabi

Fresenius Kabi (www.fresenius-kabi.com/us (www.fresenius-kabi.com/us)) is a global health care company that specializes in medicines and technologies for infusion, transfusion and clinical nutrition. The company's products and services are used to help care for critically and chronically ill patients. The company's U.S. headquarters is in Lake Zurich, Illinois. The company's global headquarters is in Bad Homburg, Germany. For more information about Fresenius Kabi worldwide, please visit [www.fresenius](http://www.fresenius.com) (<http://www.fresenius-kabi.com/>) [↗](#) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)- (<http://www.fresenius-kabi.com/>) [↗](#) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)[kabi.com](http://www.fresenius-kabi.com) (<http://www.fresenius-kabi.com/>) [↗](#) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>). (<http://www.fresenius-kabi.com/>) [↗](#) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

Company Contact Information

Consumers:

Fresenius Kabi

☎ 1-800-551-7176

✉ productcomplaint.USA@fresenius-kabi.com, adverse.events.USA@fresenius-kabi.com
(<mailto:productcomplaint.USA@fresenius-kabi.com>, <mailto:adverse.events.USA@fresenius-kabi.com>)

Media:

Matt Kuhn

☎ (847) 550-5751

✉ matt.kuhn@fresenius-kabi.com (<mailto:matt.kuhn@fresenius-kabi.com>)

Product Photos







Fluorouracil Injection, USP

5 grams per 100 mL
(50 mg per mL)

NOVAPLUS®

GTIN: 00363323117696



LOT: 65384173870583
EXP: 6120341
MFG: 04/20

For information and proper use of container.)

Fluorouracil Injection, USP

**PHARMACY BULK PACKAGE—
Not for Direct Infusion**

5 grams per 100 mL
(50 mg per mL)

**FOR INTRAVENOUS
USE ONLY**

100 mL

Rx only

NOVAPLUS®

621362A

Fluorouracil Injection, USP

PHARMACY BULK PACKAGE - Not for Direct Infusion

5 grams per 100 mL
(50 mg per mL)

FOR INTRAVENOUS USE ONLY

100 mL Rx only

Sterile, Nonpyrogenic

Each mL contains 50 mg Fluorouracil. It is adjusted to approximately 0.2% with sodium hydroxide.

(Each 100 mL contains 5 grams with an isotonic solution.)

A single entry through the vent septum should be made utilizing a suitable sterile dispensing set or transfer device.

If a prescriber finds a defect in the product, a maximum of 4 hours from the time of initial entry is allowed to complete the transferring operations. Contact the manufacturer at 1-800-345-6229 or visit our website for more information. For Package Insert for complete storage information and other information, visit www.fresenius-kabi.com.

Store at 20° to 25° (68° to 77°) (see USP Controlled Room Temperature), DO NOT FREEZE. Protect from LIGHT.



Lot 6120425
Exp 04/20

4016516
LEOSP

VIAL ENTRY: Date: _____
 Place: _____



3 NDC 63323-117-01 0

5 grams per 100 mL (50 mg per mL)

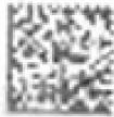
Fluorouracil Injection, USP

Fluorouracil
Injection, USP

5 grams per 100 mL

(50 mg per mL)

GTIN: 00363323117610



100000538751
6120420
04/20

CONTAINERS
after initial closure puncture. (See
Package Insert for complete dosage
information and proper use of
container.)



Fluorouracil
Injection, USP

**PHARMACY BULK PACKAGE—
Not for Direct Infusion**

5 grams per 100 mL

(50 mg per mL)

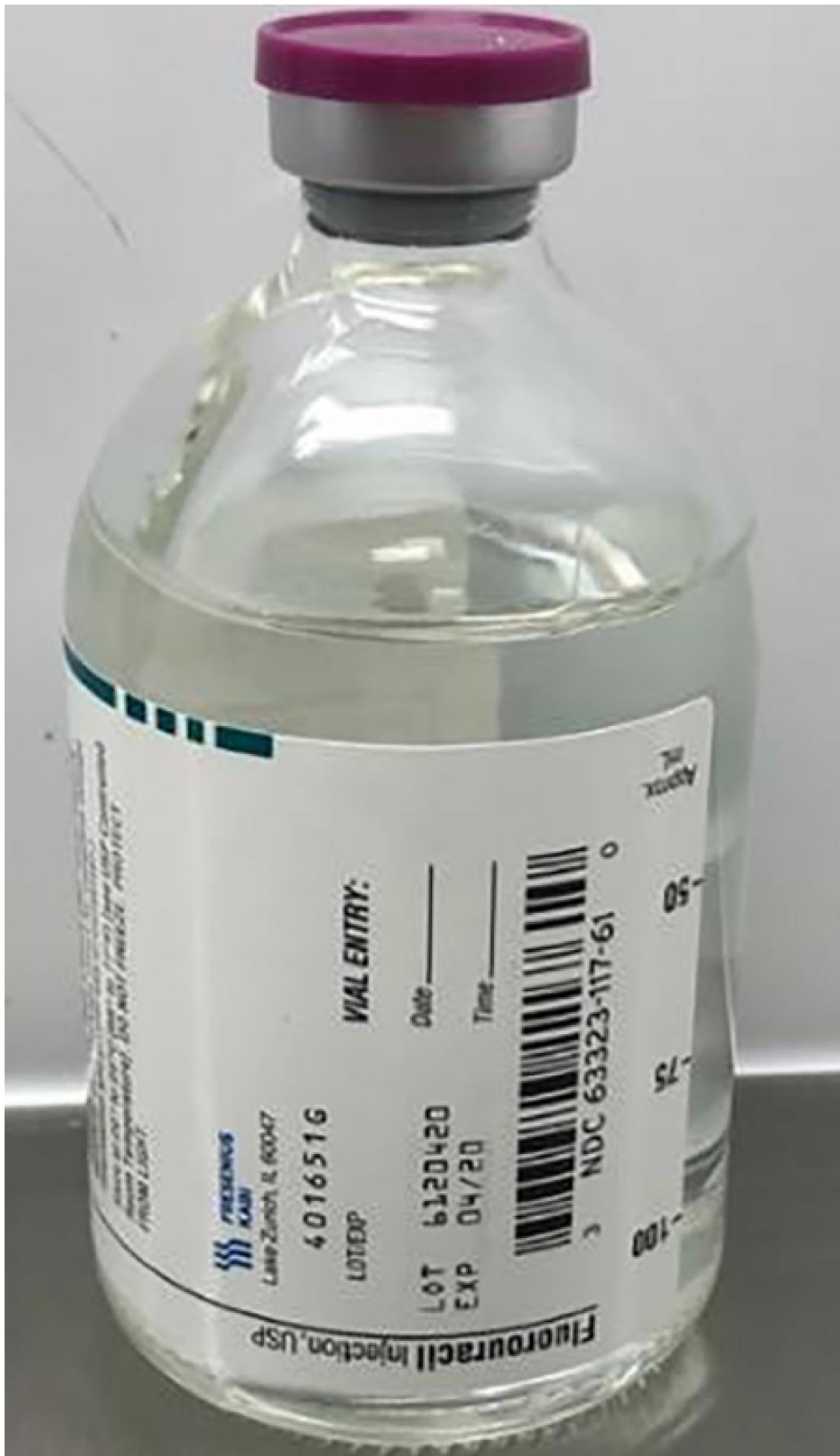
**FOR INTRAVENOUS
USE ONLY**

100 mL

Rx only



62523F



➔ More Recalls, Market
Withdrawals, &
Safety Alerts (/safety/recalls)

