



Fresenius Kabi USA – Recall of fluorouracil

- On June 28, 2019, [Fresenius Kabi USA announced](#) a voluntary, consumer-level recall of two lots of [fluorouracil](#) injection due to the potential for glass particulate.
 - Additional information may be found in the [press release](#).
- The recalled fluorouracil injection lots were distributed between December 6 2018 and February 20, 2019:

Product Description	NDC#	Lot# (Expiration Date)
Fluorouracil injection 5g/100mL (50mg/mL), 100mL fill in a 100mL vial	63323-117-69	6120341 (4/2020)
	63323-117-61	6120420 (4/2020)

- Fluorouracil is a chemotherapy drug that is administered intravenously and indicated for the treatment of a variety of cancers.
- Fresenius Kabi has decided to take this action due to glass particulates found in 5 vials of the remaining inventory of lot 6120341 during an inspection for a quality investigation. Lot 6120420 is included in this recall as a precautionary measure because it was filled immediately post lot 6120341 as part of the same filling campaign.
- The administration of glass particulate, if present in a parenteral drug, poses a moderate safety risk to patients. 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 adverse event reports related to the recalled product.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled fluorouracil injection.
- Pharmacies and healthcare facilities that have the recalled drug product should immediately quarantine and stop dispensing the recalled drug product.
- For more information regarding this recall, contact Fresenius Kabi by phone at **1-800-551-7176** or by email at productcomplaint.USA@fresenius-kabi.com.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at optum.com.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2019 Optum, Inc. All rights reserved.