

# **Lactated Ringer's Injection Recall Alert**

Date of Notice: 05/08/2020

## **Brief Description of Recall**

On May 8, 2020, ICU Medical, Inc. is voluntarily recalling one lot of lactated ringer's injection due to the presence of particulate matter identified as iron oxide.

Administration of a drug product that contains metal particulate matter could result in adverse events ranging from inflammation at the site of injection to more serious events that could include the formation of a blood clot obstructing the flow of blood which could lead to end-organ damage or death.

## **Affected Products**

Drug Name & Strength	NDC	Lot	Expiration Date
Lactated Ringer's Injection, USP	0409-7953-09	07-514-FW	07/01/2021

#### **Prescriber Information**

To date, there are no adverse event reports received due to this recall.

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 <u>Online</u>
- Regular Mail or Fax: <u>Download form</u> 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

#### **Member Information**

Members should contact their prescriber if they have experienced any problems that may be related to taking or using this drug product.

#### **RxAdvance Response**

RxAdvance is in the process of contacting members and prescribers to advise those impacted by this recall.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

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