RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Phytonadione Injectable 10mg/ml Recall Alert

Date of Notice: 03/26/2020

Brief Description of Recall

On March 26, 2020, Dr. Reddy's Laboratories Ltd. issued a voluntary recall on four lots of phytonadione injectable, 10mg/ml single-dose ampules. The product is being recalled due to complaints received due to ampules breaking and shattering upon opening.

The company has received reports of cuts in skin and lacerations to health care professionals. There may be a reasonable probability of flying glass injuring skin, eye and/or other parts which could result in either temporary or permanent injury.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Phytonadione Injectable Emulsion USP, 10 mg/mL Single-Dose Ampules	43598-405-16	ACB902 ACB903	03/2021
		ACB904	04/2021
		ACB905	06/2021

Prescriber Information

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
- Regular Mail or Fax: Download form 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 with general questions can contact Dr. Reddy's Laboratories 1-866-733-3952 between the hours of 8 a.m. to 5 p.m. EST, Monday through Friday. For medical information or to report an adverse event and/or product complaint, please contact Dr. Reddy's Laboratories at 1-888-375-3784 between the hours of 9 a.m. to 7 p.m. EST, Monday through Friday.

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

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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RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise them of this recall.

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