



<<Date>>

<<First Name>> <<Last Name>>

<< Address line 1>>

<< Address line 2>>

<<City>> <<ST>> << Zip Code>>

IMPORTANT RECALL INFORMATION

Dear <<First Name>> <<Last Name>>,

We are sending you information about Phytonadione Injectable Emulsion that may be valuable to you.

On April 8, 2020, the United States Food and Drug Administration (FDA) issued a notice regarding a voluntary recall of Phytonadione Injectable Emulsion manufactured by Dr. Reddy's Laboratories. **Dr. Reddy's issued this recall after receiving complaints of ampules breaking and shattering upon opening. This could pose a health hazard or safety risk to individuals who may be using product affected by this recall.**

Our records show you may have received a prescription for this medicine recently from your retail pharmacy.

A list of the affected products and lot numbers is provided at the end of this letter.

To see if you have affected product, please check the lot number. The lot number is located on the manufacturer's label on each vial under the bar code and on the manufacturer's carton. If your product is not from one of these affected lots, it is not affected by this recall. **Please call your doctor right away for advice if you may be using affected product or if you do not know if you used affected product.** Your doctor is familiar with your medical history and can suggest the best treatment option for you.

For more information, call Dr. Reddy's Medical Information toll-free at 1-888-375-3784, Monday through Friday, 9:00 a.m. to 7:00 p.m. (ET). You may also call the FDA consumer inquiry toll-free at 1-888-INFO-FDA (1-888-463-6332) or visit www.fda.gov.

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This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.
Your privacy is important to us. Our employees are trained regarding the appropriate way to handle your private health information. This information is not a substitute for medical advice or treatment. Talk to your doctor or health care provider about this information and any health-related questions you have. CVS Caremark assumes no liability whatsoever for the information provided or for any diagnosis or treatment made as a result of this information.

- This material is available in other languages. Please call our member services department at the toll-free number listed on your benefit ID card. TTY users should call 1-800-863-5488.
- Esta información está disponible en otros idiomas. Por favor llame a nuestro departamento de servicios al cliente al número gratuito que aparece en su tarjeta de identificación. Los usuarios de equipo teleescritor (TTY) deben llamar al 1-800-863-5488.

Sincerely,

CVS Caremark® Medical Affairs

Product Name	NDC #	Affected Lots
Phytonadione Injectable Emulsion 10 mg/mL, Single-Dose Ampules	43598-0405-11	ACB905 exp. 06/2021, ACB904 exp. 04/2021, ACB903 exp. 03/2021, ACB902 exp. 03/2021
Phytonadione Injectable Emulsion 10 mg/mL, Carton 25 Ampules	43598-0405-16	ACB905 exp. 06/2021, ACB904 exp. 04/2021, ACB903 exp. 03/2021, ACB902 exp. 03/2021