

<<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 Nizatidine Oral Solution 15 mg/mL that may be valuable to you.

On April 15, 2020, the United States Food and Drug Administration (FDA) issued a notice regarding a recall of Nizatidine Oral Solution 15 mg/mL manufactured by Amneal Pharmaceuticals. This recall was issued because an unexpected impurity was found in the active ingredient used in these products that could be a health hazard or safety risk to plan members 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.

If you received a prescription for this product, please contact the pharmacy that filled your prescription. They will provide more information regarding this recall including return instructions.

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. A list of recalled products is provided at the end of this document.

Amneal has advised that consumers who have Nizatidine Oral Solution which is being recalled should stop using the product and can call Inmar toll-free at 1-855-319-4807, Monday through Friday, 8:00 am to 5:00 pm (ET) for further information. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the use of this drug product. If you need a prescription for a different medicine, please contact your doctor.

For more information, please call Amneal Drug Safety toll-free at 1-877-835-5472, Monday through Friday, 8:00 am to 6:00 pm (ET) or visit www.amneal.com. You may also call the United States Food and Drug Administration (FDA) consumer inquiry line 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

Affected Products

NDC No.	Description	Lot	Expiration Date
60846-301-15	Nizatidine Oral	06598004A	04/2020
	Solution		
60846-301-15	Nizatidine Oral	06599001A	12/2020
	Solution		
60846-301-15	Nizatidine Oral	06599002A	12/2020
	Solution		