



<<Date>>

Dr. << Dr. Name MD>>

<<Dr. Address>>

<<Dr. Address>>

<<City>>, <<State>> <<ZIP>>

IMPORTANT WITHDRAWAL INFORMATION

Dear Dr. [Dr. Name]:

On April 3, 2020, Zydus issued a notice that it is conducting a voluntary market withdrawal of ranitidine injection products. Zydus initiated the withdrawal of these products at the request of the United States Food and Drug Administration (FDA). The FDA previously announced that it is requesting manufacturers withdraw all prescription and over-the-counter (OTC) ranitidine drugs (commonly known by the brand name Zantac) from the market immediately. The Agency has determined that the impurity known as N-Nitrosodimethylamine (NDMA) in some ranitidine products increases over time and when stored at higher than room temperatures and may result in consumer exposure to unacceptable levels of this impurity.

As ranitidine injection is indicated for short-term use in hospitalized patients, Zydus is conducting this market withdrawal at **HOSPITAL LEVEL**.

A complete list of Zydus ranitidine injection products is provided at the end of this document.

For more information, please contact Zydus Drug Safety/Medical Affairs at 1-877-993-8779, Monday through Friday, 9:00 am to 5:00 pm (ET) and select option 2. You may also contact the FDA consumer inquiry line at 1-888-INFO-FDA (1-888-463-6332) or visit www.fda.gov.

CVS Caremark® is committed to providing you with the latest information to support safe use of medications. To assist you in identifying patients prescribed Zydus ranitidine injection products, we have included the names and dates of birth of your CVS Caremark® patients who have received prescriptions for this product between October 6, 2019 and April 6, 2020 at their participating retail pharmacy. You may find this information useful should you wish to review your patient's therapy and discuss other available options.

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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®. Plan member privacy is important to us. Our employees are trained regarding the appropriate way to handle plan members' private health information.

The information contained in this communication is provided in summary form. It is not intended for use as the sole basis of clinical treatment, as a substitute for reading the original research, nor as a substitute for the knowledge, skill and judgment of the medical provider.

Please consider any formulary requirements or other prescribing limitations that your patient's health plan may have in place and communicate any prescription changes directly to your patient's pharmacy.

Sincerely,

CVS Caremark® Medical Affairs

Affected Products

Product Name	NDC #	Affected Lots
Ranitidine Injection, USP, 25 mg/mL, 2 mL	68382-0422-02	All lots within expiry
Ranitidine Injection, USP, 25 mg/mL, 6 mL	68382-0423-06	All lots within expiry
Ranitidine Injection, USP, 25 mg/mL, 40 mL	70710-1550-01	All lots within expiry



Patient Profile

Page: [Profile Page #]

Health Care Provider Name: [Dr. Name]

Analysis Period: October 6, 2019 through April 6, 2020

Listed below are your CVS Caremark® patients identified as having had a prescription filled recently for Zydus ranitidine injection products at their participating retail pharmacy.

Brand-name drugs may have a higher copayment for your patients than generic drugs (if applicable).

The use of Protected Health Information (PHI) in this publication is permitted under the HIPAA Privacy Standards.

Patient Name	Patient ID	Date of Birth	Drug Name
XXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXX
XXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXX
XXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXX

Note: We endeavor to provide you with accurate information. If you receive information you believe to be incorrect, or information about a patient not currently under your care, please let us know. We ask that you also destroy the information in a confidential manner.

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