ARIZONA DEPARTMENT of CHILD SAFETY

Mike Faust, Director
Douglas A. Ducey, Governor

IMPORTANT HEALTH PLAN INFORMATION

TO: Member or Caregiver

FROM: CMDP

DATE: November 22, 2019

RE: DRUG RECALL NOTICE - RANITIDINE

Dear Caregiver,

Our records show that you may have recently filled a prescription for the medication or product below. Here are details about the recall:

Name of recalled medication or product:	**Ranitidine**
Date of recall:	11/6/2019
Recalled by:	Aurobindo
Reason for recall:	Some prescription and over-the-counter (OTC) ranitidine products were recalled because of purity issues.

What should you do if you have received the recalled medication or product?
Check with your pharmacy to find out if you received the recalled medication or product. You may also check your prescription against the table on the following page to find out if you received the recalled medication or product. If the label on your prescription does not show the NDC or lot number, please contact your pharmacy to find out if you received the recalled medication or product.

Please talk to your healthcare provider about your therapy. If you have the recalled medication or product, your pharmacy may be able to give you a safe replacement.

If you are not able to obtain a replacement for your current ranitidine prescription from your pharmacy, please alert your healthcare provider to discuss the alternative treatment options.
It is possible that you already received a letter regarding a ranitidine recall. The FDA continues to monitor this situation and investigates additional ranitidine products which may be impacted

by the purity issue. We continue to notify any potentially impacted members as the FDA announces the recall of additional ranitidine products.

To date, other companies have also recalled OTC brand and generic ranitidine products. If you are taking an OTC ranitidine product, you may consider using other OTC products approved for your condition. Examples may include Pepcid® (famotidine), Tagamet® (cimetidine), Nexium® (esomeprazole), Prevacid® (lansoprazole), and Prilosec® (omeprazole). FDA's tests of these alternatives do not show impurities at this time.

Questions?
If you have health concerns or questions about using ranitidine, talk with your healthcare provider. Or you can contact Aurobindo by phone at 1-866-850-2876 (8:30 am – 5:00 pm EST, Monday through Friday) or by email at pvg@aurobindousa.com for more information.

Sincerely,
CMDP

Product Description	NDC#	Lot# (Expiration Date)
Ranitidine 150 mg capsules	59651-144-60	RA1518001-A (Jul-2020)
		RA1518002-A (Jul-2020)
	59651-144-05	RA1518002-B (Jul-2020)
		RA1518003-A (Jul-2020)
		RA1518004-A (Aug-2020)
		RA1518005-A (Aug-2020)
	59651-144-60	RA1518005-B (Aug-2020)
		RA1518006-A (Aug-2020)
	59651-144-05	RA1518007-A (Sep-2020)
		RA1518008-A (Sep-2020)
		RA1518009-A (Sep-2020)
		RA1518010-A (Oct-2020)
		RA1518011-A (Nov-2020)
		RA1518012-A (Nov-2020)
		RA1518013-A (Nov-2020)
		RA1518014-A (Nov-2020)
		RA1518015-A (Nov-2020)
	59651-144-60	RA1519003-A (May-2021)
	59651-144-05	RA1519003-B (May-2021)
		RA1519004-A (May-2021)
		RA3018001-A (Jul-2020)
		RA3018002-A (Jul-2020)

Ranitidine 300 mg capsules	59651-145-30	RA3018003-A (Jul-2020)
		RA3018004-A (Aug-2020)
		RA3018005-A (Aug-2020)

References:

1. FDA Safety Alert. Aurobindo Pharma USA, Inc. Initiates Voluntary Nationwide Consumer Level Recall of 38 Lots of Ranitidine Tablets 150mg, Ranitidine Capsules 150mg, Ranitidine Capsules 300mg and Ranitidine Syrup 15mg/mL Due to the Detection of NDMA (Nitrosodimethylamine) Impurity. FDA website. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-usa-inc-initiates-voluntary-nationwide-consumer-level-recall-38-lots-ranitidine. Accessed November 8, 2019.
2. FDA Updates and Press Announcements on NDMA in Zantac (ranitidine). FDA website. https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine. Accessed November 8, 2019.
3. FDA Questions and Answers: NDMA impurities in ranitidine (commonly known as Zantac). FDA website. https://www.fda.gov/drugs/drug-safety-and-availability/questions-and-answers-ndma-impurities-ranitidine-commonly-known-zantac. Accessed November 8, 2019.