SANDOZ Une division Novartis

URGENT
TYPE I, LEVEL II DRUG RECALL

Pharmacy Notice

RA# SDZ091619

DATE: **2019-09-16**

TO THE ATTENTION OF: **Director of Pharmacy**

Dear Customer,

***The following product is subject to an immediate Type I, Level II (Pharmacy) recall*:**

Sandoz Ranitidine film-coated tablets all strengths

DIN :	**UPC:**	**Lot :**
02243229 (150 mg)	**057513219450** **057513219443** **628037115155** **628037115117** **628037115063**	**All lots**
02243230 (300 mg)	**057513219436** **628037115315** **628037115230**	

The recall decision was taken due to the presence of the impurity NDMA in the Active Pharmaceutical Ingredient Ranitidine. **Patients must not stop using this product without consulting their physician**. The risk classification associated with this product recall is Type I, a situation in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death.

WE ASK YOU TO PLEASE IMMEDIATELY STOP THE SALE AND DISTRIBUTION OF THE **ABOVE MENTIONED PRODUCT (ALL LOTS)**. Please note that Health Canada has been advised of this recall.

1. **What you need to do:**

We ask that you immediately remove all units of the above mentioned product from your inventory, then to complete and send the attached form (even if you have no inventory of this lot) within 48 hours by email to **mtirecall@inmar.com.** For additional information or questions, please call 1-800-361-3062 or contact your Regional Manager.

2. **Replacement Product:**

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The present recall only affects the above specified product.

No other lots of Sandoz Ranitidine FCT (all strengths) are currently available for sale at Sandoz Canada.

Your immediate attention to the above instructions is required. Follow up contact will be made if no responses have been received by September 20, 2019.

Please download an Inmar Return form (www.returns.org) and return all units of the affected product lot *via* Purolator Collect to:

Inmar
50, Dynamic Drive, Unit 2
Scarborough, ON
M1V 2W2
Canada
Waybill sender reference SDZ091619

Purolator phone number: 1-888-SHIP-123

Purolator account number 7983131
*Affix Inmar's box label to the exterior of your shipment

We regret any inconvenience this recall may have caused and thank you for your patience and assistance in this matter.

Abran Daniel

Digitally signed by Abran Daniel
DN: dc=com, dc=novartis, ou=people, ou=TO, serialNumber=925184, cn=Abran Daniel
Date: 2019.09.16 15:38:08 -04'00'

Daniel Abran, Ph. D.
Executive Directeur, QA Commercial Operations

encl. Drug Recall Form