SANOFI

10/22/2019

URGENT: VOLUNTARY DRUG RECALL
Depth of Recall: Retail and ECommerce Outlets
NDC Number: 41167-0300-0, 1, 2,3,5,6, 7, 8
41167-0310-0, 1, 2, 3, 4, 5, 6, 7, 8, 9
41167-0320-0, 1, 2, 3, 4, 5, 6, 7
0597-0120-06, 08, 09, 24, 38, 50, 76, 78, 80, 82, 87
0597-0121-01, 06, 08, 09, 11, 24, 38, 50, 64, 66, 68,
0597-0121-78, 80, 82, 85, 90, 94
0597-0122-01, 08, 13, 34, 37, 40, 54, 61, 81, 96
66715-9736-2, 3, 8
67751-151-01
67751-152-01, 02
68151-2584-0
502-220-25, 50269-222-25

Product Description	Expiration Date
Regular Strength Zantac 75®	All product within expiry
Maximum Strength Zantac 150®	All product within expiry
Maximum Strength Zantac 150® Cool Mint Tablets	All product within expiry

To Whom It May Concern,

This letter is to inform you that Sanofi is initiating as a precautionary measure **a voluntary recall** of all batches within expiry of **Regular Strength Zantac® 75, Maximum Strength Zantac® 150, Maximum Strength Zantac® 150 Cool Mint Tablets**

This recall is being taken due to possible contamination with a nitrosamine impurity called N-nitrosodimethylamine (NDMA).

Our records indicate that you have received product that is subject to this recall. Distribution of recalled product by Sanofi started on 01/04/2017 and ended on 10/11/2019.

Required Actions:

- **Immediately discontinue distribution of Regular Strength Zantac 75 mg, Maximum Strength Zantac 150 mg, Maximum Strength Zantac 150 mg Cool Mint Tablets.**
- **Please notify any of your customers who have purchased Regular Strength Zantac® 75 mg, Maximum Strength Zantac® 150 mg, Maximum Strength Zantac® 150 mg Cool Mint Tablets and instruct them to discontinue use and return any product within expiry to your retail outlet.**

SANOFI US 55 Corporate Drive, Bridgewater, New Jersey 08807 Tel : 908.981.5000

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- **Sanofi will reimburse retail outlets for product returned to Sanofi. Sanofi will not be able to refund individual consumers.**
- **To obtain a return kit please contact INMAR at 877-275-0993 Option 1**
- **If you prefer to fax this request, the fax number is 336-499-8145; alternatively the email contact is zantacrecall@inmar.com.**

Sanofi will issue retail outlets credit for product within 10-15 days after the receipt of the returned recalled product by INMAR.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. Your assistance with this product recall is greatly appreciated. Direct Accounts may contact Sanofi Consumer Healthcare if you require additional information.

All questions of a medical or clinical nature, or regarding product quality should be sent to Sanofi Medical Information Services in the U.S. at 1-800-633-1610, option #. If you have questions on any other topics, please call **877-275-0993 Option 2**

Thank you.

Sincerely,

Allison Steele
Director, Regulatory Compliance
Recall Leader, Sanofi U.S.