Aspen Pharmacare Australia Pty Ltd
ABN: 51 096 236 985
34-36 Chandos Street, St Leonards NSW 2065
Phone: (61 2) 8436 8300 ~ Fax: (61 2) 9437 0081
Email: aspen@aspenpharmacare.com.au
Web: www.aspenpharma.com.au

URGENT MEDICINE RECALL

ZANTAC Ranitidine
All dosage forms & strengths
All batches within expiry

AUST R	PRODUCT NAME
35188	ZANTAC ranitidine 150mg/10mL (as hydrochloride) oral liquid bottle
53324	ZANTAC ranitidine 150mg (as hydrochloride) tablet blister pack
53323	ZANTAC ranitidine 300mg (as hydrochloride) tablet blister pack
45993	ZANTAC ranitidine 150mg (as hydrochloride) effervescent tablet tube
12536	ZANTAC ranitidine 50mg/2mL (as hydrochloride) injection ampoule
95076	ZANTAC DOUBLE STRENGTH ranitidine 300mg (as hydrochloride) tablet blister pack
71786	ZANTAC ranitidine 150mg (as hydrochloride) tablet blister pack

TGA Ref: RC-2019-RN-01448-1
Date: 1st October 2019

Dear Wholesaler,

Following consultation with the Therapeutic Goods Administration (TGA), Aspen Pharmacare Australia Pty Ltd is undertaking a Retail Level Recall of these products. We are contacting you as our records indicate potentially affected product has been supplied to your warehouse.

ISSUE	• Aspen Pharmacare has initiated this retail level recall following the confirmation of trace amounts of N-Nitrosodimethylamine (NDMA) as being present, which is consistent with several other products globally.
HAZARD	• NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. It is also a known environmental contaminant found in water and foods, including meats, dairy products, and vegetables; and • The actual health risks depend on dose and will vary from person to person. While long-term exposure, over years, can increase an individual's risk of developing cancer, the risks from short-term use are expected to be extremely low.
CUSTOMER ACTIONS	• Inspect stock on hand and quarantine all impacted product to prevent further use; • Complete and return the attached Acknowledgement Form to Aspen at **aspenrecalls@linfox.com.au** even if you do not have

	impacted stock in your inventory; • If you have supplied or transferred a potentially affected product to another facility or organisation, let that facility know of the recall immediately by providing them a copy of this letter. • Return of Stock: - Contact Linfox Healthcare Logistics by email at **aspenrecalls@linfox.com.au** to arrange for the return of the stock and a suitable refund will be applied.
ADVICE FOR CONSUMERS	• Patients and customers who wish to use a substitute medicine should speak to their doctor or pharmacist in the first instance. For patients that have been prescribed ranitidine, the risks of sudden cessation and/or not treating their condition at all, will likely pose a greater risk to their health than what this anomaly poses. Therefore, these individuals should not stop taking ranitidine until they have spoken to their doctor or pharmacist about alternative treatments.
CONTACT INFORMATION	For further information or guidance regarding this letter, please contact: **Aspen Contact Centre** **Tel: 1300 659 646**

Further information will be available on the TGA website which will be periodically updated: https://www.tga.gov.au/alert/ranitidine.

This is a global anomaly, that affects more than one type and brand of medicine.

Please place this letter in a prominent position for one month to cover any stock that happens to be in transit currently.

Thank you for your assistance in helping us to manage this recall. We apologise for any inconvenience caused.

Yours sincerely,

Evelyn Anderson
Regional Head of Scientific Affairs

Customer acknowledgement form

Please complete this form *even if you do not have any affected stock.*

URGENT MEDICINE RECALL

TGA Recall Reference Number: RC-2019-RN-01448-1

AUST R	PRODUCT NAME	GTIN/Barcode
35188	ZANTAC ranitidine 150mg/10mL (as hydrochloride) oral liquid bottle	9331134927279
53324	ZANTAC ranitidine 150mg (as hydrochloride) tablet blister pack	9331134927255
53323	ZANTAC ranitidine 300mg (as hydrochloride) tablet blister pack	9331134927262
45993	ZANTAC ranitidine 150mg (as hydrochloride) effervescent tablet tube	9331134927248
12536	ZANTAC ranitidine 50mg/2mL (as hydrochloride) injection ampoule	9331134927231
95076	ZANTAC DOUBLE STRENGTH ranitidine 300mg (as hydrochloride) tablet blister pack	9331134928474 9331134927712
71786	ZANTAC ranitidine 150mg (as hydrochloride) tablet blister pack	9331134927682 9331134927699 9331134927705

On behalf of this organisation I acknowledge receipt of the ZANTAC Recall notice dated 1st October 2019 relating to the above products.

FROM:

Organisation	
Position	
Name	
Email or fax no.	
Telephone no.	
Date	
Signature	

Affected Stock

If you have **no affected** stock, tick this box: ☐ If you have affected stock, please complete the stock details table below.

Product	Batch no.	Expiry date	Quantity of stock

Total number of affected products:			
Other relevant details:			

Other organisations

Has your organisation supplied potentially affected product to any other organisation?

☐ No

☐ Yes I/we will forward all the recall information to the suppliers/distributors/customers

OR

☐ Yes (please supply names and contact information of the organisations)

Return completed forms by email to:

Organisation	Aspen Pharmacare Australia Pty Ltd
Address	34-36 Chandos St, St Leonards NSW 2065, Australia
Email	aspenrecalls@linfox.com.au
Subject of email	ZANTAC RECALL
Telephone no.	1300 659 646
Fax no.	(02) 9437 0081