# Zantac Recall

Two pharmaceutical companies have voluntarily recalled the ranitidine-containing indigestion medication Zantac after a potentially carcinogenic impurity was identified in it last month.

On 23 September, Medsafe issued an alert that all medicines containing ranitidine may contain an impurity called N-nitrosodimethylamine (NDMA).

While Medsafe’s alert says the potential NDMA contamination would only be at a low level and poses no immediate health risk, there is a small long-term risk NDMA may cause cancer.

Medsafe did not issue a recall notice for the products, but two of the four New Zealand suppliers of ranitidine-containing medicines have since independently taken action.

The notice comes after the US Food and Drug Administration found “unacceptable” levels of the impurity in the drugs, prompting GSK, the manufacturer of the ranitidine-containing medicine brand Zantac, to issue a global recall notice.

Reporting by the *BBC* says GSK is currently investigating the source of the NDMA contamination.

According to Medsafe, all products containing ranitidine sold in New Zealand may be affected. These are:

* Zantac solution for injection sponsored by GSK New Zealand
* Zantac 150mg and 300mg tablets sponsored by Aspen Pharmacare New Zealand
* Peptisoothe syrup sponsored by AFT Pharmaceuticals
* Ranitidine Relief 150mg and 300mg sponsored by Mylan New Zealand

# Zantac tablets and injections recalled

Healthcare Logistics issued a recall notice for Zantac 150mg and 300mg tablets on behalf on the products’ sponsor Aspen Pharmacare New Zealand, on 4 October. The tablets are available over the counter.

In an emailed statement, Aspen’s consumer business manager Carol Gardiner says the recall was done following Medsafe’s advice.

“Aspen New Zealand treats the quality of its products with the utmost diligence and will continue to work closely with Medsafe on this matter,” Ms Gardiner says.

The company confirmed the recall notice had been sent to all pharmacies, but was unable to provide figures for how much product had been returned to date.

GSK New Zealand is also recalling all doses of Zantac Injection, Zantac’s injectable solution, which is available by prescription.

GSK head of communications Australia New Zealand Madeleine Breckon says, via email, it is too early in the recall process to say how many units have been recalled.

AFT Pharmaceuticals was approached for comment but had not responded at the time this article was published.

Meanwhile, Mylan New Zealand’s head of marketing Barnaby Luff confirms his company has not recalled its Ranitidine Relief products as there is no recall in New Zealand.

Mylan is continuing its discussions with Medsafe about ranitidine, Mr Luff says.

# Medsafe watching situation

Medsafe compliance manager Derek Fitzgerald says the regulator is aware ranitidine-containing products have been recalled or their supply put on hold in some other countries.

“Medsafe is in the process of confirming the situation with the four companies involved in supplying ranitidine products in New Zealand and we hope to update our website as soon as we have this information confirmed,” Mr Fitzgerald says.

He is not aware of any adverse reaction reports of cancer in relation to long term ranitidine use in New Zealand, but says Medsafe has asked the Centre for Adverse Reactions Monitoring for an update.

Medsafe is also working with international regulators and the suppliers of medicines containing ranitidine to investigate issues relating to impurities in the medicines.

# How dangerous is NDMA?

Mr Fitzgerald says NDMA is commonly found in some foods, water and air, and acceptable levels of nitrosamines are based on safe levels if taken every day for 70 years.

The levels of NDMA impurity detected in ranitidine to date, if taken over decades, may modestly increase the risk of developing cancer, he says.

“It is not possible to provide an accurate estimate of the magnitude of carcinogenic risk associated with NDMA impurity based on currently available safety data.”

He advises health professionals with a patient who is worried about taking ranitidine to change them to an alternative treatment.

“The risks for patients taking low dose, occasional ranitidine remain very low.”