



SINGAPORE, 16 SEPTEMBER 2019

## HSA UPDATES

***“HSA UPDATES” addresses topics of current public interest, and is subject to change as more information becomes available.***  
**HSA UPDATES NO 8/2019**

### **HSA STOPS SUPPLY OF EIGHT BRANDS OF RANITIDINE PRODUCTS IN SINGAPORE**

Eight brands of ranitidine medicines have been found to contain trace amounts of a nitrosamine impurity, N-nitrosodimethylamine (NDMA), which are above the internationally acceptable level. As a precautionary measure, the Health Sciences Authority (HSA) is stopping the sale and supply of the affected ranitidine medicines at clinics, hospitals and pharmacies [see Table A for full list of medicines].

**Table A. List of recalled ranitidine-containing products**

	<b>Product name</b>	<b>Local supplier</b>
1	Aciloc 150 Tablet 150 mg Aciloc 300 Tablet 300 mg	Uni Drug House
2	Apo-Ranitidine Tablet 150 mg	Pharmaforte Singapore Pte Ltd
3	Hyzan Tablet 150 mg	Apex Pharma Marketing Pte Ltd
4	Neoceptin R-150 Tablet 150 mg	Pharmatech Resources (FE) Pte Ltd
5	Vesyca Film Coated Tablet 150 mg	Yung Shin Pharmaceutical (Singapore) Pte Ltd
6	Xanidine Tablet 150 mg	Polymedic Trading Enterprise Pte Ltd
7	Zantac Injection 25 mg/ml Zantac Syrup 150 mg/10 ml Zantac Tablet 150 mg	GlaxoSmithKline Pte Ltd
8	Zynol-150 Tablet 150 mg	Naina Mohamed & Sons Private Limited

2. The potential risk of nitrosamines is associated with long term exposure, and patients who have been prescribed with the affected ranitidine medicine for short term use may continue with their medicine. Patients who have any questions about their current treatment can speak to their doctor or pharmacist. There are several other medicines that can be used as alternatives to manage the same conditions.

3. Ranitidine is a medicine used to reduce the production of acid in the stomach in patients with conditions such as heartburn and gastric ulcers. It is generally prescribed for short term use of a few days to a few weeks, and used only when necessary.

4. HSA has tested all locally marketed brands of ranitidine and found trace amounts of the NDMA nitrosamine, that exceeded the internationally acceptable level, in eight brands. Acceptable levels of nitrosamines are set in nanograms (ng), i.e., one billionth of a gram, and is based on what is considered as reasonably safe if a patient continues to take the affected medicine every day for a lifetime of 70 years.

5. In line with the stringent standards set by HSA on the quality of medicines in Singapore, HSA has directed the companies to stop the sale and supply of the affected brands of ranitidine medicines at clinics, hospitals and pharmacies. HSA is also working with the companies supplying these medicines and international regulatory agencies to verify the causes of the contamination, and to identify the necessary measures to address the issue.

### **About NDMA**

6. NDMA is a nitrosamine impurity. Nitrosamines are environmental contaminants and can be found in food or the environment in very minute amounts. For example, NDMA can be found in processed food (pickled vegetables, salted fish, processed meat products such as bacon and sausages). Nitrosamine impurities have recently also been found to be formed unexpectedly during the manufacture of some medicines. Recalls had been undertaken worldwide for affected products found to contain these impurities above the acceptable levels. Studies have reported that exposure over a prolonged period of time to doses of nitrosamine impurities that are much higher than usual human exposure could cause cancer in animals.

**HEALTH SCIENCES AUTHORITY  
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#### ▪ **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

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