



SINGAPORE, 4 DECEMBER 2019

HSA UPDATES

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HSA UPDATES NO 11/2019

HSA RECALLS THREE OUT OF 46 METFORMIN MEDICINES

Three metformin 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 recalling these three metformin medicines that are used to control high blood sugar levels in diabetic patients [see Table A for the list of recalled metformin medicines].

Table A: List of recalled metformin medicines

	Product name	Batch Recalled	Local supplier
1	Glucient XR Tablet 500mg	One batch: 2881382	Glorious Dexa Singapore
2	Meijumet Prolonged Release Tablet 750mg	All batches	Pharmazen Medicals Pte Ltd
3	Meijumet Prolonged Release Tablet 1000mg	All batches	Pharmazen Medicals Pte Ltd

Please refer to Annex A for photos of the recalled metformin medicines.

2. HSA has tested all 46 locally marketed metformin medicines. 3 out of 46 metformin medicines were found to contain NDMA above the acceptable level. The other 43 metformin medicines are not affected.

3. The risk to patients who have been taking the 3 affected metformin medicines is very low. This is because the potential risk of nitrosamines is associated with long-term use, and the 3 affected medicines have only been supplied locally for a short period of time since last year.

4. Patients taking the affected metformin medicines are advised not to stop treatment on their own, as the sudden stopping of medicines will raise blood sugar levels, which may pose a greater health risk than the trace amounts of NDMA in the affected medicines.

5. HSA has advised healthcare professionals to contact their patients who are taking the affected medicines to arrange for an exchange of their medicines as soon as practicable. Patients who are concerned about their current treatment can speak to their doctor or pharmacist.

6. HSA is 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.

7. Consumers can contact HSA at 6866-3538 or email to contact_hprg@hsa.gov.sg if they have further enquiries.

About NDMA

8. NDMA is a type of nitrosamine impurity that can be found in food or the environment. They are commonly found in low levels in processed food (pickled vegetables, salted fish, processed meat products such as bacon and sausages) and in air pollution. 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. 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 years¹. The additional risk posed by NDMA from metformin, at the levels detected, is considered very low.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
4 DECEMBER 2019**

▪ **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/>.

¹ For example, the added cancer risk from an additional 6-month exposure is estimated to be less than 0.00002%.

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The “HSA Updates” seeks to provide current information, in a consistent and accurate manner, on topics of public interest. For all issues of HSA Updates, please visit www.hsa.gov.sg click “News & Events”, and select “HSA Updates”.

Media representatives are welcome to send any queries to the Corporate Communications Department @ HSA.

Photos of recalled products

Glucient XR Tablet 500mg



Meijumet Prolonged Release Tablet 750mg



Meijumet Prolonged Release Tablet 1000mg

