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Product Recall

Product Name	Licence Number	Batch No.
Zantac 150 mg Film-coated Tablets	PA1077/13/3	All in-date batches

3rd October 2019

Dear Pharmacist,

Further to GSK's recall letter of 24th September 2019, we wish to advise you that all in-date batches of Zantac 150 mg Film-coated Tablets are being recalled with immediate effect.

Please note that, at this time, no additional batches of the intravenous and syrup presentations of Zantac have been included in this second recall action, on the basis that there is no evidence that the impurity has caused any harm to patients and that there are no immediate alternatives to these prescribed medicines. This is at the request of the Health Products Regulatory Authority (HPRA).

This recall is going to **pharmacy level**. Please note that there is no requirement to contact patients.

This action has been agreed with the HPRA.

The reason for the recall is the following:

- A nitrosamine impurity has been identified in ranitidine active substance batches manufactured at a manufacturing site in India. Ranitidine active substance from that site was included in the above product. This impurity, N-Nitroso dimethylamine (NDMA), has been classified as a probable human carcinogen.
- At present, there is no evidence that this impurity has caused any harm to patients and this pharmacy level recall is being undertaken as a precautionary measure.

Please perform the following actions:

1. Immediately quarantine any units of the above referenced product which are in your possession. For hospital pharmacies, this includes wards, clinics and any other relevant locations within the hospital.

2. Hospital Pharmacists: Please inform relevant prescribers within your hospital of this recall action so that they can be made aware of it.

3. Quarantined stock should be returned via the wholesaler from which you sourced the product, clearly stating your pharmacy address details and the number of units being returned. In order to avail of credit, please ensure that quarantined stock is returned by 15th October 2019.

IMPORTANT: There is no requirement to contact patients, as this is a pharmacy level recall.

The HPRA is working with the HSE to identify, where possible and appropriate, suitable alternatives for Zantac 25 mg/ml Solution for Injection/Infusion (PA1077/13/1) and Zantac 150 mg/10ml Syrup (PA1077/13/2). This is an evolving issue and it is possible that a recall by GSK of the Zantac IV and/or syrup product batches may be required from the Irish market at a later date. An update in relation to these presentations will be provided in the coming days.

If you have supplied the above-listed product, Zantac 150 mg Film-coated Tablets, to another pharmacy or clinic, please contact them in order that they return the units to you.

Replacement stock of these products is not available to order.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact GSK Quality at telephone number 0876055816.

Yours sincerely,

Bartosz Romanowski
LOC Quality Manager & Responsible Person