Medicinal Products containing Ranitidine – Guidance for Prescribers

Precautionary recalls of a number of presentations of medicinal products containing the active ingredient **ranitidine** have occurred in Ireland. The recalls were to pharmacy level; packs at patient level were not recalled. These medicinal products are used to treat duodenal and gastric ulcers, post-operative ulcers, reflux oesophagitis, Zollinger-Ellison syndrome and other conditions where reduction of gastric acid secretion is likely to be beneficial. They are also used for the prevention of non-steroidal anti-inflammatory drug-associated duodenal ulcers, especially in patients with a history of peptic ulcer disease.

The medicinal products recalled included **Zantac®**, **Gertac®** and **Ranitic®** tablets. The recalls followed the identification of an impurity called N-Nitroso dimethylamine (NDMA) which is classified as a probable human carcinogen. The Human Products Regulatory Authority (HPRA) co-ordinated these recall actions and issued a safety notice on the HPRA website that indicated that there is no evidence to date that this impurity has caused any harm to patients.

Certain batches of the intravenous and syrup presentations of Zantac® were not included in the recall. This was to ensure continuity of supply for paediatric and other patients who may have required these products. The available supplies of these products are likely to be very limited at this time, and therefore patients currently prescribed Zantac®, Gertac® and Ranitic® tablets **should not be switched to Zantac® Syrup.**

Prescribers should anticipate a shortage of Zantac®, Gertac® and Ranitic® tablets for the foreseeable future which will have implications as over 16,000 patients are in receipt of ranitidine on the community drug schemes on a monthly basis.

Action for Prescribers

Prescribers will be required to prescribe an alternative drug for their patients due to the unavailability of medicinal products containing ranitidine. The HSE-Medicines Management Programme (MMP) has reviewed the Summary of Product Characteristics of medicinal products containing ranitidine that are available on the community drug schemes and the associated therapeutic indications. Proton Pump Inhibitors (PPIs) represent a suitable alternative treatment for the vast majority of patients who are currently prescribed ranitidine in the primary care setting. The MMP has reviewed this drug class and recommends **Pantoprazole** as the preferred PPI.

The table overleaf outlines the licensed therapeutic indications for tablet presentations of medicinal products containing ranitidine that are available on the community drug schemes (i.e. Zantac®, Gertac® and Ranitic® tablets), and the corresponding licensed doses of pantoprazole for these indications.

Table 1: Licensed indications for tablet presentations of medicinal products containing ranitidine and the corresponding licensed doses of pantoprazole

Licensed indications for medicinal products containing ranitidine	Licensed doses of Pantoprazole	Points to note
Treatment of duodenal ulcer	40 mg daily*	Two-week treatment course is usually sufficient
Treatment of gastric ulcer	40 mg daily*	Four-week treatment course is usually sufficient
Treatment of reflux oesophagitis	40 mg daily*	Four-week treatment course is usually required
Long-term management and prevention of relapse in reflux oesophagitis	20 mg daily	• Increase to 40 mg daily if a relapse occurs • Reduce dose to 20 mg daily upon healing of the relapse
Treatment of Zollinger-Ellison syndrome	80 mg daily initially	• Dose can be titrated up or down as needed using measurements of gastric acid secretion to guide • With doses above 80 mg daily, the dose should be divided and given twice daily
Prevention of non-steroidal anti-inflammatory drug-associated duodenal ulcers	20 mg daily	

*In individual cases, the dose may be doubled to 80 mg daily especially when there has been no response to other treatment

Dual Prescribing of Ranitidine and a Proton Pump Inhibitor

Analysis of pharmacy claims submitted to the HSE-Primary Care Reimbursement Service indicate that approximately 20% of patients who are in receipt of ranitidine on the community drug schemes are also dispensed a PPI. The MMP recommends that these patients continue on treatment with their current PPI, and should be reviewed if they present with recurring symptoms.

Resources for Prescribers

The MMP has published prescribing tips and tools for Proton Pump Inhibitors for the treatment of gastro-oesophageal reflux disease.

The Summary of Product Characteristics for medicinal products containing pantoprazole are available on the HPRA website; these should be consulted in advance of prescribing pantoprazole.