Ranitidine – MHRA drug alert issued for Teva UK recall

The MHRA has issued an alert to healthcare professionals, as Teva UK Ltd is recalling all unexpired stock of certain batches of 2 types of Ranitidine medicines used to treat conditions such as heartburn and stomach ulcers.

The 2 products affected are Ranitidine Effervescent Tablets 150 micrograms and 300 micrograms. The list of batches affected can be checked on the MHRA's drug alert.

Healthcare professionals have been told to stop supplying the two products immediately. All remaining stock should be quarantined and returned without delay to the supplier.

Patients should not stop taking their medication, and a treatment review is not necessary until the next routine appointment.

The recall is a precautionary measure due to possible contamination of the active substance in Zantac, ranitidine, with an impurity called NDMA (N-nitrosodimethylamine) which has been identified as a risk factor in the development of certain cancers.

The MHRA is actively involved with the European Medicines Agency (EMA) and other medicines regulators to determine the impact of what is an ongoing, global issue. On 8 October, a drug alert was also issued regarding the withdrawal of four types of prescription-only Zantac products.

An investigation into other potentially impacted products is continuing and further updates will be provided as the investigation progresses. Other Ranitidine products have been quarantined, and the Department of Health and Social Care (DHSC) issued an alert on 15 October regarding shortages of the medicine and advice to healthcare professionals on alternative treatments.

Dr Andrew Gray, MHRA Deputy Director of Inspections, Enforcement & Standards, comments:

"Whilst this action is precautionary, the MHRA takes patient safety very seriously.

"Patients should keep taking their current medicines but should speak to their doctor or pharmacist if they are concerned and should seek their doctor's advice before stopping any prescribed medicines.

"We have asked companies to quarantine batches of potentially affected medicines whilst we investigate and we will take action as necessary, including product recalls where appropriate.

"We have also requested risk assessments from the relevant companies which will include the testing of potentially affected batches.

“Currently, there is no evidence that medicines containing nitrosamines have caused any harm to patients, but the Agency is closely monitoring the situation, and working with other Regulatory Agencies around the world.”

ENDS

Note to editors:

1. Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

2. MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). MHRA is an executive agency of the Department of Health and Social Care.