Zantac – MHRA drug alert issued as GlaxoSmithKline recalls all unexpired stock

The MHRA has issued an alert to heathcare professionals, as GlaxoSmithKline is recalling all unexpired stock of four types of Zantac, the medicine used to treat conditions such as heartburn and stomach ulcers.

The four products affected are Zantac 150mg/10ml Syrup, Zantac 50mg/2ml Injection, Zantac 150mg Tablets and Zantac 300mg Tablets. All four are prescription only medicines. Over-the-counter products (Zantac 75 Relief (PL 02855/0081 [GSL]) and Zantac 75 Tablets (PL 02855/0082 [P]) are produced by a different company and are not affected by this recall.

The MHRA is advising that patients should not to stop taking their medication, and do not need to see their doctor until their next routine appointment but should seek their doctor's advice if they have any concerns.

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.

Healthcare professionals have been told to stop supplying the products immediately, quarantine all remaining stock and return it to their supplier.

An MHRA investigation into other ranitidine medicines which may also be affected is continuing and further updates will be provided as this investigation progresses. The MHRA has asked manufacturers to quarantine all ranitidine products which may contain the active pharmaceutical ingredient that is potentially affected by this issue.

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 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.