NHS Midlands and Lancashire Commissioning Support Unit

Prescribing tip for information and action

MHRA warning: Supply disruption of ranitidine containing products

An investigation by Swiss and German regulatory agencies and the FDA has identified a contaminant, N-nitrosodimethylamine (NDMA), a probable human carcinogen, in samples of ranitidine active substance. Several ranitidine products manufactured for the UK market may contain this active substance contaminated with NDMA. The Medicines and Healthcare products Regulatory Agency (MHRA) has requested all UK manufacturers using active ingredient from this source quarantine all stock whilst further investigations are ongoing

What action has been taken by manufacturers to date?

The MHRA issued an alert to heathcare professionals, as GlaxoSmithKline recalled all unexpired stock of four types of Zantac, the medicine used to treat conditions such as heartburn and stomach ulcers. **Healthcare professionals have been told to stop supplying the products immediately, quarantine all remaining stock and return it to their supplier**.

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 Department of Health and Social Care (DHSC) have issued an alert on 15th October 2019 stating **all oral formulations of ranitidine are anticipated to be out of stock with no date for resupply until further notice.**

All stock manufactured for the UK using the affected ranitidine active substance has been quarantined whilst MHRA undertake further investigations. Currently all but three UK manufacturers are affected by this situation although this could change at any time as investigations continue. **There are insufficient supplies available from the unaffected manufacturers to continue to support current usage of oral ranitidine across the UK.**

Although all oral formulations are expected to be out of stock, very limited supplies of unaffected oral ranitidine products may remain available and should be reserved for those patients in whom alternatives are not clinically appropriate.

Advice for practices

1. Identify current patients prescribed ranitidine tablets, effervescent tablets and oral solutions and review if ongoing treatment is still required.
2. If ongoing treatment is still required, then consider switching to an alternative treatment. Further information on suitable alternatives can be found here. It is recommended that omeprazole is the first-choice proton pump inhibitor (PPI) where clinically appropriate as there are currently sufficient supplies to manage an increase in demand.
3. **It is recommended that patients are not switched to an alternative H2-receptor antagonist in the first instance as this may exacerbate a shortage of these products. Sufficient supplies will continue to be available to meet existing demand.**

To contact the Medicine Optimisation Team please phone 01772 214302