Precautionary recall of antidepressant medication due to manufacturing error

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The MHRA has advised healthcare professionals to stop supplying the affected batch of Sertraline 100mg and return all remaining stock to their suppliers.

Amarox Limited is recalling one batch of Sertraline 100mg film-coated tablets as a precautionary measure due to a manufacturing error that led to two antidepressant medicines being packaged incorrectly.

The recall follows a patient complaint which helped identify that a pack of Sertraline 100mg film-coated tablets contained one blister strip of Citalopram 40mg film-coated tablets inside the sealed carton.

Sertraline and citalopram are both selective serotonin reuptake inhibitors (SSRIs) used to treat depression, anxiety disorders, and related mental health conditions by boosting brain serotonin.

Both SSRI medications are produced by the same manufacturer, at the same site, and the error appears to have occurred during secondary packaging of the blister strips into the cartons.

Patients who believe they have already taken any Citalopram 40mg tablets by mistake or are experiencing side effects, are advised to seek medical advice immediately.

Dr Alison Cave, MHRA Chief Safety Officer, said:

“If you have been prescribed Sertraline 100mg tablets and have received batch number V2500425, please check the carton contains the right medication. You can find the batch number and expiry date printed on the side of the outer packaging.

“If the blister strips inside the carton are labelled Citalopram 40mg, please contact your pharmacy as soon as possible. If they are labelled Sertraline 100mg, no further action is needed.”

“Patients who have accidentally taken citalopram instead of - or as well as - sertraline, may experience some heightened serotonergic side effects. These can include nausea, headache, sleep changes, and mild anxiety.”

Pharmacists, or any other healthcare professionals involved in dispensing should identify and contact any patients who may have been dispensed the impacted product and request it be returned if they have any remaining medicine.

If any patients are identified with this product, pharmacists and other healthcare professionals involved in dispensing should contact the patients’ GP, or clinician responsible for the care of the patient, to discuss treatment review and whether a new prescription is required for ongoing resupply.

Patients may need to be monitored by their doctor or another healthcare professional, particularly if they are over 65 or under 18, have cardiac or liver conditions, or have been told that their body processes certain medicines differently.

Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

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Notes to editors

- Please see MHRA's Class 2 recall for further information and images of the affected product.

- The MHRA 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.

- The MHRA is an executive agency of the Department of Health and Social Care.

- For media enquiries, please contact the newscentre@mhra.gov.uk, or call on 020 3080 7651.

https://www.gov.uk/government/news/precautionaryrecall-of-antidepressant-medication-due-to-manufacturing-error