Precautionary recall of specific batches of blood pressure drug irbesartan

Press release

As a precaution, companies are recalling some batches of irbesartan medicines due to presence of a chemical substance (AZBT) in an amount over the limit permitted for this product. Patients taking irbesartan medicines should continue to take their medication.

A total of 44 batches of irbesartan medicines are being recalled as a precaution from pharmacies and wholesalers due to presence of a chemical substance (AZBT) formed in the manufacturing process that is over the limit permitted for this product.

Irbesartan medicines treat high blood pressure to help prevent heart attacks and stroke. They are also used in patients with heart failure or those who had a recent heart attack.

Patients being prescribed these medicines should continue to take their medication since the risk from stopping is greater than the risk associated with short-term exposure to ABZT above its acceptable level from packs that they already have. Not treating a patient’s high blood pressure or heart problems may lead to harms, so patients should not stop their treatment unless clinically advised.

Laboratory testing has found that long-term exposure to this chemical substance (AZBT) above acceptable limits may potentially increase the risk of cancer, but there is no UK or international evidence that this substance has caused any harm to patients. The MHRA, in collaboration with regulatory counterparts around the world, has set internationally-recognised acceptable daily intake limits for AZBT. If medicines contain levels of AZBT above this limit, these need to be recalled by the manufacturer as a precaution.

The MHRA continues to work with its international counterparts to better

understand the risk and with the Department of Health and Social Care to ensure that an adequate supply of these medicines remains available for patients.

Dr Alison Cave, MHRA Chief Safety Officer, said:

“Patient safety is at the heart of everything we do. This recall is a precautionary measure to prevent further exposure to AZBT above the acceptable safety limit. There is no evidence that this substance has caused any harm to patients. “It’s vitally important that you continue to take your medicine but do contact your doctor or pharmacist if you have any questions.

“It’s important that healthcare professionals check their stock to quarantine and return these batches to their supplier using their supplier’s approved process.

“The MHRA has asked companies to implement control measures to ensure that the levels of the substance are at or below the required level. We are also working with our international counterparts, given this is a global issue, to ensure the safety of patients.”

Notes to Editor

Published 30 November 2021