<u>MHRA recalls contaminated Irbesartan-</u> <u>batches as precautionary measure</u>

Press release

Patients should not stop any treatments without consulting their doctor or pharmacist



The MHRA today has issued a recall for 25 batches of Irbesartan-containing medicinal products due to contamination with an impurity that could potentially increase the risk of cancer over time.

This is a precautionary measure to prevent further use and there is no evidence that this impurity (5-(4'-(azidomethyl)-[1,1'-biphenyl]-2yl)-1H-tetrazole), has caused any harm to patients. The recall is for pharmacies and wholesalers and is not a patient-level recall. Suddenly stopping medication for high blood-pressure can be risky, so patients should not stop any treatments without consulting their healthcare team.

The MHRA continues to work with the Department of Health and Social Care to ensure that an adequate supply of these products remains available for patients.

See all batch numbers at <u>Class 2 Medicines Recall: Various Marketing</u> <u>Authorisation Holders and parallel distributor companies, Irbesartan-</u> <u>containing products, EL (21)A/19</u>

Dr Alison Cave, MHRA Chief Safety Officer, said:

Patient safety is at the heart of what we do. We're recalling batches of certain sartan-containing products as a precautionary measure while we continue our investigation. It's important that healthcare professionals check their stock to quarantine and return these batches. If you've been taking one of the affected products, continue to take your medication. Speak with your doctor or pharmacist before stopping any treatment — they can address any concerns and can advise you on the best course of action.

Previous recalls of these types of products in 2018, 2019 and June 2021 are part of an ongoing investigation. The MHRA is working with other medicines regulators on this issue.

Notes to editors

- The 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.
- Sartan-containing medicines are indicated for essential hypertension, heart failure, and treatment of renal disease in adult patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive regimen

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