

MHRA recalls contaminated Irbesartan and Losartan batches as precautionary measure

Press release

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



The MHRA today has issued a recall for 31 batches of Irbesartan-containing medicinal products and 2 batches of Losartan-containing medicinal products due to contamination with azido-tetrazole (a substance that can potentially increase the risk of cancer over time).

This is a precautionary measure to prevent further exposure and there is no evidence that this impurity 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 are advised not to stop any treatments without consulting their healthcare team.

The MHRA has already contacted UK licence holders for the affected batches, who have been asked to quarantine the affected stock while the investigation continues. We continue 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 [Class 2 Medicines Recall: Bristol Laboratories Limited, Brown & Burk UK Ltd, Teva UK Ltd, Irbesartan-containing and Losartan-containing products, EL \(21\)A/14](#)

Dr June Raine, MHRA Chief Executive, said:

Patient safety is our watchword. 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, 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 and 2019 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

Published 17 June 2021