Press release: Blood pressure and heart medication recalled from Pharmacies

Pharmacies in the UK are being advised to recall all batches of valsartan containing medicines made by Dexcel Pharma Ltd and Accord Healthcare (previously known as Actavis Group) as a precaution, the Medicines and Healthcare products Regulatory Agency's (MHRA) has warned today. This follows an urgent investigation in to medicines containing valsartan used to treat high blood pressure and heart conditions.

A recall is underway across Europe following recent and emerging information that an impurity has been identified as part of the manufacturing process in a valsartan active substance manufactured at one facility based in China. This facility has supplied the manufacturers with the valsartan active substance. The impurity (N-nitrosodimethylamine), which may have carcinogenic potential, is a result of a change in the manufacturing process. This active substance is used in a number of medicines marketed in Europe.

The European Medicines Agency and other EU regulators are working together to investigate the extent of the issue and any possible impact for patients.

If you are taking any of the affected valsartan products, it is vital that you do not stop taking your medication but you should get in touch with a doctor or healthcare professional as soon as possible. Alternative valsartan containing products, that are unaffected by this issue, are available in the UK.

Patient safety is our top priority and we will provide further updates as the investigation progresses.

Dr Sam Atkinson, MHRA's Director of the Inspection, Enforcement and Standards Division said:

People taking valsartan medication affected by this recall are advised to not stop taking their medication, but to speak to their doctor or healthcare professional who can advise on alternative treatment.

We continue to undertake an urgent review of all these products that may pose a low risk to public health.

We will communicate the outcome of our investigations and ensure that any other affected products are recalled.

Our highest priority is to ensure that the medicines you take are safe.

If you are concerned, please speak to your GP, pharmacist or other healthcare professional.

We strongly encourage anyone taking Valsartan medicines to report any suspected side effects, to us via our <u>Yellow Card Scheme</u>.

Notes to Editor

- 1. MHRA is responsible for regulating all medicines and medical devices in the UK. All our work is underpinned by robust and fact-based judgments to ensure that the benefits justify any risks. MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The Agency is an executive agency of the Department of Health. www.mhra.gov.uk
- 2. Link to Yellow Card Scheme
- 3. [MHRA Drug Alerts](https://www.gov.uk/drug-device-alerts

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Office hours are Monday to Friday, 8:30am to 5pm. For real-time updates including the latest press releases and news statements, see our Twitter channel at https://www.twitter.com/mhrapress