Press release: MHRA recalls Valsartan blood pressure and heart medication from pharmacies

The Medicines and Healthcare products Regulatory Agency (MHRA) are undertaking a pharmacy level recall of all affected batches of Valsartan containing medicines made by Mylan and Teva as a precautionary measure.

This follows an earlier pharmacy level recall in July, when MHRA recalled affected batches of valsartan containing medicines from Dexcel and Actavis (now Accord), also to pharmacy level.

That recall occurred across Europe, following information that an impurity, N-nitrosodimethylamine (NDMA) was identified as part of the manufacturing process in a valsartan active substance manufactured at one facility based in China.

During the course of the investigation into NDMA, another impurity, N-nitrosodiethylamine (NDEA), was discovered in valsartan drug substance. MHRA, together with other EU regulators, are continuing to investigate other sartan products which share a similar chemical structure to valsartan.

At present there is no evidence that this impurity has caused any harm to patients. This recall is being undertaken as a precautionary measure to prevent further exposure to this impurity in the affected medicines whilst the investigation is ongoing. Due to the risk associated with suddenly stopping high blood pressure medication, people are therefore advised not to stop any treatments without consulting their doctor or pharmacist.

We are working closely with other EU member states, the European Medicines Agency (EMA) and the European Directorate for the Quality of Medicines (EDQM) to ensure a thorough investigation and we will consider the impact in the UK and what actions may be necessary.

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

> Our highest priority is making sure the medicines you take are safe.
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> We are undertaking a pharmacy level recall of all affected batches of Valsartan containing medicines made by Mylan and Teva. This is a precautionary measure to prevent any further exposure to the impurity in the affected medicines whilst the investigation continues and further updates will be provided.
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> Because of the risk associated with suddenly stopping high blood pressure medication, people are advised not to stop any treatments

without consulting their doctor or pharmacist.

We strongly encourage anyone taking valsartan medicines to report any suspected side effects, to us via our Yellow Card Scheme.

Please speak to your GP, pharmacist or any other healthcare professional if you take the affected medicines and they will be able to advise and answer any questions.

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. Link to Drug Alert