Press release: Additional blood pressure and heart medication recalled from pharmacies

The Medicines and Healthcare Products Regulatory Agency (MHRA) today recalled 3 batches of Irbesartan. The affected batches can be viewed here.

The recall is taking place as part of the continued investigation into potential N nitrosodiethylamine (NDEA) contamination of sartan containing medicines, a class of medicine to treat blood pressure and heart attacks and heart failures.

Currently there is no evidence that the NDEA impurity can cause harm and patients are being advised to continue taking their medication.

MHRA twice recalled Irbesartan containing products in early and late January 2019 after testing revealed possible NDEA contamination.

The investigation into possible contamination began in 2018, after another impurity, N-nitrosodimethylamine (NDMA), was identified as part of the manufacturing process in a valsartan active substance manufactured at one facility based in China. NDEA was discovered after further testing.

Last year MHRA recalled batches of valsartan to pharmacy level in July and November after due to possible NDMA contamination.

The MHRA continues to monitor the situation in the UK and are comprehensively investigating the issue alongside the European Medicines Agency (EMA) and the European Directorate for the Quality of Medicines (EDQM).

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

> Patient safety is our top priority and we will take any necessary steps to protect public health.
>
> Today's Irbesartan recall shows we are continuing to investigate potential contamination of sartan containing medicines.
>
> There is no evidence at present that medicines containing NDMA or NDEA have caused any harm to patients the recall is occuring as a precaution.
>
> Because of the risk associated with suddenly stopping high blood pressure medication, continue to take your medicines as prescribed by your doctor."
>
> Please speak to your doctor or pharmacist if you have any concerns

about your medicine.

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.
2. In July, MHRA advised pharmacies to recall affected batches of Valsartan containing medicines made by Mylan and Teva as a precautionary measure.
3. In November, we advised pharmacies to recall batches of valsartan from Dexcel and Actavis as a precautionary measure.
4. Earlier this January, MHRA advised pharmacies to recall all affected batches of Irbesartan containing medicines made by Actavis as a precautionary measure. More information [here].(https://www.gov.uk/government/news/irbesartan-blood-pressure-and-heart-medication-recalled-from-pharmacies-by-mhra).
5. In late January, MHRA advised pharmacies to recall all affected batches of Irbesartan containing medicines made by Macleods Pharma UK as a precautionary measure. More information here
6. Find out more about our Yellow Card Scheme.
7. Read the Drug Alert in full for further information.