Press release: Irbesartan blood pressure and heart medication recalled from pharmacies by MHRA

Today the Medicines and Healthcare products Regulatory Agency (MHRA) are recalling certain irbesartan containing products made by Actavis (now Accord) as a precautionary measure, due to possible N-nitrosodiethylamine (NDEA) contamination.

There is no evidence at present that the impurity has caused any harm to patients and not all irbesartan products are affected. People should not stop their medication and should speak to a doctor or pharmacist if they have any concerns.

The recall follows a Europe-wide investigation into contamination of sartan products. MHRA twice recalled batches of valsartan to pharmacy level in 2018; valsartan containing medicines from Dexcel and Actavis (now Accord) were recalled in July and batches of valsartan containing medicines made by Mylan and Teva, were also recalled to pharmacy level in November.

The first recall occurred after 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. A second impurity, NDEA, was later discovered.

MHRA 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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> Our investigation into potential contamination of sartan containing medicines, including irbesartan, is ongoing.
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> At present, there is no evidence that medicines containing NDMA or NDEA have caused any harm to patients.
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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.

Notes to editor

1. In July, MHRA advised pharmacies to recall affected batches of Valsartan containing medicines made by Mylan and Teva as a precautionary measure.
2. In November, we advised pharmacies to recall batches of valsartan from Dexcel and Actavis as a precautionary measure.
3. Find out more about our Yellow Card Scheme.
4. Read the Drug Alert in full for further information.