Press release: MHRA recalls more blood pressure and heart medication from pharmacies as a precaution

Today's recall affects 3 batches of Irbesartan 150mg and 300mg tablets which reached the UK market, supplied by Macleods Pharma UK. Information on which batches are affected can be found here.

The pharmacy-level recall is being undertaken as a precaution as testing revealed 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 continue to take their medication and should speak to a doctor or pharmacist if they have any concerns.

Earlier this month, MHRA advised pharmacies to recall all affected batches of Irbesartan containing medicines made by Actavis.

In 2018, the Agency 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 initial 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.

The MHRA continues to thoroughly investigate the issue alongside the European Medicines Agency (EMA) and the European Directorate for the Quality of Medicines (EDQM). We will continue to monitor the situation in the UK and consider what actions are necessary to protect public health.

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

> Our most important concern is the safety of the medicines you take.
>
> As today shows, we continue to investigate potential contamination of sartan containing medicines such as Irbesartan. We will continue to act and provide updates when appropriate.
>
> Currently, there is no evidence that medicines containing NDMA or NDEA have caused any harm to patients.
>
> Because of the risk associated with suddenly stopping high blood pressure medication, continue to take your medicines as prescribed

by your doctor.

If you have any concerns about your medicine, please speak to your 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. 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. 4. Find out more about our Yellow Card Scheme.