



EUROPEAN MEDICINES AGENCY
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EMA reviewing medicines containing valsartan from Zhejiang Huahai following detection of an impurity

Some valsartan medicines being recalled across the EU

The European Medicines Agency (EMA) is reviewing medicines containing the active substance valsartan that is supplied by Zhejiang Huahai Pharmaceuticals, a company in Linhai, China.

The review was triggered after the company detected an impurity, N-nitrosodimethylamine (NDMA), in the valsartan active substance which the company supplies to manufacturers producing some of the valsartan medicines available in the EU.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured.

While the review is underway, national authorities across the EU are recalling medicines containing valsartan supplied by Zhejiang Huahai.

Valsartan medicines are used to treat patients with high blood pressure in order to reduce complications such as heart attack and stroke. It is also used in patients who have had heart failure or a recent heart attack.

EMA's review will investigate the levels of NDMA in these valsartan medicines, its possible impact on patients who have been taking them and what measures can be taken to reduce or eliminate the impurity from future batches produced by the company. As a precaution, the review will also consider whether other valsartan medicines may be affected.

The review will be carried out by EMA's Committee for Medicinal Products for Human Use (CHMP).

Information for patients

- An unexpected impurity has been found in the active ingredient used to make some valsartan medicines.
- Only some valsartan medicines in the EU are affected and these are being recalled.
- You should not stop taking your valsartan medicine unless you have been told to do so by your doctor or pharmacist.



- You may be given a different valsartan medicine (or an alternative treatment) when you go for your next prescription.
- If you have any questions about your treatment, speak to your pharmacist who can tell you if your medicine is being recalled.
- If you are in a clinical trial with valsartan and have any questions, speak to the doctor treating you in the trial.
- EMA will assess whether the impurity may pose any risk for patients. Further information will be provided once available.

Information for healthcare professionals

- N-nitrosodimethylamine (NDMA) has been detected in the valsartan active substance manufactured by Zhejiang Huahai Pharmaceuticals.
- As a result, valsartan medicines containing the active substance from Zhejiang Huahai are being recalled in the EU.
- National authorities are contacting pharmacists with information on the medicines to be recalled.
- EMA is now evaluating potential impact on patients of the exposure to NDMA in valsartan medicines. Further information will be provided once available.

More about the medicine

Valsartan is an angiotensin-II-receptor antagonist used to treat hypertension (high blood pressure), recent heart attack and heart failure. It is available on its own or in combination with other active substances.

The review covers all medicines that contain valsartan supplied by Zhejiang Huahai Pharmaceuticals. As a precaution, the review will also consider whether other valsartan medicines may be affected.

More about the procedure

The review of medicines containing valsartan supplied by Zhejiang Huahai Pharmaceuticals was triggered on 5 July 2018 by the request of the European Commission, under [Article 31 of Directive 2001/83/EC](#).

The review will be carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.