19 November 2018
EMA/809509/2018

Valsartan from Mylan laboratories in India can no longer be used in EU medicines due to NDEA impurity

Authorities in the EU are taking action after an impurity, N-nitrosodiethylamine (NDEA), was found in some batches of valsartan made by Mylan Laboratories Limited in Hyderabad, India.

EDQM[1] has now suspended the manufacturer's CEP[2] (a certificate of compliance with European standards for quality testing), effectively prohibiting the use of its valsartan in EU medicines.

In addition, national authorities in the EU have started recalling affected batches of medicines containing Mylan's valsartan and are conducting further tests to determine the extent of the contamination.

NDEA and the related compound N-nitrosodimethylamine (NDMA), which have been seen in 'sartans' from other manufacturers, are classified as probable human carcinogens (substances that could cause cancer).

As with previous findings of NDEA and NDMA, there is no immediate risk to patients. It is riskier for patients to suddenly stop taking high blood pressure medication. Patients should therefore not stop any treatments without consulting their doctor or pharmacist.

The presence of impurities in valsartan medicines and other sartans is thought to be linked to the synthesis of a specific ring structure (tetrazole) which is present in some sartan medicines. EMA's review of sartans with this structure is continuing and the Agency is working closely with national authorities, international partners and the EDQM.

Companies marketing sartan medicines in the EU have been asked to test their products for these impurities. Additional testing is being carried out by EU laboratories. EMA will update the public as soon as new information becomes available.

EMA is also working with manufacturers to determine what measures can be taken to reduce or eliminate the impurities from future batches of their products.

[1] European Directorate for the Quality of Medicines and Healthcare
[2] CEP: certificate of suitability to the monographs of the European Pharmacopoeia

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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.

Medicines containing valsartan as the only active substances have been authorised in the EU via national authorities. Nine products containing valsartan in combination with other active substance have been authorised centrally.

More about the procedure

The review of valsartan medicines was triggered by the European Commission on 5 July 2018 under Article 31 of Directive 2001/83/EC. On 20 September 2018, the review was extended to include medicines containing candesartan, irbesartan, losartan and olmesartan.

The review is being 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.