



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA to review ranitidine medicines following detection of NDMA

At the request of the European Commission, EMA is to start a review of ranitidine medicines after tests showed that some of these products contained an impurity called N-nitrosodimethylamine (NDMA).

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) on the basis of animal studies. It is present in some foods and in water supplies but is not expected to cause harm when ingested in very low levels.

EMA is evaluating the data to assess whether patients using ranitidine are at any risk from NDMA and will provide information about this as soon as it is available.

Ranitidine medicines are used widely to reduce the production of stomach acid in patients with conditions such as heartburn and stomach ulcers. They are available over-the-counter and on prescription.

Patients who have any questions about their current treatment can speak to their doctor or pharmacist. There are several other medicines used for the same conditions as ranitidine that could be used as an alternative.

In 2018, NDMA and similar compounds known as nitrosamines were found in a number of blood pressure medicines known as 'sartans', leading to some recalls and to an [EU review](#), which set strict new manufacturing requirements for these medicines.

EMA is [currently working on guidance](#) for avoiding nitrosamines in other classes of medicines. EMA will continue to cooperate with national authorities, [EDQM](#) and international partners to protect patients and ensure that effective measures are taken to prevent these impurities from being present in medicines.

More about the medicine

Ranitidine belongs to a class of medicines known as H2 (histamine-2) blockers, which work by blocking histamine receptors in the stomach and reducing the production of stomach acid.

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It is used to treat and prevent conditions caused by excess acid in the stomach such as heartburn and stomach ulcers. Ranitidine-containing medicines are authorised by national authorities and are available as tablets and injectable formulations.

More about the procedure

The review of ranitidine medicines was initiated on 12 September 2019 at 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 an 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.