# EMA starts a review on ranitidine-containing products following detection of NDMA

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## Information on Ranitidine medicines

- Ranitidine belongs to a class of medicines known as H2 (histsamine-2) blockers, which work by blocking histamine receptors in the stomach and reducing the production of stomach acid
- Ranitidine medicines are used widely to reduce the production of stomach acid in patients with conditions such as heartburn and stomach ulcers
- Ranitidine 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 and are available over-the-counter and on prescription.

## Information from the EMA about NDMA presence in ranitidine products

The Committee for Medicinal Products for Human Use (CHMP) started a review on ranitidine medicines, following the request of the European Commission. The review was started after an impurity called N-nitrosodimethylamine (NDMA) was detected in some products after tests. EMA is now 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.

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

In 2018, NDMA and similar compounds known as nitrosamines were found in some blood pressure medicines known as 'sartans', leading to an EU review, which set strict new manufacturing requirements for these medicines.

To protect patients and ensure that effective measures are taken to prevent these impurities from being present in medicines, the EMA is currently working on guidance for avoiding nitrosamines in other classes of medicines.

The CHMP opinion will be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

For more information please see the European Medicines Agency's press release on Ranitidine

**Reporting Adverse Drug Reactions**

Healthcare professionals and patients are encouraged to maintain vigilance on ranitidine medicines. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.>

**Post-Licensing Directorate**
**Medicines Authority**

***Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.***

**Feedback Form**

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

**Feedback:**

We thank you for your interest and look forward to hearing your opinion.

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Malta Life Sciences Park

San Ġwann SĠN 3000