Metformin diabetes medicines: an update from EMA

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Information on Metformin diabetes medicines

- Metformin is widely used alone or in combination with other medicines to treat type 2 diabetes. It is usually the first-line treatment, and it works by reducing the production of glucose in the body and reducing its absorption from the gut.

Information from the EMA about the safety concern

EMA is aware that trace amounts of an impurity, N-nitrosodimethylamine (NDMA), have been found in a small number of metformin diabetes medicines outside the EU.

The levels of NDMA in the affected non-EU metformin medicines are very low and appear to be within or even below the range that people can be exposed to from other sources, including certain foods and water.

At this point, there are no data indicating that EU metformin medicines are affected. Authorities in the EU are in the process of working with companies to test EU medicines and will provide further updates as more information becomes available.

Patients in the EU should continue taking their metformin medicines as normal. The risk from not having adequate diabetes treatment far outweighs possible effects of the low levels of NDMA seen in tests. Healthcare professionals should remind patients of the importance of keeping their diabetes under control.

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 it is not expected to cause harm when ingested in very low levels.

Last year, NDMA and other impurities of the same class (nitrosamines) were found in some blood pressure medicines known as sartans. Subsequently, EMA started a review of ranitidine medicines and launched a procedure to request companies to take specific measures to avoid the presence of nitrosamines in human medicines, including metformin.

This procedure, known as an Article 5 (3) procedure, is still ongoing and will be used to provide guidance to companies and support the evaluation of data on nitrosamines. The expedited testing of metformin medicines in the EU is part of this procedure.

EMA and national authorities together with international partners and the European Directorate for the Quality of Medicines & HealthCare (EDQM) are continuously sharing information about impurities such as NDMA and are taking action to protect patients and reassure them about the quality of their medicines.

In Malta

For Healthcare Professionals

- Continue prescribing metformin medicines as normal and await further information from authorities in the EU.
- Advise your patients against stopping their diabetes treatment.
- Remind your patients of the importance of keeping their diabetes under control.

Advice for Patients

- Metformin is an effective medicine for controlling blood sugar
- Continue taking your metformin medicine to keep your diabetes under control
- Stopping treatment could make your diabetes become uncontrolled and leave you open to symptoms caused by high blood sugar, including thirst, drowsiness and blurred vision
- Long-term complications of uncontrolled diabetes include heart disease, nerve problems, kidney damage, eye problems and damage to the foot that can lead to amputation.

For more information visit the European Medicines Agency's website at www.ema.europa.eu

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on metformin-containing products. 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:

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Pharmacovigilance Section

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