

Metformin – Safety update

- On December 5, 2019, the [FDA announced](#) that it is investigating whether metformin in the U.S. market contains N-nitrosodimethylamine (NDMA), and whether it is above the acceptable daily intake limit of 96 nanograms.
- Metformin is a prescription drug used to control high blood sugar in patients with type 2 diabetes.
- The agency will also work with companies to test samples of metformin sold in the U.S. and will recommend recalls as appropriate if high levels of NDMA are found.
 - If as part of its investigation, metformin drugs are recalled, the FDA will provide timely updates to patients and health care professionals.
- The FDA is aware that some metformin diabetes medicines in other countries were reported to have low levels of NDMA. Based on the information the FDA has available, the levels of NDMA seen outside the U.S. are within the range that is naturally occurring in some foods and in water.
 - While the FDA is aware that some regulatory agencies outside the U.S. may be recalling some metformin drugs, there are no metformin recalls affecting the U.S. market at this time.
- Improved technology enables the FDA to detect even trace amounts of impurities in drug products and may be the reason why more products have been found to have low levels of NDMA. The FDA also works closely with international drug regulatory agencies so that it can leverage resources and testing done outside the U.S. which can help inform testing of the U.S. drug supply. As the FDA's investigations and testing continues, along with the investigations done by other drug regulatory agencies, the FDA may find low levels of nitrosamines in additional drugs.
- Patients should continue taking metformin to keep their diabetes under control. It could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their health care professional.
- The FDA recommends prescribers continue to use metformin when clinically appropriate, as the FDA investigation is still ongoing, and there are no alternative medications that treat this condition in the same way.
- The FDA will communicate any information it has scientifically confirmed to ensure the public knows as much as possible as soon as possible.