

Batch of metformin oral solution recalled by MHRA due to nitrosamine impurity

Press release

Patients should not stop any treatments without consulting their doctor or pharmacist.



A recall notice for one batch (10,452 units) of metformin oral solution has today been issued by the Medicines and Healthcare products Regulatory Agency (MHRA) as a precautionary measure after it was found to contain a nitrosamine impurity above accepted levels.

The impurity, nitrosodimethylamine (NDMA), has been identified as a risk factor in the development of certain cancers.

At the very low levels that have been detected, nitrosamines only have a potentially harmful effect if consumed over a long period of time and to date there is no evidence that this impurity has caused any harm to patients. The [Class 2 recall](#) to wholesaler dealer and pharmacy level is precautionary to prevent further exposure.

All medicines in the UK are independently tested for quality prior to being made available to the public and there are strict controls in place to limit the presence of this impurity in metformin products. During testing prior to batch release, levels of the impurity NDMA in batch number 0LL0018 of metformin oral solution were found to be within acceptable limits. However, routine monitoring of the batch while on the market showed that levels of NDMA were no longer acceptable at 9 months.

The marketing authorisation holder has placed all remaining stock of metformin oral solution on hold while they investigate this issue further. No other batches have been found to be affected.

Patients are advised to continue taking their medication as directed by their

HCP and should not stop any treatments without consulting their healthcare team. The risks of suddenly stopping medication for type 2 diabetes is higher than the potential risk presented by the impurity. Individuals who are concerned should talk to their pharmacist or GP.

The MHRA continues to work with the Department of Health and Social Care to ensure that an adequate supply of these products remains available for patients.

Dr Alison Cave MHRA Chief Safety Officer, said:

Patient safety is at the heart of everything we do. This recall of one batch of metformin oral solution is a precautionary measure to prevent further exposure to the nitrosamine impurity. There is no evidence to date that this impurity has caused any harm to patients.

Individuals who have metformin oral solution from this batch at home should continue to take their medication. It is very important to speak to your doctor or pharmacist before stopping any treatment – they can address any concerns you may have and can advise you on the best course of action.

Healthcare professionals should check their stock to quarantine and return any units from this batch to their supplier using their supplier's approved process.

Notes to editors

- The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
- Metformin is widely used to treat type 2 diabetes.

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