HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Important – Valsartan-containing Tablet & Capsule Medicines – Precautionary Recall

November 27th, 2018

Dear Doctor,

The Health Products Regulatory Authority (HPRA) wishes to advise you about a pharmacy level recall of a number of additional valsartan-containing medicines on the Irish market that is due to commence tomorrow, November 28th, 2018.

As part of the ongoing investigation into the valsartan recall of July 2018:

- A new nitrosamine impurity has been identified in a valsartan active substance manufactured by a Mylan manufacturing plant in India. This new impurity is called N-nitrosodiethylamine (NDEA).
- NDEA is similar to the impurity N-nitrosodimethylamine (NDMA) which led to the July 2018 valsartan recalls.
- Like NDMA, the impurity NDEA is also a probable human carcinogen.

At present there is no evidence that this impurity has caused any harm to patients. However, this recall is being undertaken as a precautionary measure to prevent any further exposure to the impurity in affected medicines whilst the investigation is ongoing. The health risk of abruptly discontinuing the medicine is higher than any potential risk presented by the impurity.

This recall action differs from the recall in July 2018 as there is no requested action for patients. This is a pharmacy level recall only. It is not anticipated that this recall should affect prescribers and replacement unaffected stock is available. However, the HPRA wishes to make prescribers aware of this issue in the event that their patients contact them with questions.

The medicines being recalled all contain the valsartan active substance from a Mylan manufacturing plant in India. These medicines are marketed by Mylan, and Teva. Some are combination products, with hydrochlorothiazide. Of note, not all Teva stock is being recalled as there are unaffected Teva batches on the market which contain an active substance manufactured at a different site.

Work is currently ongoing at a European level and internationally to better understand the potential impact of this impurity, and as a precautionary measure at this time, this recall is being undertaken to prevent further patient exposure.

Patients should continue taking their medicines. The recall will ensure that no further affected batches containing the NDEA impurity will be dispensed to patients.

Further information on this issue is available at www.hpra.ie and www.ema.europa.eu .

Yours sincerely,

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