HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Advance Notice for Pharmacists

Precautionary recall of additional Valsartan products tomorrow, 28 November 2018

This recall is to pharmacy level only and there is no need to contact patients

27 November 2018

Dear Pharmacist,

The purpose of this letter is to give you advance notice about a pharmacy level recall of additional valsartan-containing products which is due to begin tomorrow, November 28th, 2018.

The Health Products Regulatory Authority (HPRA) wishes to advise you that, as part of the ongoing EU-wide investigation into the valsartan impurity issue:

- 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 (a substance that could cause cancer).
- 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 the 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.
- The levels of the NDEA impurity in the products being recalled at this time are significantly lower than the levels of NDMA present in batches associated with the July 2018 recalls. This is why this current recall is only extending to pharmacy level.

The products being recalled will be provided in tomorrow's recall letter. They all contain the valsartan active substance from a Mylan manufacturing plant in India. These products are marketed by both Teva and Mylan, and are of various strengths. Some are combination products, with hydrochlorothiazide. Of note, not all Teva stock will be recalled as there are unaffected Teva batches of on the market which contain an active substance manufactured at a different site.

While most of the products being recalled are authorised in Ireland, some are exempt medicinal products (EMPs) – they are not authorised in Ireland.

Replacement unaffected stock is available to order. This includes unaffected batches of the Teva valsartan products.

At this time, there are no parallel imported or parallel distributed products affected by the issue.

How the recall will work:

- The HPRA will issue a recall letter to all pharmacies in Ireland tomorrow, November 28th.
- That letter will be sent to all registered pharmacists in Ireland by email by the Pharmaceutical Society of Ireland (PSI) on behalf of the HPRA. The HPRA recall letter will list all of the product names and batch numbers that are subject to the recall. It will also be posted on the HPRA's website (www.hpra.ie) tomorrow – in a section on the website homepage called *Valsartan*. The recall letter will also be disseminated by the Irish Pharmacy Union (IPU) to its members.
- There are five companies involved in this recall – Teva, Mylan, and three wholesalers that supplied the EMP valsartan products to certain pharmacies - Medisource, McDowell Pharmaceuticals and Merit Pharmaceuticals.
- Each of the five companies will issue via the post their own recall letters to pharmacies starting tomorrow.
    - The Teva and Mylan recall letters will be sent to all pharmacies in the country.
    - However, the recall letters from Medisource, McDowell Pharmaceuticals and Merit Pharmaceuticals will only be sent to those pharmacies that received the batches in question that are subject to the recall.

Actions to take when you receive the HPRA recall letter tomorrow:

Pharmacists will be requested in the recall letter to perform the following actions:

1. To immediately quarantine any units from the batches / products listed in Appendix 1 of the letter. For hospital pharmacies, this will include wards, clinics and any other relevant locations within the hospital.

2. Hospital pharmacists will be requested to inform relevant prescribers within their hospital of this recall action so that they can be made aware of it.

3. To return the quarantined units to your wholesaler within the next 7 days. Your wholesaler will be in a position to advise you about receiving credit for the packs that you return.

IMPORTANT: There is no requirement to contact patients, as this is a pharmacy level recall.

Similar recalls are happening across Europe at this time, and it is possible that some patients will contact you with questions about the issue. Patients can be advised that there is no immediate risk presented by the impurity and that the recall action being undertaken at this time will ensure that no additional packs with the impurity present are dispensed to them. Patients should be advised that they should not stop taking their medicine.

Yours sincerely,

Kevin O'Donnell, PhD,
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