HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Advance Notice for Pharmacists

Precautionary recall of
Batch No. 150118 of Irprezide 150mg/12.5mg film coated tablets, PA 1380/80/1
Batch No. 059118 of Irprezide 300mg/12.5mg film coated tablets, PA 1380/80/2
to begin tomorrow, 21st December 2018

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

20 December 2018

Dear Pharmacist,

The purpose of this letter is to give you advance notice about a pharmacy level recall of two batches of Teva's Irprezide (Irbesartan/Hydrochlorothiazide) 150mg/12.5mg and 300mg/12.5mg Tablets which is due to begin tomorrow, December 21st, 2018.

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

- A nitrosamine impurity called NDEA (N-nitrosodiethylamine) has been identified in the batches of Irbesartan active substance used in the manufacture of the above tablet batches.
- Note: Irprezide 300mg/25mg film coated tablets, PA 1380/80/3, are not affected.
- NDEA is 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 above batches are lower than the levels of NDEA in the valsartan batches recalled in November 2018, and the safety thresholds of NDEA in valsartan and irbesartan products are similar. This is why this current recall is only extending to pharmacy level.

Please note:
- This recall only applies to packs of the above Irprezide 150mg/12.5mg and Irprezide 300mg/12.5mg tablet batches.
- There may be temporary interruptions in the supply of these strengths of Irprezide.
- Other Irbesartan / Hydrochlorothiazide medicines are not affected by this recall and are available for pharmacies to order.

How the recall will work:

- Teva will post the recall letter to all pharmacies in Ireland tomorrow, December 21st 2018. Some pharmacies may not receive the letter until after the Christmas break.
- The HPRA will upload the Teva recall letter onto its website (www.hpra.ie) at 12 noon tomorrow – in a section on the website homepage called *Irbesartan/Hydrochlorothiazide.*
- The recall letter will also be disseminated by the Irish Pharmacy Union (IPU) to its members.

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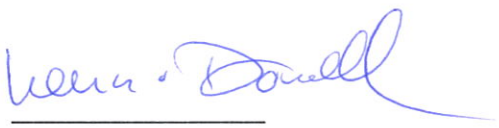
IMPORTANT: There is no requirement to contact patients, as this is a pharmacy level recall.

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.

Please Note: It is possible that there will be additional recalls of sartan-containing products in the coming weeks and months, as new test results become available on impurity levels in those products. The approach which will be taken in relation to those recalls is as follows:

- Where such sartan recalls are to pharmacy level only, no advance letters will be issued by the HPRA to pharmacies.
- The Marketing Authorisation Holder (MAH) companies will send out the recall letters via the post to pharmacies as per normal procedure.
- The HPRA will upload those recall letters onto its website (www.hpra.ie) at the same time as the mailing of the hard-copy recall letters begins.

Yours sincerely,



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