HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Product Recall

A number of Valsartan-containing Film Coated Tablet Products See Appendix 1 for the Product List

July 5th, 2018

Dear Pharmacist,

The Health Products Regulatory Authority (HPRA) wishes to advise you that the batches of valsartan-containing film coated tablet products listed in Appendix 1 are being recalled with immediate effect.

This is a precautionary recall action and is being conducted to pharmacy level. Note that specific advice in relation to this issue is also being given by the HPRA to patients (see below for details).

Not all valsartan-containing medicines are affected by the recall. There are alternative valsartan-containing medicines and other treatments available to patients. Switching existing patients to alternative valsartan-containing medicines which are not on the list in Appendix 1 should be feasible at present, given current stocks. However, the situation may change and prescribers may have to consider other treatment options for patients requiring such medicines.

The reason for the recall is as follows:

- An impurity has been identified in the valsartan active substance used in the listed medicinal products; this impurity is N-nitrosodimethylamine (NDMA) and it has been classified as a probable human carcinogen. At present there is no evidence that this impurity has caused any harm to patients; however, this recall action 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 active substance manufacturer, Zhejiang Huahai Pharmaceuticals, located in China, has reported that the impurity is linked to changes made to the manufacturing process.

This is an emerging issue. At present, the risk is theoretical and there is no direct evidence of harm having been caused by this impurity. The HPRA is actively involved with the European Medicines Agency and with other medicines regulators to determine any possible impact on patients who have been taking these medicines. In this regard, work is currently ongoing at a European level to better understand the potential impact of this impurity, and as a precautionary measure at this time, this recall is being undertaken.

Please perform the following actions:

1. Immediately quarantine any units from the batches / products listed in Appendix 1 which you have in your pharmacy. For hospital pharmacies, this includes wards, clinics and any other relevant locations within your hospital.

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2. Hospital pharmacists are requested to inform relevant prescribers within their hospital of this recall action.

3. Please 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.

As this is a pharmacy level recall, contacting patients to whom the attached listed products have been dispensed is not required at this time.

Advice being given to patients by the HPRA:

- Patients are being advised that it is important not to stop taking their valsartan medicine abruptly. The health risk of abruptly discontinuing this medicine is higher than any potential risk presented by the impurity.
- They should return to their pharmacist to seek an alternative valsartan-containing medicine.
- In the event that the pharmacist is unable to dispense an alternative valsartan-containing medicine, patients should see their doctor at an early opportunity to discuss alternative medicines.
- Patients are being advised to bring their valsartan-containing medicine with them when they visit their pharmacy or doctor.

Taking benefit/risk considerations into account, as well as the current information which is available on this issue, and the availability of replacement stocks to meet patient needs for these medicines, a pharmacy level recall is being performed as a precautionary measure.

Further information on this issue is available on the HPRA website, at www.hpra.ie and this will be kept updated as the investigation progresses.

Contact details for each of the three Marketing Authorisation Holder companies for the attached listed products are as follows:

- **Actavis Group PTC**.: Medical Information, medinfo@accord-healthcare.com , Tel. +44 (0) 1271 385257

- **Clonmel Healthcare**: Julia Ryan, Quality Manager, jryan@clonmel-health.ie , Tel. 052 6177719

- **Rowex Limited**: Mr. Jerry Cleary, QA Manager, jcleary@rowa-pharma.ie , Tel. 027 50077

Note: A number of other valsartan-containing products are being reviewed at this time to determine if they contain the above impurity. Therefore, it is possible that additional products may need to be recalled in the coming days or weeks, as more information becomes available.

We will keep you informed as the situation evolves.

Yours sincerely,

Kevin O'Donnell

Kevin O'Donnell, PhD,
Market Compliance Manager, HPRA

Appendix 1 - List of Valsartan-containing products being recalled to Pharmacy Level

	Product Name	PA Number	Marketing Authorisation Holder Name	Batch Numbers
1	Valtan 40 mg film-coated tablets	PA0126/211/001	Clonmel Healthcare Ltd.	72733
2	Valtan 80 mg film-coated tablets	PA0126/211/002	Clonmel Healthcare Ltd.	73920 72293 70489
3	Valtan 160 mg film-coated tablets	PA0126/211/003	Clonmel Healthcare Ltd.	73338 72325V 64314
4	Co-Vatan 80 mg/12.5 mg Film-coated Tablets	PA0711/182/001	Rowex Ltd.	All In-date Batches
5	Co-Vatan 160 mg/12.5 mg Film-coated Tablets	PA0711/182/002	Rowex Ltd.	All In-date Batches
6	Co-Vatan 160 mg/25 mg Film-coated Tablets	PA0711/182/003	Rowex Ltd.	All In-date Batches
7	Vatan 40 mg Film-coated Tablets	PA0711/183/001	Rowex Ltd.	All In-date Batches
8	Vatan 80 mg Film-coated Tablets	PA0711/183/002	Rowex Ltd.	All In-date Batches
9	Vatan 160 mg Film-coated Tablets	PA0711/183/003	Rowex Ltd.	All In-date Batches
10	Valsartan Actavis 40 mg film-coated tablets	PA1380/022/001	Actavis Group PTC	All In-date Batches
11	Valsartan Actavis 80 mg film-coated tablets	PA1380/022/002	Actavis Group PTC	All In-date Batches
12	Valsartan Actavis 160 mg film-coated tablets	PA1380/022/003	Actavis Group PTC	All In-date Batches
13	Valsartan/Hydrochlorothiazide 80 mg/ 12.5 mg Film-coated Tablets	PA1380/101/001	Actavis Group PTC	All In-date Batches
14	Valsartan/Hydrochlorothiazide 160 mg/ 12.5 mg Film-coated Tablets	PA1380/101/002	Actavis Group PTC	All In-date Batches
15	Valsartan/Hydrochlorothiazide 160 mg/ 25 mg Film-coated Tablets	PA1380/101/003	Actavis Group PTC	All In-date Batches