HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Important Information concerning a number of Valsartan-containing Film Coated Tablet Products

See Appendix 1 for Product Details

July 5th, 2018

Dear Doctor,

The Health Products Regulatory Authority (HPRA) wishes to advise you about a pharmacy level recall of a number of valsartan-containing medicines on the Irish market. These are listed in Appendix 1.

The reason for the recall is as follows:

- An impurity has been identified in the valsartan active substance used in the attached list of medicines; 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 across Europe. 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 to prevent further exposure.

The HPRA is advising all patients not to stop taking their valsartan-containing medicine abruptly and to attend their pharmacist if they are taking one of the valsartan containing medicines on the attached list. The pharmacist should be able to provide an alternative valsartan-containing medicine for them. However, this is an evolving issue and there is potential for current stock levels of non-affected valsartan-containing medicines to be impacted; therefore if patients are unable to obtain an alternative valsartan-containing medicine from their pharmacist, they will be advised by their pharmacist to attend their doctor.

Given the current issue, it is advisable not to commence new patients on valsartan-containing medicines, where possible, whilst this investigation is ongoing. This is because there is the potential for stocks of unaffected medicines to be in short supply.

Healthcare professionals may also need to consider potential alternatives to valsartan-containing medicines for the treatment of an individual patient's condition, in the event that valsartan-containing medicines are not available for a period of time.

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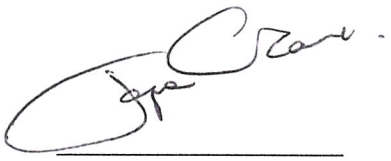
Further information on this issue is available at www.hpra.ie .

We are closely monitoring this situation and will keep the HPRA website updated with any new information on the issue as it arises.

Yours sincerely,



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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