

Recall Letter

Certain Valsartan-containing Tablet & Capsule Products - See Appendix 1 for List

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

November 28th, 2018

Dear Pharmacist,

Further to the HPRA's letter of November 27th, 2018, we wish to advise you that the batches of valsartan-containing products listed in Appendix 1 are being recalled with immediate effect.

This is a precautionary recall action and is being conducted to pharmacy level – see details below.

- 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 pharmacy level 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.
- The margin by which the levels of the NDEA impurity in the products listed in Appendix 1 exceeds the acceptable intake levels is significantly lower than the margin by which the levels of NDMA present in batches in the July 2018 recalls exceeded the acceptable intake levels. This is why this current recall is extending to pharmacy level and not to patient level.
- Replacement unaffected stock is available to order.

Please note: While many batches are being recalled, the actual number of packs from those batches which may be at pharmacies at this time and which need to be recalled is likely to be relatively low. Thus, the impact of this recall on pharmacies is likely to be much lower than that in July. There is replacement stock available and the HPRA is actively working with the wholesalers to ensure that adequate supplies continue to be made available for individual pharmacies.

Please perform the following actions:

1. Please immediately quarantine any units from the batches listed in Appendix 1 which are in your possession. For hospital pharmacies, this includes wards, clinics and any other relevant locations within the hospital.
2. 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.
3. **Hospital Pharmacists:** Please inform relevant prescribers within your hospital of this recall action so that they can be made aware of it.

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

If you have supplied units of the products detailed in Appendix 1 to any other pharmacy or clinic, please contact them and request that they also perform the above actions.

There are five companies involved in this recall – Teva, Mylan, and three wholesalers that supplied unlicensed valsartan products to certain pharmacies via the Exempt Medicinal Products (EMP) route - Medisource, McDowell Pharmaceuticals and Merit Pharmaceuticals. Each of the five companies will issue their own recall letters via the post to pharmacies.

Contact details for the two Marketing Authorisation Holder (MAH) companies for the attached listed products are as follows:

- **Mylan:**

- Mr. Richard Barton
Quality Director/QP, Regional EU Mylan
Tel: +353 1 871 1647
richard.barton@mylan.com

- **Teva Pharma BV:**

- Mr. Kevin Woods
Senior Manager Commercial Quality/RP
Teva Pharmaceuticals Ireland, Tel: +353 42 9364984, Mob: +353 87 2392797
kevin.woods@teva.ie

Thank you.

Yours sincerely,



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

**Appendix 1 - List of Valsartan-containing products being recalled to Pharmacy Level
28 November 2018**

Product Name / Strength / Form	PA No.	MAH / Supplier Name	Batch No.	Expiry Date
Valsartan Teva 40 mg Film-coated Tablets	PA0749/084/001	Teva Pharma B.V.	W31038	31/12/2018
			W31040	31/03/2019
			W31041	31/03/2019
			W31043	30/09/2019
			W31046	29/02/2020
			W31048	30/04/2020
Valsartan Teva 80 mg Film-coated Tablets	PA0749/084/002	Teva Pharma B.V.	0002629	31/03/2019
			0003108	30/04/2019
			0003109	30/04/2019
			0003726	31/05/2019
Valsartan Teva 160 mg Film-coated Tablets	PA0749/084/003	Teva Pharma B.V.	0001497	31/12/2018
			0001687	31/01/2019
			0001689	31/01/2019
			0002637	31/03/2019
Valsartan / Hydrochlorothiazide Teva 80 mg/12.5 mg Film-coated tablets	PA0749/047/001	Teva Pharma B.V.	6P511064	30/11/2018
			6P601163	31/01/2019
			6P607001	31/07/2019
			6P607002	31/07/2019
			0001584	31/12/2019
			0002627	31/03/2020
			0002627A	31/03/2020
			0003214	30/04/2020
			0004744	31/08/2020
Valsartan / Hydrochlorothiazide Teva 160 mg/25 mg Film-coated tablets	PA0749/047/002	Teva Pharma B.V.	6P601082	31/01/2019
			6P601084	31/01/2019
			6P606268	30/06/2019
			6P606290	30/06/2019
			6P606321	30/06/2019
			0000352	30/09/2019
			0002314	29/02/2020
			0003617	31/05/2020
0004700	31/08/2020			
Valsartan/Hydrochlorothiazide Teva 160 mg/12.5 mg Film-coated Tablets	PA0749/047/003	Teva Pharma B.V.	6P511072	30/11/2018
			6P607166	31/07/2019
			2000000422	30/09/2019
			0001520	31/12/2019
			0002298	29/02/2020
			0003663	31/05/2020
0004670	31/08/2020			

Valsartan Mylan 40mg Film-coated Tablets	PA0577/134/001	McDermott Laboratories Ltd. t/a Gerard Laboratories	All in-date batches	Various
Valsartan Mylan 80mg Film-coated Tablets	PA0577/134/002	McDermott Laboratories Ltd. t/a Gerard Laboratories	All in-date batches	Various
Valsartan Mylan 160mg Film-coated Tablets	PA0577/134/003	McDermott Laboratories Ltd. t/a Gerard Laboratories	All in-date batches	Various
Valsartan Mylan 320mg Film-coated Tablets	PA0577/134/004	McDermott Laboratories Ltd. t/a Gerard Laboratories	All in-date batches	Various
Exempt Medicinal Products				
VALSARTAN TEVA 40mg film coated tablets	N/A - Exempt Medicinal Product	Medisource	W31044	09/2019
VALSARTAN 80mg CAPSULES	N/A - Exempt Medicinal Product	Medisource	8049768	10/2019
VALSARTAN/HYDROCHLOROTHIAZIDE 160mg/25mg tablets	N/A - Exempt Medicinal Product	Medisource	0003615	05/2020
VALSARTAN/HYDROCHLOROTHIAZIDE 80mg/12.5mg tablets	N/A - Exempt Medicinal Product	Medisource	0003214	04/2020
VALSARTAN HCTZ 80mg/12.5mg tablets	N/A - Exempt Medicinal Product	Merit Pharmaceuticals	0002626	03/2020
			0003214	04/2020
VALSARTAN 40mg CAPSULES	N/A - Exempt Medicinal Product	McDowell Pharmaceuticals	8060483	Jan-2019
VALSARTAN 80mg CAPSULES	N/A - Exempt Medicinal Product	McDowell Pharmaceuticals	8056387	Oct-2019
			8057216	Oct-2019
VALSARTAN/HYDROCHLOROTHIAZIDE 80mg/12.5mg Tablets	N/A - Exempt Medicinal Product	McDowell Pharmaceuticals	0002626	Mar-2020
			0004744	Aug-2020
VALSARTAN/HYDROCHLOROTHIAZIDE 160mg/12.5mg Tablets	N/A - Exempt Medicinal Product	McDowell Pharmaceuticals	0004670	Aug-2020
VALSARTAN/HYDROCHLOROTHIAZIDE 160mg/25mg Tablets	N/A - Exempt Medicinal Product	McDowell Pharmaceuticals	0003615	May-2020