



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy Level Recall

Date: 30 November 2018

EL (18) A/17

Our Ref: MDR 094-06/18

Dear Healthcare Professional,

Teva UK Limited

Valsartan 320mg Film-coated Tablets, PL 00289/1238

Batch Number	Expiry Date	Pack Size	Date of First Distribution
100433	28/02/2019	1 x 28	21/06/2017
101777	31/07/2019	1 x 28	15/01/2018

Valsartan 40mg Film-coated Tablets, PL 00289/1235

Batch Number	Expiry Date	Pack Size	Date of First Distribution
100350	28/02/2019	1 x 7	01/06/2017
100938	30/04/2019	1 x 7	03/01/2018
101776	31/08/2019	1 x 7	13/09/2018

Valsartan / Hydrochlorothiazide 80 / 12.5mg Film-coated Tablets, PL 00289/1233

Batch Number	Expiry Date	Pack Size	Date of First Distribution
6P601163	31/01/2019	1 x 28	23/06/2016
6P606333	30/06/2019	1 x 28	07/10/2016
0001584	31/12/2019	1 x 28	26/04/2017
0002626	31/03/2020	1 x 28	25/08/2017
0002627	31/03/2020	1 x 28	05/07/2017
0003214	30/04/2020	1 x 28	30/10/2017
0004744	31/08/2020	1 x 28	27/12/2017

Valsartan / Hydrochlorothiazide 160 / 12.5mg Film-coated Tablets, PL 00289/1215

Batch Number	Expiry Date	Pack Size	Date of First Distribution
6P607166	31/07/2019	1 x 28	07/10/2016
0000426	30/09/2019	1 x 28	13/02/2017
0001520	31/12/2019	1 x 28	04/05/2017
0001521	31/12/2019	1 x 28	25/05/2017
0002298	29/02/2020	1 x 28	16/08/2017
0003663	31/05/2020	1 x 28	27/09/2017
0004670	31/08/2020	1 x 28	11/12/2017



Valsartan / Hydrochlorothiazide 160 / 25mg Film-coated Tablets, PL 00289/1234

Batch Number	Expiry Date	Pack Size	Date of First Distribution
6P601084	31/01/2019	1 x 28	19/05/2016
6P606270	30/06/2019	1 x 28	13/09/2016
0000350	30/09/2019	1 x 28	23/01/2017
0000352	30/09/2019	1 x 28	12/04/2017
0001997	31/01/2020	1 x 28	12/06/2017
0002338	29/02/2020	1 x 28	16/08/2017
0003615	31/05/2020	1 x 28	27/09/2017

Mylan

Valsartan 40mg Capsules	PL 04569/1000
Valsartan 80mg Capsules	PL 04569/1001
Valsartan 160mg Capsules	PL 04569/1002
Valsartan 40mg Film-coated Tablets	PL 04569/1175
Valsartan 320mg Film-coated Tablets	PL 04569/1178

Further to Drug Alert number EL (18) A/11, issued in July 2018 in connection with Valsartan containing products contaminated with N-nitrosodimethylamine (NDMA), we have become aware of another nitrosamine contaminant in batches of Valsartan active substance.

This contaminant is N-nitrosodiethylamine (NDEA), which also has genotoxic and carcinogenic potential. Valsartan containing products from UK suppliers Teva UK Limited and Mylan are affected.

Teva is recalling the listed batches and Mylan is recalling all unexpired batches of the above products from pharmacies as a precautionary measure at a European level due to possible contamination with NDEA.

Healthcare Professionals and wholesalers

- Stop supplying the above products / batches listed above immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- If you receive queries about this issue from patients, advise them not to stop taking their medication as the health risk of discontinuing the medicine is higher than the potential risk presented by the contaminant. A treatment review is not necessary until the next routine appointment.



- We do not anticipate any shortages of Valsartan containing products. It is possible, however, that there may be some local supply issues, in which case patients should be advised to speak to their doctor to discuss alternative treatments.

This is a developing issue and the MHRA is actively involved with the European Medicines Agency and with other medicines regulators to determine any possible impact. An investigation into other potentially impacted products is continuing and further updates will be provided as the investigation progresses.

Company contacts for further information

Teva UK Limited :

- For stock control: general.enquiries@tevauk.com
- For medical information enquiries: medinfo@tevauk.com

Mylan:

- For stock control: mguk_customer.services@mylan.co.uk, 01707 853100
- For medical information enquires: info@mylan.co.uk, 01707 853 000, Option 1

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

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