Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 2nd August 2018 Our Ref: MDR 04-7-2018

Dear Healthcare Professional,

Valsartan Containing Products

The Medicines Authority, as authorised by the Licensing Authority, is carrying out a precautionary Class II recall of a number of specific medicinal products containing the active ingredient valsartan that are used to treat blood pressure and heart conditions. All the products listed below are being recalled from pharmacies as a precautionary measure at a European level. This is due to contamination with an impurity N-nitrosodimethylamine (NDMA) which has probable carcinogenic potential. This is an emerging situation and the Medicines Authority is actively involved with the European Medicines Agency and with other medicines regulators to determine any possible impact.

Medicinal Product Name	Authorisation Number	Authorisation Holder	Licence Number in source country (AA only)
Valsarten Zentiva 80mg film-coated tablets	AA082/08401	Sanofi Malta Ltd.	Italy - 040723076
Valsarten Zentiva 160mg film-coated tablets	AA082/08402	Sanofi Malta Ltd.	Italy – 040723126
Valsotens 80mg coated tablets	MA628/02402	Actavis Group PTC ehf	
Valsotens 160mg coated tablets	MA628/02403	Actavis Group PTC ehf	
Vapress 80mg film-coated tablets	AA497/00601	Europharma Ltd.	Cyprus - 21419
Vapress 160mg film-coated tablets	AA497/00602	Europharma Ltd.	Cyprus – 21420
Valsaben 160mg film-coated tablets	34227/19-04-2016	Bennett	
Valsartan Auro 160mg film-coated tablets	RVG 101567	Aurobindo BV	
Valsartan-1A Pharma 80mg film-coated tablets	AA939/02201	1A Pharma GmbH	Germany – 76616.00.00
Valsartan-1A Pharma 160mg film-coated tablets	AA939/02202	1A Pharma GmbH	Germany – 76617.00.00

Patients are to be told not to stop taking this medicinal product but to go to their pharmacist and physician at the earliest opportunity to discuss their treatment. It is emphasized that stopping this medicinal product abruptly could cause more harm than any potential risk presented by this impurity and thus patients should continue treatment until they speak to their doctor or pharmacist.

For those patients on the POYC scheme, alternative Candesartan stock will now be provided in lieu of the valsartan stocks impacted as a temporary measure until stocks of unaffected valsartan arrive.

Yours faithfully

Muriel Giglio
Medicines Inspector
Medicines Authority