

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 28th November 2018

Our Ref: MDR 06-011/2018

Dear Healthcare Professional,

Valsartan containing medicinal products

The Medicines Authority is carrying out a further precautionary Class II recall of a brand of medicinal products containing the active ingredient valsartan that is used to treat blood pressure and heart conditions.

The first Class II recall in Malta for valsartan containing medicinal products was issued on the 2nd August 2018 following the publication of a press release by the European Medicines Agency (EMA) where it was established that these products were contaminated with the impurity N-nitrosodimethylamine (NDMA). Since then, further contaminant impurity N—nitrosodiethylamine (NDEA) was also found in these products. Therefore, the European Medicines Agency (EMA) issued a press release for further action by the National Competent Authorities.

NDEA and related compound NDMA, that have also been seen in `sartans` from other manufacturers, are classified as probable human carcinogens (substances that could cause cancer).

The batches listed below, containing valsartan active substance manufactured by Mylan Laboratories, India are being recalled from pharmacies in Malta as a precautionary measure at a European level, in view of the contamination with impurity NDEA, which was found to exceed the acceptable limits during testing.

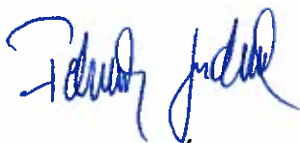
This is an emerging situation and the Malta Medicines Authority is working closely with the EMA, European Directorate for the Quality of Medicines (EDQM) and other Competent National Authorities to determine any possible impact and to gather more data in order to monitor continuously the situation with sartan products.

Valsartan Mylan generics Italia 80mg and 160mg capsules

Medicinal product name	Authorisation number	Authorisation Holder	Batch number	Expire date
Valsartan Mylan generics Italia 80mg capsules	AA565/20404 A/C 040225043	CPSU Malta / Mylan Generics, IT	8058241	30/11/2019
Valsartan Mylan generics Italia 80mg capsules	AA565/20404 A/C 040225043	CPSU Malta / Mylan Generics, IT	8063282	31/08/2020
Valsartan Mylan generics Italia 80mg capsules	AA565/20404 A/C 040225043	CPSU Malta / Mylan Generics, IT	8065675	28/02/2020
Valsartan Mylan generics Italia 160mg capsules	AA565/20405 A/C 040225068	CPSU Malta / Mylan Generics, IT	8047046	31/10/2019
Valsartan Mylan generics Italia 160mg capsules	AA565/20405 A/C 040225068	CPSU Malta / Mylan Generics, IT	8057459	31/10/2019
Valsartan Mylan generics Italia 160mg capsules	AA565/20405 A/C 040225068	CPSU Malta / Mylan Generics, IT	8068065	30/09/2020
Valsartan Mylan generics Italia 160mg capsules	AA565/20405 A/C 040225068	CPSU Malta / Mylan Generics, IT	8063873	28/02/2020

As with previous findings of products containing NDMA and now NDEA there is no immediate risk to patients. Patients are therefore advised not to stop taking their sartan medicines without speaking to their doctor.

Yours faithfully,



Judit FEHER
Medicines Inspector