



9th July 2018

Dear Pharmacist,

Further to the circular dated 6 July 2018, find below the list of products with the active substance valsartan that may be potentially impacted by the N-nitrosodimethylamine (NDMA) impurity.

Medicine Name	Auth. Number	Authorization Holder	Licence Number in source country (AA only)
Asbima 10mg/160mg film coated tablets	MA1023/00703	Zentiva k.s.	
Asbima 5mg/160mg film coated tablets	MA1023/00702	Zentiva k.s.	
Asbima 5mg/80mg film coated tablets	MA1023/00701	Zentiva k.s.	
Valsartan Zentiva 160mg film-coated tablets	AA082/08402	Sanofi Malta Limited	ITALY - 040723126
Valsartan Zentiva 80mg film-coated tablets	AA082/08401	Sanofi Malta Limited	ITALY - 040723076
Valsotens 320mg film coated tablets	MA628/02404	Actavis Group PTC ehf	
Valsotens Coated tablets 160mg	MA628/02403	Actavis Group PTC ehf	
Valsotens Coated tablets 40mg	MA628/02401	Actavis Group PTC ehf	
Valsotens Coated tablets 80mg	MA628/02402	Actavis Group PTC ehf	
Vapress 160mg film-coated tablets	AA497/00602	Europharma Limited	CYPRUS - 21420
Vapress 80mg film-coated tablets	AA497/00601	Europharma Limited	CYPRUS - 21419

Products that were previously authorised and which may be still on the market:

Valsartan -1A Pharma 160mg film-coated tablets	AA939/02202	1 A Pharma GmbH	GERMANY - 76617.00.00
Valsartan -1A Pharma 80mg film-coated tablets	AA939/02201	1 A Pharma GmbH	GERMANY - 76616.00.00
Valsartan Farmoz 160mg film-coated tablets	AA1050/00102	Farmoz-Sociedade Tecnico Medicinal S.A.	PORTUGAL - 5445432
Valsartan Farmoz 80mg film-coated tablets	AA1050/00101	Farmoz-Sociedade Tecnico Medicinal S.A.	PORTUGAL - 5445408

If your patient is on any of these products, we advise that you refer the patient to his/her medical practitioner so he will prescribe alternative medicinal products. Patients presenting with prescriptions for the above-mentioned products should be referred back to their GP. Note that the patient will only need a prescription to be supplied treatment, as the department will make the necessary arrangements with respect to the entitlement for:

Bendroflumethiazide

Bumetanide

Carvedilol

Atenolol

Enalapril

Lisinopril

Perindopril

Amlodipine

POYC pharmacies are advised that, on presentation of a prescription, they are to dispense stock where this is available; as long as the patient has a valid entitlement for Valsartan under Schedule V.

If a patient presents a prescription for which stock is not available, the pharmacist may make a request for an urgent delivery using the normal channels and POYC will endeavour to supply within 48 hrs.



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Patients should be advised not to stop taking their anti hypertensive medicines before consulting their doctor as the health risk of discontinuing this medicine is high.

The Health Authorities are following the issue closely and taking the necessary steps to procure supplies of valsartan from alternative sources in the shortest time possible. Further information will be provided as soon as it is available.

Yours' truly,

Dr Charmaine Gauci MD, MSc, PhD, FRSPH, FFPH
Director General/Superintendent of Public Health