

11 July 2018

Dear Pharmacist,

It is being brought to your attention that **ONLY** the following products with the active substance valsartan **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

Pharmacists should continue to dispense the valsartan supplied by POYC until the patient has an alternative.

As a precautionary measure, pharmacists are to advice patients who are taking any of the valsartan medicines above to speak to their doctor. Treatment should not be stopped until the doctor has prescribed an alternative. The health risk of discontinuing this medicine is higher than any potential risk presented by the impurity. At present there is no evidence that the impurity in some stocks of valsartan has caused any harm to patients.

11 July 2018

Għażiż spizjar/a,

Qed niġbdulek l-attenzjoni li dawn il-medicini indikati BISS li għandhom l-ingredjent farmaċewtiku attiv valsartan huma **potenzjalment** milquta mill-impurità N-nitrosodimethylamine (NDMA).

Isem tal-medicina	Numru tal-awtorizzazzjoni	Detentur tal-Awtorizzazzjoni tat-tqegħid fis-suq	Numru tal-Liċenzja fil-pajjiż minn fejn ġejja l-medicina (AA biss)
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
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Vapress 160mg film-coated tablets	AA497/00602	Europharma Limited	CYPRUS - 21420
Vapress 80mg film-coated tablets	AA497/00601	Europharma Limited	CYPRUS - 21419

Prodotti li m'għadhomx awtorizzati u li jista' jkun għadhom fuq is-suq:

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
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Spizjara għandhom ikomplu jagħtu mediċini bl-ingredjent valsartan mis-sistema tal-POYC sakemm l-pazjent jingħata alternattiva.

Bħala miżura ta' prekawzjoni, spizjara għandhom javżaw pazjenti li qed jieħdu xi mediċini bil-valsartan indikati hawn fuq biex jiddiskutu t-trattament tagħhom mat-tabib. Il-mediċini m'għandhomx jitwaqqfu qabel it-tabib jordna alternattivi. Ir-riskju li wieħed jwaqqaf il-mediċina valsartan huwa ikbar mir-riskju ta' ħsara li jista' jkun assoċjat ma' l-impurità. Fil-preżent m'hemm l-ebda evidenza li l-impurità f'ċertu mediċini tal-valsartan waslet għal xi periklu fis-saħħa tal-pazjenti.