

27 August 2018

Dear Pharmacist,

In view of emerging information, it is being brought to your attention an updated list of products with the active substance valsartan that **may be potentially impacted** by the N-nitrosodimethylamine (NDMA) impurity.

Name of Medicine	Authorisation Number or Licence number in source country	Authorisation
Asbima 5mg/80mg film coated tablets	MA1023/00701	Zentiva k.s.
Asbima 5mg/160mg film coated tablets	MA1023/00702	Zentiva k.s.
Asbima 10mg/160mg film coated tablets	MA1023/00703	Zentiva k.s.
Valsaben 160mg film-coated tablets	GREECE 34227/19-04-2016	Bennett
Valsartan Auro 160mg film-coated tablets	RVG 101567	Aurobindo BV
Valsartan Zentiva 160mg film-coated tablets	ITALY 040723126	Sanofi Malta Limited
Valsartan Zentiva 80mg film-coated tablets	ITALY 040723076	Sanofi Malta Limited
Valsotens 40mg coated tablets	MA628/02401	Actavis Group PTC ehf
Valsotens 80mg coated tablets	MA628/02402	Actavis Group PTC ehf

Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann
SĠN 3000 info.medicinesauthority@gov.mt | (+356) 23 439 000
www.medicinesauthority.gov.mt

Name of Medicine	Authorisation Number or Licence number in source country	Authorisation
Valsotens 160mg coated tablets	MA628/02403	Actavis Group PTC ehf
Valsotens 320mg film-coated tablets	MA628/02404	Actavis Group PTC ehf
Vapress 80mg film-coated tablets	CYPRUS 21419	Europharma Limited
Vapress 160mg film-coated tablets	CYPRUS 21420	Europharma Limited

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

Name of Medicine	Authorisation Number or Licence number in source country	Authorisation
Valsartan -1A Pharma 80mg film-coated tablets	GERMANY 76616.00.00	1 A Pharma GmbH
Valsartan -1A Pharma 160mg film-coated tablets	GERMANY 76617.00.00	1 A Pharma GmbH
Valsartan Farmoz 80mg film-coated tablets	PORTUGAL 5445408	Farmoz-Sociedade Tecnico Medicinal S.A.
Valsartan Farmoz 160mg film-coated tablets	PORTUGAL 5445432	Farmoz-Sociedade Tecnico Medicinal S.A.

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

As a precautionary measure, pharmacists are to advise 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.

Patient safety is a top priority for the Medicines Authority and further updates will be provided as more information becomes available.

27 t' Awwissu 2018

Għażiż spizjar/a,

Hawn taħt għandek issib lista aġġornata ta' mediċini li għandhom l-ingredjenti farmaċewtiku attiv valsartan li **potenzjalment** huma affetwati mill-impurità N-nitrosodimethylamine (NDMA).

Isem tal-mediċina	Numru tal-awtorizzazzjoni jew Numru tal-liċenzja fil-pajjiż minn fejn ġejja l-mediċina	Detentur tal- awtorizzazzjoni tqegħid fis-suq
Asbima 5mg/80mg film coated tablets	MA1023/00701	Zentiva k.s.
Asbima 5mg/160mg film coated tablets	MA1023/00702	Zentiva k.s.
Asbima 10mg/160mg film coated tablets	MA1023/00703	Zentiva k.s.
Valsaben 160mg film-coated tablets	GREECE 34227/19-04-2016	Bennett
Valsartan Auro 160mg film-coated tablets	RVG 101567	Aurobindo BV
Valsartan Zentiva 160mg film-coated tablets	ITALY 040723126	Sanofi Malta Limited
Valsartan Zentiva 80mg film-coated tablets	ITALY 040723076	Sanofi Malta Limited
Valsotens 40mg coated tablets	MA628/02401	Actavis Group PTC ehf

Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann
SĠN 3000 info.medicinesauthority@gov.mt | (+356) 23 439 000
www.medicinesauthority.gov.mt

Isem tal-mediċina	Numru tal-awtorizzazzjoni jew Numru tal-liċenzja fil-pajjiż minn fejn ġejja l-mediċina	Detentur tal- Awtorizzazzjoni tqegħid fis-suq
Valsotens 80 mg coated tablets	MA628/02402	Actavis Group PTC ehf
Valsotens 160mg coated tablets	MA628/02403	Actavis Group PTC ehf
Valsotens 320mg film-coated tablets	MA628/02404	Actavis Group PTC ehf
Vapress 80mg film-coated tablets	CYPRUS 21419	Europharma Limited
Vapress 160mg film-coated tablets	CYPRUS 21420	Europharma Limited

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

Isem tal-mediċina	Numru tal-awtorizzazzjoni jew Numru tal-liċenzja fil-pajjiż minn fejn ġejja l-mediċina	Detentur tal- Awtorizzazzjoni tqegħid fis-suq
Valsartan -1A Pharma 80mg film-coated tablets	GERMANY 76616.00.00	1 A Pharma GmbH
Valsartan -1A Pharma 160mg film-coated tablets	GERMANY 76617.00.00	1 A Pharma GmbH
Valsartan Farmoz 80mg film-coated tablets	PORTUGAL 5445408	Farmoz-Sociedade Tecnico Medicinal S.A.
Valsartan Farmoz 160mg film-coated tablets	PORTUGAL 5445432	Farmoz-Sociedade Tecnico Medicinal S.A.

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

Bħala miżura ta' prekawzjoni, spiżjara 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.

Is-sigurta' tal-pazjent hija priorita' għall-Aworita' dwar il-Mediċini għalhekk aktar informazzjoni tkun provduta 'il quddiem.