

The Medicines Authority would like to inform of an emerging situation that is evolving in all EU Member States regarding a number of valsartan containing products. An impurity has been identified as part of the manufacturing process in a valsartan active substance manufacturing site in China. The active substance is used in a number of medicines marketed in Europe. The Medicines Authority is working together with the European Medicines Agency and other regulators to get more information about the issue.

The impurity N-nitrosodimethylamine (NDMA), found in the active substance is a probable carcinogen. There is no evidence at present that this impurity has caused any harm to patients.

Valsartan is used to treat high blood pressure and heart failure and patients are advised that it is vital not to stop taking this important medicine but to go to their pharmacist or doctor at the earliest opportunity to discuss their treatment. **It is emphasized that stopping this medicine abruptly could cause more harm than any potential risk presented by the impurity and patients should continue treatment until they speak to their doctor or pharmacist.**

List of products with the active substance valsartan that may potentially be impacted by this 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 |

For further information please call on 23439202 or 99439122 and or send an email to [caroline.g.muscat@gov.mt](mailto:caroline.g.muscat@gov.mt).