Ref: 10/2021/PLD
13/10/2021

Direct Healthcare Professional Communication

VAXZEVRIA™/COVID-19 Vaccine AstraZeneca: Risk of thrombocytopenia (including immune thrombocytopenia) with or without associated bleeding

Dear Healthcare Professional,

Please also refer to previous Direct Healthcare Professional Communications (DHPCs) of 24th March, 13th April, 02nd June and 23rd June 2021.

AstraZeneca AB, in agreement with the European Medicines Agency and the Malta Medicines Authority, would like to provide you with the following updated information:

Summary

- **Cases of thrombocytopenia, including immune thrombocytopenia (ITP), have been reported after receiving Vaxzevria, typically within the first four weeks after vaccination.**
- **Very rarely, these events of thrombocytopenia presented with very low platelet levels (<20,000 per µL) and/or were associated with bleeding.**
- **Some of these cases occurred in individuals with a history of immune thrombocytopenia.**
- **Cases with fatal outcome have been reported.**
- **If an individual has a history of a thrombocytopenic disorder, such as immune thrombocytopenia, the risk of developing low platelet levels should be considered before administering the vaccine and platelet monitoring is recommended after vaccination.**

Background on the safety concern

Vaxzevria is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older.

Cases of thrombocytopenia, including the autoimmune condition of immune thrombocytopenia (ITP), have been reported after receiving Vaxzevria, typically within the first four weeks after vaccination. Very rarely, these events of thrombocytopenia presented with very low platelet levels (<20,000 per microliter) and/or were associated with bleeding. Cases with fatal outcome have been reported.

The European Medicines Agency has recommended an update to the product information of the Vaxzevria suspension for injection to reflect the current knowledge of the safety topic.

Call for reporting

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are reminded to continue to report suspected adverse reactions associated with Vaxzevria in accordance with the national spontaneous reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Post-licensing directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta or sent by email to postlicensing.medicinesauthority@gov.mt.

Please note the importance of reporting the vaccine product name and batch details.

Company contact point

Should you have any questions or require additional information, please contact AstraZeneca Medical Information at:

Company	Product Name	Website	Phone
Associated Drug Company Limited Triq l-Esportaturi, Zone 1, Central Business District, Birkirkara CBD 1040 Malta	Vaxzevria	www.azcovid-19.com	+356 22778134

Yours faithfully,

Post-Licensing Directorate

Medicines Authority

Disclaimer

This Direct Healthcare Professional Communication has been submitted to you on behalf of AstraZeneca AB and the local agent Associated Drug Company Limited.