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Direct Healthcare Professional Communication

COVID-19 Vaccine AstraZeneca: Risk of thrombocytopenia and coagulation disorders

Dear Healthcare professional,

AstraZeneca AB in agreement with the European Medicines Agency and the Malta Medicines Authority would like to inform you of the following:

Summary

- **COVID-19 Vaccine AstraZeneca: benefits outweigh the risks despite possible link to very rare blood clots with low blood platelets.**

- **A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine AstraZeneca.**

- **Healthcare professionals should be alert to the signs and symptoms of thromboembolism and or thrombocytopenia.**

- **Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches and blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.**

Background on the safety concern

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

Cases of thromboembolic events have been reported following administration of COVID-19 Vaccine AstraZeneca in several EEA countries, some leading to local suspensions of specific batches or to the use of the vaccine itself.

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine AstraZeneca. This includes severe cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, mesenteric vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of these cases occurred within the first seven to fourteen days following vaccination and occurred in women under 55 years of age, however this may reflect the increased use of the vaccine in this population. Some cases had a fatal outcome.

Based on these events, the PRAC has initiated signal procedure in order to further investigate the issue.
The PRAC has performed a full investigation under accelerated timetable including a careful review of EudraVigilance case reports of blood clots and thrombocytopenia in individuals who received the vaccine paying special attention to the information on the sex, age, risk factors, COVID-19 diagnosis (if available), time-to-onset, outcome, and clinical entity. The investigation has also included a related literature review, an observed to expected analysis conducted with EudraVigilance case reports (i.e. including the following Preferred Terms: (Cerebral) venous sinus thrombosis, disseminated intravascular coagulation and thrombotic thrombocytopenic purpura.

While further evidence is being collected, the PRAC has recommended an update to the product information of the COVID-19 Vaccine AstraZeneca suspension for injection to reflect the current knowledge of the safety issue.

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 COVID-19 Vaccine AstraZeneca 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

Company contact point

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

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Yours faithfully,
Post-Licensing Directorate
Medicines Authority

Disclaimer

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