



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals – Part 1 – Vaxzevria

Adopted at the 27-30 September 2021 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals.

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

COVID-19 vaccine (ChAdOx1-S [recombinant]) – Vaxzevria – Immune thrombocytopenia (EPITT no 19678)

Summary of product characteristics

4.4. Special warnings and precautions for use

Coagulation disorders

Thrombosis with thrombocytopenia syndrome ~~and coagulation disorders~~

[...]

Thrombocytopenia

Cases of thrombocytopenia, including immune thrombocytopenia (ITP), have been reported after receiving Vaxzevria, typically within the first four weeks after vaccination. Very rarely, these presented with very low platelet levels (<20,000 per μ L) 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.

¹ Expected publication date. The actual publication date can be checked on the webpage dedicated to [PRAC recommendations on safety signals](#).



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, leg pain, persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches, blurred vision, confusion or seizures after vaccination, or who experiences spontaneous bleeding, skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

[...]

4.8. Undesirable effects

Table 1

Blood and lymphatic system disorders

Frequency not known: immune thrombocytopenia^b

^b Cases have been reported post-marketing (see also section 4.4).

Package leaflet

2. What you need to know before you are given Vaxzevria

Blood disorders

[...]

Very low levels of blood platelets (immune thrombocytopenia), that can be associated with bleeding, have been reported very rarely, usually within the first four weeks following vaccination with Vaxzevria.

[...]

Also, seek immediate medical attention if you experience after a few days following vaccination severe or persistent headaches, blurred vision, confusion or seizures (fits) after vaccination, or experience unexplained bleeding or skin bruising or pinpoint round spots beyond the site of vaccination which appears after a few days (see section 4).

4. Possible side effects

Common (may affect up to 1 in 10 people)

- mild and transient decreased low level of blood platelets (laboratory findings)

Not known (cannot be estimated from the available data)

- very low levels of blood platelets (immune thrombocytopenia) that can be associated with bleeding (see section 2, Blood Disorders)