



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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News

New safety information for healthcare professionals (*from the Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 27 – 30 September 2021*)

New safety information for healthcare professionals

As part of its advice on safety-related aspects, the PRAC agreed on direct healthcare professional communications (DHPCs) containing important safety information for COVID-19 Vaccine Janssen and Vaxzevria.

COVID-19 Vaccine Janssen: risk of immune thrombocytopenia and venous thromboembolism

This DHPC informs healthcare professionals about immune thrombocytopenia (ITP) and venous thromboembolism (VTE).

For ITP, the DHPC highlights that cases of ITP have been reported within the first four weeks after receiving COVID-19 Vaccine Janssen, and that it included serious cases with very low platelet counts.

If an individual has a history of ITP, healthcare professionals should consider the risk of developing low platelet levels prior to administering the vaccine. In individuals with a history of ITP, it is recommended to monitor platelet levels following vaccination with COVID-19 Vaccine Janssen.

For VTE, it is described that VTE has been observed rarely following vaccination with COVID-19 Vaccine Janssen and that the risk of VTE should be considered for individuals with increased risk factors for thromboembolism (blood clots).

Individuals diagnosed with thrombocytopenia within three weeks after vaccination with COVID-19 Vaccine Janssen should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within three weeks of vaccination should be evaluated for thrombocytopenia. This is important, to assess a potential diagnosis of thrombosis with thrombocytopenia syndrome (TTS), which requires specialised clinical management.

Vaxzevria: risk of thrombocytopenia including immune thrombocytopenia

This DHPC informs healthcare professionals of cases of thrombocytopenia (low levels of blood platelets) including immune thrombocytopenia (ITP) that have been reported with Vaxzevria, typically within the first four weeks after vaccination.

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Very rarely, these events of thrombocytopenia presented with very low platelet levels and/or were associated with bleeding.

If an individual has a history of a thrombocytopenic disorder, healthcare professionals are advised to consider the risk of developing low platelet levels such as ITP, before administering the vaccine. Additionally, platelet monitoring is recommended after vaccination in an individual who has a history of ITP.

The DHPCs for COVID-19 Vaccine Janssen and Vaxzevria will be forwarded to EMA's human medicines committee, the CHMP. Following the CHMP agreement, the DHPCs will be disseminated to healthcare professionals by the marketing authorisation holders, according to an agreed communication plan, and published on [EMA's website](#) and in [national registers](#) in EU Member States.