



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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COVID-19 Vaccine Janssen: Guillain-Barré syndrome listed as a very rare side effect

Guillain-Barré syndrome (GBS) will be listed as a very rare side effect of COVID-19 Vaccine Janssen and a warning will be included in the product information to raise awareness among healthcare professionals and people taking the vaccine.

GBS is a rare neurological disorder in which the body's immune system damages nerve cells which can result in pain, numbness and muscle weakness, progressing to paralysis in the most severe cases. Most people fully recover from the disorder.

EMA's safety committee, PRAC, assessed the available evidence, including cases reported to the European database for suspected side effects (EudraVigilance), and information from scientific literature. PRAC looked at 108 cases of GBS reported worldwide as of 30 June, when over 21 million people had received the vaccine.¹ There was one reported death among these reports.

After assessing the available data, PRAC considered that a causal relationship between COVID-19 Vaccine Janssen and GBS is possible.

Although cases of GBS after vaccination with COVID-19 Vaccine Janssen have been reported very rarely, healthcare professionals should be alert to signs and symptoms of GBS, in view of the seriousness of this condition, to allow for early diagnosis, supportive care and treatment.

Vaccinated people are advised to seek immediate medical attention if they develop signs and symptoms suggestive of GBS, such as weakness in the extremities, double vision or difficulty moving eyes (see below for list of symptoms).

EMA confirms that the benefits of COVID-19 Vaccine Janssen continue to outweigh the risks of the vaccine.

A review of GBS cases has also taken place recently for [Vaxzevria](#) (previously COVID-19 Vaccine AstraZeneca). The product information of Vaxzevria now includes a warning on GBS and PRAC continues to closely monitor this issue.

No association has been identified between GBS and the COVID-19 vaccines Comirnaty and Spikevax (previously COVID-19 Vaccine Moderna).

¹ See COVID-19 Vaccine Janssen [safety update](#) from 14 July for cases reported in the EEA.



As for all vaccines, EMA will continue to monitor the vaccines' safety and effectiveness and provide the public with the latest information.

Information for vaccinated people

- Guillain-Barré syndrome (GBS) has occurred very rarely in people who have had COVID-19 Vaccine Janssen.
- GBS is a rare neurological disorder in which the body's immune system mistakenly attacks nerves located outside the brain and spinal cord. Symptoms of GBS range from mild weakness to more severe paralysis. Most people eventually fully recover even from the most severe symptoms, while some may continue to have some degree of weakness.
- Seek immediate medical attention if you develop symptoms of GBS after being vaccinated with COVID-19 Vaccine Janssen.
- Symptoms to watch out for include:
 - double vision or difficulty moving eyes
 - difficulty swallowing, speaking, or chewing
 - coordination problems and unsteadiness
 - difficulty walking
 - tingling sensations in the hands and feet
 - weakness in the limbs, chest or face
 - problems with bladder control and bowel function.

Information for healthcare professionals

- Cases of GBS have occurred very rarely after vaccination with COVID-19 Vaccine Janssen.
- Advise people receiving COVID-19 Vaccine Janssen to seek immediate medical attention if they develop symptoms suggestive of GBS.
- Be alert to signs and symptoms of GBS to ensure correct diagnosis, to initiate adequate supportive care and treatment and to rule out other causes.
- The product information for COVID-19 Vaccine Janssen will list GBS as a very rare side effect (section 4.8). Section 4.4 is also being updated with a warning.

More about the medicine

COVID-19 Vaccine Janssen is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older. COVID-19 is caused by SARS-CoV-2 virus.

COVID-19 Vaccine Janssen is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making a protein found on SARS-CoV-2.

COVID-19 Vaccine Janssen does not contain SARS-CoV-2 itself and cannot cause COVID-19.

More about the procedure

This review was carried out by EMA's Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, in the context of a procedure known as a 'type II variation'. The PRAC's recommendations have been endorsed by EMA's human medicine committee, CHMP.