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

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Information on COVID-19 Vaccine Janssen

- 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.

The following products are authorised via centralised procedure.

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
COVID-19 vaccine (Ad26.COV2-S [recombinant])	COVID-19 Vaccine Janssen	Concentrate for dispersion for injection (sterile concentrate)	POM	EU/1/20/1525	Janssen-Cilag International NV

Information from the EMA about the safety concern

- 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 submitted to EMA's human medicine committee, and CHMP, has endorsed them.

- 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.

- 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).

- 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).

- EMA confirms that the benefits of COVID-19 Vaccine Janssen continue to outweigh the risks of the vaccine. As for all vaccines, EMA will continue to monitor the vaccines' safety and effectiveness and provide the public with the latest information.

In Malta

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.

Advice 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

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

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.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance with COVID-19 Vaccine Janssen. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to: Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 **or** online to http://www.medicinesauthority.gov.mt/adrportal or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate

Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health.

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this form (address side up), stapling the ends and then posting (no stamp required).

Feedback:

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Pharmacovigilance Section

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