



## Pharmacovigilance Drug Safety Alert

July 15, 2021

### FDA warns of Increased Risk of Guillain-Barré syndrome following Janssen (Johnson & Johnson) COVID-19 vaccination; Revises Fact Sheets

On July 13, 2021, the FDA announced revisions to the vaccine recipient and vaccination provider fact sheets for the Johnson & Johnson (Janssen) COVID-19 Vaccine to include information pertaining to an observed increased risk of Guillain-Barré syndrome following vaccination.<sup>1</sup>

Guillain-Barré syndrome is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. While its cause is not fully understood, the syndrome often follows infection with a virus or bacteria. Each year in the United States, an estimated 3,000 to 6,000 people develop Guillain-Barré syndrome. Most people fully recover from Guillain-Barré syndrome, but some have permanent nerve damage.<sup>2</sup>

The CDC's Advisory Committee on Immunization Practices COVID-19 Vaccine Safety Technical Work Group has reviewed post-authorization vaccine safety data weekly or biweekly since the start of the U.S. COVID-19 vaccination program in December 2020. During the Vaccine Safety Technical Work Group meeting on June 28, 2021, members reviewed data on reports of Guillain-Barré syndrome among persons who received COVID-19 vaccination. The data are from several sources, including passive surveillance in the Vaccine Adverse Event Reporting System (VAERS) and active surveillance in the Vaccine Safety Datalink and the Department of Veteran Affairs.<sup>3</sup>

- The number of preliminary cases of Guillain-Barré syndrome reported to VAERS among persons after they received the Janssen COVID-19 vaccine was greater than the expected number of Guillain-Barré syndrome cases. The reports were not limited to a specific age group, and there was no geographic clustering. **The number of observed versus expected reports was not elevated for the mRNA COVID-19 vaccines.**
- Neither the Vaccine Safety Datalink nor the Department of Veteran Affairs data indicated that rates of Guillain-Barré syndrome in the window following any of the COVID-19 vaccines differ from expected at this time; however, in Vaccine Safety Datalink the rate of Guillain-Barré syndrome following Janssen COVID-19 vaccine was higher than the rate following the mRNA vaccines.
- Guillain-Barré syndrome has been reported after receiving AstraZeneca COVID-19 vaccine, which is used in other countries. **Both Janssen and AstraZeneca COVID-19 vaccines are adenovirus vector vaccines.**
- Review and adjudication of Guillain-Barré syndrome case reports and diagnoses are underway in U.S. surveillance systems.
- Ongoing monitoring of Guillain-Barré syndrome among persons who received the Janssen COVID-19 vaccine in the United States is needed.
- The Vaccine Safety Technical Work Group will continue to review data on Guillain-Barré syndrome after COVID-19 vaccination.

The FDA said 100 preliminary reports of Guillain-Barré syndrome had been filed with VAERS, out of 12.8 million Janssen vaccines given. **In most cases, symptoms began within 42 days following vaccination. Healthcare professionals should inform patients to seek immediate medical attention if they develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:**<sup>1,4</sup>

- ***Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body***
- ***Difficulty walking***
- ***Difficulty with facial movements, including speaking, chewing, or swallowing***
- ***Double vision or inability to move eyes***
- ***Difficulty with bladder control or bowel function***

The Fact Sheets for Healthcare Providers Administering Vaccine and Recipients and Caregivers have been revised to include information about Guillain-Barré syndrome.<sup>5,6</sup>

- **Updated EUA Fact Sheets (both revised 7/08/2021)**
  - [Healthcare Providers Administering Vaccine](#)
  - [Recipients and Caregivers](#)

**\*\*Report all significant or unusual Adverse Vaccine Events (AVE) to the VAERS program as described in the [Indian Health Manual](#). Instructions for submitting an AVE can be found on the [IHS Pharmacovigilance website](#). Please ensure that you document "IHS" in field #26 of the form.**

**References:**

1. US Food and Drug Administration. FDA News Release. [Coronavirus \(COVID-19\) Update: July 13, 2021](#). Accessed 7/15/21.
2. Centers for Disease Control & Prevention. [Guillain-Barré syndrome and Vaccines](#). Accessed 7/13/21.
3. CDC Advisory Committee on Immunization Practices. [COVID-19 Vaccine Safety Technical Work Group Report, June 28, 2021](#). Accessed 7/13/21.
4. Johnson & Johnson website. [Johnson & Johnson Statement on COVID-19 Vaccine \(7/12\)](#). Accessed 7/13/21.
5. FDA EUA Fact Sheet for Healthcare Providers Administering Vaccine. [Janssen COVID-19 Vaccine](#). Revised 7/8/21.
6. FDA EUA Fact Sheet for Recipients and Caregivers. [Janssen COVID-19 Vaccine](#). Revised 7/8/21.