The Medical Letter®

on Drugs and Therapeutics

Volume 63 August 9, 2021

ISSUE No. 1630

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The Medical Letter®
on Drugs and Therapeutics

Volume 63 (Issue 1630) August 9, 2021

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IN BRIEF

Guillain-Barré Syndrome with the Johnson & Johnson COVID-19 Vaccine

On July 12, 2021, the FDA added a warning to the Fact Sheet for the Johnson & Johnson (Janssen) adenovirus-based COVID-19 vaccine about an increased risk of Guillain-Barré syndrome (GBS) following administration of the product.[1]

The warning is based on 100 cases of GBS that were reported to the Vaccine Adverse Events Reporting System (VAERS) following administration of the Johnson & Johnson vaccine. Most of the cases occurred within 42 days of vaccination; 95 of the 100 persons who developed GBS required hospitalization, and 1 died. About 12.5 million doses of the Johnson & Johnson vaccine had been administered at the time the warning was issued.[2,3]

According to the CDC, 3000-6000 cases of GBS are reported annually in the US. In many cases, GBS occurs following a viral or bacterial infection, including COVID-19.[4] The syndrome has been reported following administration of other vaccines, including the Oxford-AstraZeneca adenovirus-based COVID-19 vaccine (not authorized for use in the US).[5]

Recipients of the Johnson & Johnson vaccine who develop weakness or tingling in the legs or arms that worsens or spreads or who have difficulty with walking, facial or ocular movement, bladder control, or bowel function should seek immediate medical attention. The Pfizer-BioNTech and Moderna mRNA-based COVID-19 vaccines have not been associated with GBS to date.[2] ■

1. FDA. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Janssen COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). July 8, 2021. Available at: https://bit.ly/3e6KEaD. Accessed July 15, 2021.
2. FDA News Release. Coronavirus (COVID-19) update: July 13, 2021. Available at: https://bit.ly/3zg9NHt. Accessed July 15, 2021.
3. Johnson & Johnson. Johnson & Johnson statement on COVID-19 vaccine (7/12). July 12, 2021. Available at: https://bit.ly/3kmg6EY. Accessed July 15, 2021.
4. S Abu-Rumeileh et al. Guillain-Barré syndrome spectrum associated with COVID-19: an up-to-date systematic review of 73 cases. J Neurol 2021; 268:1133.
5. CM Allen et al. Guillain-Barré syndrome variant occurring after SARS-CoV-2 vaccination. Ann Neurol 2021 June 10 (epub).

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