



Pharmacovigilance Drug Safety Alert

June 28, 2021

FDA warns of Increased Risk of Myocarditis and Pericarditis after Pfizer-BioNTech and Moderna vaccination; Revises Fact Sheets

On June 25, 2021, the FDA announced revisions to the patient and provider fact sheets for the [Pfizer-BioNTech](#) and [Moderna](#) COVID-19 vaccines regarding the suggested increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following vaccination¹.

For each vaccine, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) has been revised to include a warning about myocarditis and pericarditis and the Fact Sheet for Recipients and Caregivers has been revised to include information about myocarditis and pericarditis.

- Updated Fact Sheets for Healthcare Providers Administering Vaccine^{2,3}
 - [Pfizer-BioNTech](#)
 - [Moderna](#)

This update follows an extensive review of information and the discussion by CDC's Advisory Committee on Immunization Practices meeting on Wednesday. The data presented at this meeting reinforced the FDA's decision to revise the fact sheets and further informed the specific revisions⁴.

The warning in the Fact Sheets for Healthcare Providers Administering Vaccines notes that reports of adverse events suggest increased risks of myocarditis and pericarditis, particularly following the second dose and with onset of symptoms within a few days after vaccination. ***Additionally, the Fact Sheets for Recipients and Caregivers for these vaccines note that vaccine recipients should seek medical attention right away if they have chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after vaccination.***

The FDA and CDC are monitoring the reports, collecting more information, and will follow-up to assess longer-term outcomes over several months.

****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. FDA News Release. Coronavirus (COVID-19) Update: June 25, 2021. Accessed 6-28-21. Available [here](#).
2. FDA Fact Sheet for Healthcare Providers Administering Vaccine. [Pfizer-BioNTech Vaccine](#). Updated 6-25-21.
3. FDA Fact Sheet for Healthcare Providers Administering Vaccine. [Moderna Vaccine](#). Updated 6-25-21.
4. Advisory Committee on Immunization Practices (ACIP). ACIP Meeting Presentation Sides. (June 23-25, 2021). Accessed June 28, 2021. Available [here](#).