



COVID-19 mRNA Vaccine Comirnaty: risk of myocarditis and pericarditis

Dear Healthcare professional,

BIONTECH/PFIZER in agreement with Egyptian Drug Authority would like to inform you of the following:

Summary:

- Post marketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age.
- Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.
- Healthcare professionals should advise vaccinated individuals to seek immediate medical attention should they experience chest pain, shortness of breath, or palpitations.

Background on the safety concern:

- Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the lining outside the heart. In both cases, the body's immune system is causing inflammation in response to an infection or some other trigger. Symptoms can include chest pain, shortness of breath, or palpitations.
- The severity of cases of myocarditis and pericarditis can vary. For the cases reported after mRNA COVID-19 vaccination, most who presented to medical care have responded well to medications and rest
- For initial evaluation, consider an ECG, troponin level, and inflammatory markers such as C-reactive protein and erythrocyte sedimentation rate. In the setting of normal ECG, troponin, and inflammatory markers, myocarditis or pericarditis are unlikely.

For suspected cases, consider consultation with cardiology for assistance with cardiac evaluation and management. Evaluation and management may vary depending on the patient age, clinical presentation, potential causes, or practice preference of the provider.

- It is important to rule out other potential causes of myocarditis and pericarditis. Consider consultation with infectious disease and/or rheumatology to assist in this evaluation.





- Where available, evaluate for potential etiologies of myocarditis and pericarditis, particularly acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2 infection (e.g., detection of SARS-CoV-2 nucleocapsid antibodies), and other viral etiologies (e.g., enterovirus PCR and comprehensive respiratory viral pathogen testing).

Call for Reporting:

The Egyptian Pharmaceutical Vigilance Center is reminding HCP and public to report any safety information regarding human medicinal products including adverse drug reactions, medications errors, lack of efficacy and other medicine related problems through the following contacts:

The Egyptian Pharmaceutical Vigilance Center

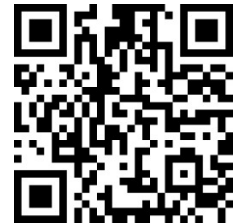
Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451

Telephone: (+2)02 25354100, Extension: 1470 Fax: +202 – 23610497

Email: Pv.follow-up@edaegypt.gov.eg

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:



Pfizer Drug Safety Unit:

Tel.: +20 2 3333-7777 (Pfizer switchboard)

Tel.: +20 2 3333-7751

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