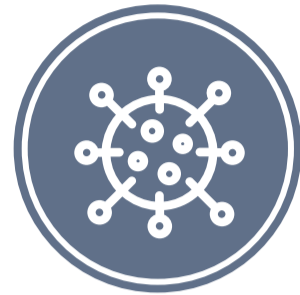


COVID-19 Burden of Disease During Pregnancy and Select COVID-19 Vaccination Recommendations

According to the CDC, pregnancy is associated with higher risk for severe COVID-19¹



COVID-19 during pregnancy is associated with severe illness and death, and pregnant women with COVID-19 are more likely to experience preterm birth, stillbirth, and other pregnancy complications²⁻³

The mortality risk of pregnant patients with COVID-19 infection at delivery was approximately 14 times higher compared with those without (64.0 vs 4.3 per 100.000 deliveries; aOR, 13.91 [95% CI, 6.36-30.42]⁴

CDC and ACIP recommend COVID-19 vaccination for persons who are pregnant, might become pregnant, recently pregnant or breastfeeding⁵

- For additional information and latest clinical consideration on the use of COVID-19 vaccines currently approved or authorized in the United States, please visit: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html>

The American College of Obstetricians and Gynecologists (ACOG) recommends pregnant and lactating individuals, receive COVID-19 vaccination⁶

- A single dose of the 2023-2024 updated COVID-19 vaccine is recommended for all eligible adults, including pregnant and lactating adults, at least two months after their last COVID-19 vaccine dose⁶
- Vaccination may occur in any trimester, and emphasis should be on vaccine receipt as soon as possible⁶
- According to ACOG, COVID-19 vaccines may be administered simultaneously with other vaccines during pregnancy⁶

Abbreviations: aOR: adjusted odds ratio

Reference: **1.** CDC Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html>. Updated Feb. 9, 2023. **2.** Zambrano LD, Ellington S, Strid P, et al.; CDC COVID-19 Response Pregnancy and Infant Linked Outcomes Team. Update: characteristics of symptomatic women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status—United States, January 22–October 3, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1641–7. <https://doi.org/10.15585/mmwr.mm6944e3> **3.** Woodworth KR, Olsen EO, Neelam V, et al.; CDC COVID-19 Response Pregnancy and Infant Linked Outcomes Team; COVID-19 Pregnancy and Infant Linked Outcomes Team (PILOT). Birth and infant outcomes following laboratory-confirmed SARS-CoV-2 infection in pregnancy—SET-NET, 16 jurisdictions, March 29–October 14, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1635–40. <https://doi.org/10.15585/mmwr.mm6944e2> **4.** Matsuo K, Green JM, Herrman SA, Mandelbaum RS, Ouzounian JG. Severe Maternal Morbidity and Mortality of Pregnant Patients With COVID-19 Infection During the Early Pandemic Period in the US. JAMA Netw Open. 2023;6(4):e237149. doi:10.1001/jamanetworkopen.2023.7149. **5.** CDC. Guidelines for Vaccinating Pregnant Women. Accessed September 27, 2023. <https://www.cdc.gov/vaccines/pregnancy/hcp-toolkit/guidelines.html>. **6.** ACOG COVID-19 Vaccination Considerations for Obstetric–Gynecologic Care. <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care> Updated September 25, 2023.



COMIRNATY[®]

(COVID-19 Vaccine, mRNA)

Indication

COMIRNATY[®] (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

Selected Safety Information

Do not administer COMIRNATY[®] (COVID-19 Vaccine, mRNA) to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of COMIRNATY or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Pfizer-BioNTech COVID-19 vaccine.

Pregnant individuals infected with SARS-CoV-2 are at increased risk of severe COVID-19 compared with non-pregnant individuals.¹

- Available data on COMIRNATY administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.¹
- It is not known whether COMIRNATY is excreted in human milk. Data are not available to assess the effects of COMIRNATY on the breastfed infant or on milk production/excretion.¹
- The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for COMIRNATY and any potential adverse effects on the breastfed child from COMIRNATY or from the underlying maternal condition.¹
- For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.¹

Selected Safety Information¹

Management of Acute Allergic Reactions¹

- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of COMIRNATY.¹

Please see additional Important Safety Information on page 5.

Please click for [COMIRNATY Full Prescribing Information](#) and [Patient Information](#).

Reference: 1. COMIRNATY® (COVID-19 Vaccine, mRNA). Full Prescribing Information. Pfizer and BioNTech; October 17, 2023.

 **COMIRNATY**[®]
(COVID-19 Vaccine, mRNA)

Important Safety Information

Do not administer COMIRNATY® (COVID-19 Vaccine, mRNA) to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of COMIRNATY or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Pfizer-BioNTech COVID-19 vaccine.

Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of COMIRNATY.

Myocarditis and Pericarditis

Postmarketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For COMIRNATY, 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. The Centers for Disease Control and Prevention (CDC) has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, including COMIRNATY. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to COMIRNATY.

Limitation of Vaccine Effectiveness

COMIRNATY may not protect all vaccine recipients.

Adverse Reactions

The most commonly reported adverse reactions ($\geq 10\%$) after a dose of COMIRNATY were pain at the injection site (up to 90.5%), fatigue (up to 77.5%), headache (up to 75.5%), chills (up to 49.2%), muscle pain (up to 45.5%), joint pain (up to 27.5%), fever (up to 24.3%), injection site swelling (up to 11.8%), and injection site redness (up to 10.4%).

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Inc. at 1-800-438-1985 or <https://www.pfizersafetyreporting.com> or VAERS at 1-800-822-7967 or <http://vaers.hhs.gov>

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Please click for COMIRNATY Full Prescribing Information and Patient Information.



Find additional resources about COVID-19 vaccines from BioNTech and Pfizer at www.cvdvaccine-us.com



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BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 10001

COVID-19 vaccines from BioNTech and Pfizer, which are based on BioNTech proprietary mRNA technology, were developed by both BioNTech and Pfizer.

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