

comirnaty

FDA APPROVED TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) CAUSED BY SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) IN INDIVIDUALS 16 YEARS OF AGE AND OLDER.

Comirnaty can cause:

- + Myocarditis (heart muscle inflammation)
- + Pericarditis (heart sac tissue inflammation)
- + Syncope (fainting)
- + Altered Immunocompetence
- + Injection site pain/swelling/redness
- + Fatigue
- + Headache
- + Muscle pain
- + Chills
- + Joint pain
- + Hyperhidrosis (abnormally increased sweating)
- + Malaise (discomfort)
- + Lymphadenopathy
- + Asthenia (lack of energy)
- + Decreased appetite
- + Lethargy
- + Night sweats
- + Fever
- + Nausea
- + Diarrhea/Vomiting
- + Severe allergic reactions including anaphylaxis
- + Rash/pruritus (itchy skin)
- + Urticaria (hives)
- + Angioedema (swelling)

SOURCES FROM FDA + PFIZER + BIONTECH

<https://www.fda.gov/media/151707/download>

Let's dig deeper into some of the listed reactions

MYOCARDITIS + PERICARDITIS



Myocarditis is a form of heart disease that results from inflammation of the muscles that comprise the heart. This inflammation can weaken your heart making it harder to pump blood to the rest of your body. Myocarditis may result in feeling shortness of breath, faster or irregular heartbeat, and chest pain. An episode of myocarditis may resolve completely or may cause long-lasting harm. The most common cause of myocarditis is a viral infection, but other types of infection can cause myocarditis. Certain chemicals have also been known to cause myocarditis.

<https://www.cdc.gov/dhdspl/myocarditis.htm>

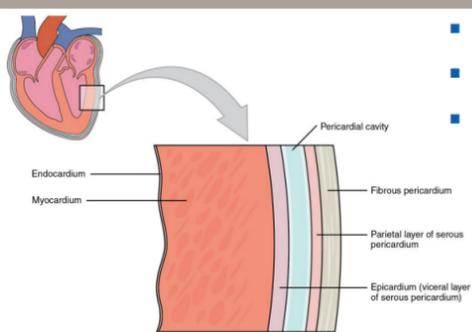


Myocarditis is inflammation of the heart muscle.

Pericarditis is inflammation of the tissue that forms a sac around the heart.

Inflammation is your body's response to infection or injury. It can affect many areas of the body and is a cause of many major diseases, including cancer, ischemic heart disease, and autoimmune diseases. Inflammation in the heart causes damage and can lead to serious health problems.

<https://www.nhlbi.nih.gov/health-topics/heart-inflammation#:~:text=Myocarditis%20is%20an%20uncommon%20disease,may%20be%20acute%20or%20chronic>



- Myocarditis: Inflammation of the myocardium (the heart muscle)
- Pericarditis: Inflammation of the pericardium (the lining around the heart)
- Myopericarditis: When both myocarditis and pericarditis are present

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/02-COVID-Oster-508.pdf>

MANUFACTURER GUIDANCE

ACCORDING TO THE FDA + MANUFACTURERS:

Pediatric Use

The safety and effectiveness of COMIRNATY in individuals younger than 16 years of age have not been established.

If the safety + effectiveness of this product has not been established for ages younger than 16 years old, then why has the FDA authorized emergency use of this product for ages 12-15 years old?

Male fertility

COMIRNATY has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility.

No clinical trial data for immunocompromised patients or patients that already had Covid-19.

The study excluded participants who were

immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19.

Why is this product recommended for those already diagnosed with Covid-19 when the Phase 3 clinical trial excluded this population?

PREGNANCY + BREASTFEEDING

ACCORDING TO THE FDA + MANUFACTURERS:

Available data on COMIRNATY administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to COMIRNATY during pregnancy. Women who are vaccinated with COMIRNATY during pregnancy are encouraged to enroll in the registry by visiting <https://mothertobaby.org/ongoing-study/covid19-vaccines/>.

MotherToBaby is enrolling pregnant people who have received a COVID-19 vaccine into an observational study. All of our research is conducted by phone — you will not be asked to visit an office. Vaccines are an important tool to prevent illness, yet there is limited data about the use of COVID-19 vaccines for people who are pregnant. Our study will provide critical information for future moms-to-be and the medical community.

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. 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. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

Vaccine-associated risks in pregnancy and the effects on the breastfed infant or on milk production/excretion are unknown. All patients currently accepting this product will be the observational data to inform future mothers of potential adverse effects.

LIMITED LONG TERM DATA

ACCORDING TO THE FDA + MANUFACTURERS:

The safety of COMIRNATY was evaluated in participants 16 years of age and older in 2 clinical studies conducted in Germany (Study 1), United States, Argentina, Brazil, Turkey, South Africa, and Germany (Study 2). Study BNT162-01 (Study 1) was a Phase 2-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age and 36 participants, 56 through 85 years of age. Study C4591001 (Study 2) is a Phase 1/2/3 multicenter, multinational, randomized, saline placebo-controlled, double-blinded (Phase 2/3), dose-finding, vaccine candidate-selection and efficacy study that has enrolled approximately 44,047 participants (22,026 COMIRNATY; 22,021 placebo) 16 years of age or older (including 378 and 376 participants 16 through 17 years of age in the vaccine and placebo groups, respectively). Upon issuance of the Emergency Use Authorization (December 11, 2020) for COMIRNATY, participants were unblinded to offer placebo participants COMIRNATY. Participants were unblinded in a phased manner over a period of months to offer placebo participants COMIRNATY.

Phase 3 Clinical Trial placebo participants were given Comirnaty during the clinical trial meaning all long-term data is compromised.

At the time of the analysis of the ongoing Study 2 with a data cut-off of March 13, 2021, there were 25,651 (58.2%) participants (13,031 COMIRNATY and 12,620 placebo) 16 years of age and older followed for ≥4 months after the second dose.

This same study is ongoing as of FDA approval. Data provided is only interim versus final clinical trial results. Estimated completion date is May 2023.

Estimated Primary Completion Date ⓘ : May 2, 2023

Estimated Study Completion Date ⓘ : May 2, 2023

<https://clinicaltrials.gov/ct2/show/NCT04368728?term=C4591001&draw=2&rank=4>

INGREDIENTS

Each dose of COMIRNATY contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each 0.3 mL dose of the COMIRNATY also includes the following ingredients: lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

Unfortunately, according to Pfizer's Chairman and CEO, the full ingredient list is protected by intellectual property rights for the mRNA vaccines.

https://www.pfizer.com/news/hot-topics/why_pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines

The biggest question is what are the ingredients used in the manufacturing process to create the 30 mcg of mRNA with the viral spike coding?

IS IT EFFECTIVE?

ACCORDING TO THE FDA + MANUFACTURERS:

5.5 Limitation of Effectiveness

COMIRNATY may not protect all vaccine recipients.

This product is intended to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), not SARS-Cov-2 itself. This limitation of effectiveness addresses the intention to prevent Covid-19 which means the following may still occur even if fully vaccinated:

- + SARS-Cov-2 transmission/infection
- + Covid-19 diagnosis
- + Complications of Covid-19
- + Hospitalizations from Covid-19 complications
- + Death from Covid-19 complications

THIS PRODUCT IS NOT GUARANTEED BY THE MANUFACTURER OR FDA TO WORK FOR EVERYONE.