

Patient Education

COVID-19 Vaccine (mRNA)

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information

Pronunciation

(KO vid nine teen vak SEEN m R N A)

Brand Names: US

Comirnaty; Moderna COVID-19 Bival Booster; Moderna COVID-19 Vac (Booster); Moderna COVID-19 Vacc 6m-5y; Moderna COVID-19 Vaccine; Pfizer COVID-19 Vac Bival 5-11; Pfizer COVID-19 Vac Bivalent; Pfizer COVID-19 Vac-TriS 5-11y; Pfizer COVID-19 Vac-TriS 6m-4y; Pfizer-BioNT COVID-19 Vac-TriS; Pfizer-BioNTech COVID-19 Vacc; Spikevax COVID-19 Vaccine

Brand Names: Canada

Comirnaty; Comirnaty (Gray Cap); Comirnaty (Purple Cap); Comirnaty Original & Omicron; Spikevax; Spikevax Bivalent; Spikevax Orig & Omicron BA.4/5

What is this drug used for?

- It is used to prevent COVID-19.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug (including polyethylene glycol); or any other drugs, foods, or substances (including polysorbate). Tell your doctor about the allergy and what signs you had.
- If you have COVID-19, if you have any symptoms that could be from COVID-19, if you are waiting to find out COVID-19 test results, or if you recently had COVID-19.
- If you have an illness with a fever.
- If you have ever had certain heart problems (myocarditis, pericarditis).
- If you have ever had a health problem called multisystem inflammatory syndrome (MIS).
- If you have bleeding problems.
- If you are taking aspirin or a blood thinner.
- If you have had a different COVID-19 vaccine.

- If you have been exposed to someone who has COVID-19 within the past 14 days.
- If you have had a smallpox or monkeypox vaccine within the past 4 weeks.
- This is not a list of all drugs or health problems that interact with this drug.
- Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- This vaccine cannot cause COVID-19.
- Be sure you know how many doses of COVID-19 vaccine you have had, how many you will need, and if you are able to get a booster dose. Talk with your doctor or pharmacist if you have any questions.
- It is not known how long people who get this vaccine will be protected from COVID-19.
- Like all vaccines, this vaccine may not fully protect all people who get it. If you have questions, talk with the doctor.
- If you have side effects after a dose, acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen or naproxen may help.
- Side effects may happen more often after the second dose. If you have questions about the second dose, talk with the doctor.
- After getting the vaccine, continue to do things that prevent the spread of COVID-19 as recommended by local public health officials. These include washing hands often, wearing a mask, staying at least 6 feet away from other people, and avoiding crowds.
- If you have a weak immune system or take drugs that weaken the immune system, talk with your doctor. This vaccine may not work as well. Some people may need to get a COVID-19 vaccine again.
- People who got this vaccine before or during a stem cell transplant or chimeric antigen receptor [CAR]-T therapy may need to get a COVID-19 vaccine again. If you have had or are having one of these treatments, talk with your doctor.
- This vaccine may affect syphilis test results. Tell all your health care providers and lab workers if you have gotten this vaccine in the past 5 months.
- If you have had a dermal filler injection, talk with your doctor. Rarely, swelling at or near the area of the filler (usually in the face or lips) has happened after a dose of this vaccine. When this happened, it did not last for long and went away with treatment.

- Rarely, cases of Bell's palsy happened in studies. It is not known if this vaccine may be the cause. Tell your doctor if you have ever had Bell's palsy. Call your doctor right away if you have signs like weak or drooping muscles on one side of your face.
- This drug may not be for use in children of all ages. Talk with the doctor before giving this drug to a child.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

What are some side effects that I need to call my doctor about right away?

- **WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:
 - Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
 - Fast or slow heartbeat, fast breathing, dizziness, passing out, weakness, anxiety, confusion, or change in eyesight or hearing. These may be other signs of an allergic reaction or other type of reaction.
 - Lowered sense of touch or feeling.
 - Numbness or tingling.
 - Some heart problems have very rarely happened with mRNA COVID-19 vaccines. Most of the time, signs started within 7 days after the second dose or first booster dose. These heart problems can happen at a higher rate in people who get COVID-19 than in those who get this vaccine. Signs may include chest pain, shortness of breath, or feeling like your heart is beating fast, fluttering, or pounding. In younger children, signs may include feeling irritable, throwing up, poor feeding, fast breathing, or sluggishness. Call the doctor right away if any of these signs happen. If you have questions or concerns about this information, talk with the doctor.

What are some other side effects of this drug?

- All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:
 - **For all patients taking this drug:**
 - Pain, redness, or swelling where the injection was given; headache; muscle or joint pain; fever of 100.4°F (38°C) or higher; chills; upset stomach, throwing up, decreased appetite, or diarrhea; swollen or tender glands; or feeling tired or unwell. Most side effects have been mild to moderate. Most of the time these happened within 3 days after the injection and went away within 1 to 3 days.

- Pain, redness, or swelling at the injection site have happened a few days to a few weeks after the first injection. If this happens, talk with your doctor. Get the second dose in the other arm.
- **Young children:**
- Feeling irritable.
- Crying.
- Feeling sleepy.
- These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.
- You may report side effects to your national health agency.
- Report side effects to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967. There is also a smartphone tool called V-safe that may be used to check how you are doing and to report side effects. This can be found at <https://vsafe.cdc.gov>. If you need help with V-safe, call 1-800-232-4636.

How is this drug best taken?

- Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.
- It is given as a shot into a muscle.
- You will be watched closely while you receive this drug and for some time after your dose. Talk with your doctor.

What do I do if I miss a dose?

- Call your doctor to find out what to do. For the most protection against COVID-19, it is important that you do not miss or skip doses.

How do I store and/or throw out this drug?

- This injection will be given to you in a healthcare setting. You will not store it at home.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Last Reviewed Date

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