

Information for Recipients and Caregivers
SPIKEVAX (pronounced SPĪK-văx)
(COVID-19 Vaccine, mRNA)
(2023-2024 Formula)

Please read this information sheet before getting SPIKEVAX. This summary is not intended to take the place of talking with your healthcare provider. If you have questions or would like more information, please talk with your healthcare provider.

What is SPIKEVAX?

SPIKEVAX is a vaccine to protect you against COVID-19. SPIKEVAX is for people 12 years of age and older. Vaccination with SPIKEVAX may not protect all people who receive the vaccine.

SPIKEVAX does not contain SARS-CoV-2, the virus that causes COVID-19. SPIKEVAX cannot give you COVID-19.

Who should not get SPIKEVAX?

You should not get SPIKEVAX if you had:

- a severe allergic reaction after a previous dose of SPIKEVAX, Moderna COVID-19 Vaccine (Original monovalent), or Moderna COVID-19 Vaccine, Bivalent¹
- a severe allergic reaction to any ingredient of this vaccine (see **What are the ingredients in SPIKEVAX?**)

What should I tell my healthcare provider?

Tell your healthcare provider about all of your medical conditions, including if you:

- have any allergies
- had a severe allergic reaction after receiving a previous dose of any COVID-19 vaccine
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received any other COVID-19 vaccine
- have ever fainted in association with an injection

How is SPIKEVAX given?

SPIKEVAX is given as an injection into the muscle.

What are the risks of SPIKEVAX?

Severe allergic reactions have occurred in some people who have received SPIKEVAX,

¹ SPIKEVAX is made the same way as the Moderna COVID-19 Vaccine (Original monovalent) and Moderna COVID-19 Vaccine, Bivalent, but it encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

Moderna COVID-19 Vaccine (Original monovalent), and Moderna COVID-19 Vaccine, Bivalent. There is a very small chance that SPIKEVAX could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of SPIKEVAX. For this reason, your healthcare provider may ask you to stay for a short time at the place where you received your vaccine. Signs of a severe allergic reaction can include:

- Trouble breathing
- Swelling of your face and throat
- A fast heartbeat
- A rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA COVID-19 vaccines, including SPIKEVAX, Moderna COVID-19 Vaccine (Original monovalent), and Moderna COVID-19 Vaccine, Bivalent. Myocarditis and pericarditis following Moderna COVID-19 vaccines have occurred, most commonly in males 18 years through 24 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. You should seek medical attention right away if you or your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a dose of the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported in clinical trials with SPIKEVAX, Moderna COVID-19 Vaccine (Original monovalent), and Moderna COVID-19 Vaccine, Bivalent include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, fever, and rash

Other side effects that have been reported include:

- Severe allergic reactions
- Urticaria (itchy rash/hives)
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine

These may not be all of the possible side effects of SPIKEVAX. Ask your healthcare provider about any side effects that concern you. You may report side effects to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or <https://vaers.hhs.gov>.

What if I am pregnant or breastfeeding?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

A pregnancy exposure registry is available. You are encouraged to contact the registry as soon as

you become aware of your pregnancy by calling 1-866-MODERNA (1-866-663-3762) or ask your healthcare provider to contact the registry for you.

What are the ingredients in SPIKEVAX?

SPIKEVAX contains the following ingredients:

- messenger ribonucleic acid (mRNA)
- lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC])
- tromethamine
- tromethamine hydrochloride
- acetic acid
- sodium acetate trihydrate
- sucrose

SPIKEVAX does not contain preservatives.

If you would like more information, talk to your healthcare provider or visit www.spikevax.com or call 1-866-MODERNA (1-866-663-3762).

Manufactured for:
Moderna US, Inc.
Princeton, NJ 08540

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SPIKEVAX is a trademark of ModernaTX, Inc.
Patent(s): www.modernatx.com/patents
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Immunization Registry Notice to Patients and Parents

Immunizations or 'shots' prevent serious diseases. Tuberculosis (TB) screening tests help to determine if you may have TB infection and can be required for school or work. Keeping track of shots/TB tests you have received can be hard. It's especially hard if more than one doctor gave them. Today, doctors use a secure computer system called an *immunization registry* to keep track of shots and TB tests. If you change doctors, your new doctor can use the registry to see the shot/TB test record. It's your right to choose if you want shot/TB test records shared in the *California Immunization Registry*.

How Does a Registry Help You?

- Keeps track of all shots and TB tests (skin tests/chest x-rays), so you don't miss any or get too many
- Sends reminders when you or your child need shots
- Gives you a copy of the shot/TB record from the doctor
- Can show proof about shots/TB tests needed to start child care, school, or a new job

How Does a Registry Help Your Health Care Team?

Doctors, nurses, health plans, and public health agencies use the registry to:

- See which shots/TB tests are needed
- Prevent disease in your community
- Remind you about shots needed
- Help with record-keeping

Can Schools or Other Programs See the Registry?

Yes, but this is limited. Schools, child care, and other agencies allowed under California law may:

- See which shots/TB tests children in their programs need
- Make sure children have all shots/TB tests needed to start child care or school

What Information Can Be Shared in a Registry?

- patient's name, sex, and birth date
- limited information to identify patients
- parents' or guardians' names
- details about a patient's shots/TB tests

What's entered in the registry is treated like other private medical information. Misuse of the registry can be punished by law. Under California law, only your doctor's office, health plan, or public health department may see your address and phone number.

Patient and Parent Rights

It's your legal right to ask:

- not to share your (or your child's) registry shot/TB test records with others besides your doctor*
- not to get shot appointment reminders from your doctor's office
- to look at a copy of your or your child's shot/TB test records
- who has seen the records or to have the doctor change any mistakes

If you DO want your or your child's records in the registry, do nothing. You're all done.

If you DO NOT want your doctor's office to share your immunization/TB test information with other registry users, tell your doctor or download a "Decline or Start Sharing/Information Request Form" from the CAIR website (<http://cairweb.org/cair-forms/>) and FAX or email it to the CAIR Help Desk at 1-888-436-8320 or CAIRHelpDesk@cdph.ca.gov.

For more information, contact the CAIR Help Desk at 800-578-7889 or CAIRHelpDesk@cdph.ca.gov

* By law, public health officials can also look at the registry in the case of a public health emergency.