

Instructions for the COVID-19 vaccination Updated booster (Spring 2023)

About the COVID-19 vaccine

This vaccine is part of the national and local governments' vaccination program for COVID-19 (SARS-CoV-2). This vaccine is covered by public funds and is available free of charge to those who wish to receive it.

Effectiveness of the vaccine and administration method

The vaccine administered at this time is the updated (bivalent) booster (ancestral [original] strain / Omicron BA.1) manufactured by Moderna. This vaccine aims to prevent the severity of symptoms, transmission and onset of COVID-19.

It has been confirmed through clinical trials carried out for people aged 18 years and older that 28 days after receiving this vaccine, neutralizing antibody value is equal to or greater than compared with the ancestral monovalent vaccine (original strain) booster shot. For this and other reasons, it can be expected to provide constant prevention of onset and severity of symptoms.

Sales name	Spikevax [®] intramuscular injection (Bivalent: original/Omicron BA.1 or original/Omicron BA.4-5)
Efficiency and effects	Prevention of infectious disease caused by SARS-CoV-2
Vaccination frequency and interval	One dose (Once 3 months or more have passed after receiving the last vaccination) *Intramuscular injection
Inoculation target	People who have completed 2-dose primary series and if they are: 1) aged 65 or over 2) 12 to 65 years old with underlying medical condition and/or those who are considered by the doctor to be at high risk of severe illness. 3) health care workers, and staff working in care homes
Inoculation amount	0.5 mL per dose, total of 1 dose

- You can receive this vaccine regardless of which type of vaccine you received for your last dose. This vaccine cannot be used for first and second doses.
- Receiving a booster dose of this vaccine will not completely prevent infection. You should continue to take appropriate infection prevention measures, regardless of whether or not you have received the vaccine.

People who cannot receive the vaccine

This vaccine cannot be administered to people to whom any of the following circumstances apply. If you think any of the following circumstances apply to you, be sure to inform the doctor during the pre-vaccination consultation.

- People with obvious symptoms of fever (*1)
- People suffering from serious acute illness
- People with a history of severe hypersensitivity (*2) to any of the ingredients of this vaccine
- People who have another condition making it inappropriate for them to receive the vaccine

(*1) An obvious symptom of fever is usually defined as a temperature of 37.5°C or higher. However, this standard does not necessarily apply if fever has been diagnosed in comparison to normal body temperature, even if the temperature reading is below 37.5°C.

(*2) Anaphylaxis and multiple symptoms suggestive of anaphylaxis, including generalized skin and mucous membrane symptoms, wheezing, dyspnea, tachycardia, hypotension, etc.

People who show these symptoms after the last vaccination cannot receive a booster dose using a vaccine containing the same ingredients.

People who need to be cautious about getting vaccinated

Those to whom any of the following circumstances apply should be cautious about receiving this vaccine. If you think any of the following circumstances apply to you, be sure to inform the doctor during the pre-vaccination consultation.

- People on anticoagulant therapy, people with thrombocytopenia or coagulation disorders
- People who have been diagnosed with immunodeficiency in the past, or people who have close relatives with congenital immunodeficiency
- People with underlying medical conditions such as heart, kidney, liver or blood disorders, or developmental disorders
- People who, after receiving vaccines in the past, have experienced symptoms indicative of an allergy, such as fever or generalized rash, within two days of vaccination
- People who have experienced convulsions in the past
- People who may be allergic to the ingredients of this vaccine

If you are pregnant, may be pregnant, or are breast-feeding, be sure to inform the doctor during the pre-vaccination consultation. However, even if you have not checked with your OB/GYN, you can still be vaccinated if the examining doctor has determined that vaccination is permitted.

This pharmaceutical product contains an additive that has never been used in a vaccine before. If you have had hypersensitivity or allergic reactions to drugs in the past, be sure to inform the doctor during the pre-vaccination consultation.

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What to do after receiving the vaccine

- After receiving this vaccine, please wait at the facility where you received the vaccine for at least 15 minutes (at least 30 minutes for those who have experienced severe allergic symptoms after vaccination in the past, including anaphylaxis, feeling sick, fainting, etc.). If you feel unwell, please contact your doctor immediately. (This makes it possible to respond to any sudden onset of side effects.)
- The injected area should be kept clean. Although bathing on the day of vaccination is not a problem, please do not rub the injected area.
- You can go about your life as normal, but please refrain from any strenuous exercise, excessive drinking, etc.

Side effects

- The principal side effects include pain in the injected area (*1), headaches, joint and muscle pain, fatigue, chills, fever, and so on. Although rare, serious side effects can include shock and anaphylaxis. As this vaccine is a new type of vaccine, it may cause unprecedented symptoms that have not yet been identified. If you notice any concerning symptoms after vaccination, consult your vaccinating doctor or family doctor.
(*1) After the primary vaccination series (1st and 2nd doses), many people feel pain the next day rather than immediately after the vaccination. Pain and swelling have also been reported to occur about a week after the vaccination.
- Although extremely rare, cases of suspected myocarditis and pericarditis have been reported after primary vaccination.(*2) If you experience symptoms such as chest pain, palpitations, shortness of breath, or swelling within a few days after vaccination, please visit a medical institution immediately.
(*2) This is more common after the second inoculation than the first inoculation, and tends to be more common among younger people, especially men.
- After the booster dose, swelling of the lymph nodes is reported more often (about 20% more) than after the first or second dose. If your symptoms are severe or protracted, please visit a medical institution.

About the Relief System for Injury to Health with Vaccination

Vaccinations can cause health problems (including illness or disability). Although this is extremely rare, the risk cannot be eliminated, and a relief system has been established for this reason.

In the case of health damage resulting from the COVID-19 vaccine, relief benefits (such as medical expenses, disability pension benefits, etc.) are available under the Immunization Act. Please consult with the municipality where you reside in regard to the procedures required for application.

About the COVID-19 infection

When an infection caused by SARS-CoV-2 develops, symptoms resembling the common cold, such as fever and cough, may be evident. While many people recover from the disease with only mild symptoms, in severe cases, pneumonia-like symptoms such as breathing difficulties can develop, and may even lead to death.

Features of the COVID-19 vaccine (updated [bivalent] booster [BA.1] manufactured by Moderna) to be administered this time

This drug is a messenger RNA (mRNA) vaccine. In this formulation, the mRNA, which is the blueprint for the spike protein (a protein necessary for the virus to enter human cells) of SARS-CoV-2 (ancestral [original] strain and Omicron strain BA.1), is encased in a lipid membrane. When mRNA is taken into human cells through inoculation with this drug, viral spike proteins are produced in the cells based on the mRNA, and neutralizing antibodies against the spike proteins and cellular immune responses are induced, which is thought to prevent infections caused by SARS-CoV-2.

This drug contains the following ingredients.

Active ingredient	◇ Elasmomeran (mRNA encoding the full-length spike protein of the ancestral [original] strain) ◇ Imelasomeran (mRNA encoding the full-length spike protein of the Omicron strain BA.1)
Additives	◇ SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate ◇ Cholesterol ◇ DSPC: 1,2-Distearoyl-sn-glycero-3-phosphocholine ◇ 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG 2000-DMG) ◇ Trometamol ◇ Trometamol hydrochloride ◇ Glacial acetic acid ◇ Sodium acetate hydrate ◇ Sucrose

For more information on the COVID-19 vaccine, please visit the Ministry of Health, Labor and Welfare website.

MHLW COVID-19 vaccine

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