

## **Instructions for the COVID-19 vaccination Booster shots (fourth dose)**

### **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. The booster shot (fourth dose) of this vaccine is available to people aged 60 years and over, and to people aged 18 years and over who have an underlying medical condition or who are deemed by their doctor to be at high risk of serious illness.

### **Effectiveness of the vaccine and administration method**

The vaccine administered at this time is manufactured by Moderna. The fourth dose of the vaccine is intended to prevent severe cases of COVID-19 virus infection.

According to results from overseas studies using the same mRNA vaccine, from Pfizer, during the period of the Omicron variant, the efficacy of the fourth dose of the vaccine in preventing infection in persons aged 60 years or older after a certain period of time had elapsed since the third dose of vaccination lasted for only a short time. However, its efficacy in preventing severe illness did not decrease, persisting even six weeks after the fourth dose of vaccination.

Sales name	Spikevax™ intramuscular injection
Efficiency and effects	Prevention of infectious disease caused by SARS-CoV-2
Vaccination frequency and interval	One dose (Once a certain period of time has passed after receiving the third vaccination) *Intramuscular injection
Inoculation target	People aged 60 years and over, and people aged 18 years and over who have an underlying medical condition or who are deemed by their doctor to be at high risk of serious illness
Inoculation amount	0.25 mL per dose, total of 1 dose

- The interval before receiving the fourth dose of the vaccine in accordance with the Immunization Act is at least five months after the completion of the third dose of the vaccine.
- This vaccine can be administered regardless of the type of vaccine used for the first, second or third doses.
- A booster shot of the vaccine does not completely prevent the onset of symptoms. 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 first, second or third vaccination cannot receive a fourth dose using the same vaccine.

### **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 (\*), 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.  
(\* ) 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 or pericarditis have been reported after vaccination.. If symptoms such as chest pain, palpitations, shortness of breath or swelling appear within a few days after vaccination, please visit a medical facility immediately. Swollen lymph nodes were reported more frequently (around 20%) after the third vaccination compared to the first and second vaccinations. If your symptoms are severe or protracted, please visit a medical institution.
- Although extremely rare, Guillain-Barré syndrome has been reported after mRNA vaccination. If symptoms such as weakness or numbness in the limbs appear after vaccination, please visit a medical facility immediately.

### 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 (vaccine 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 of SARS-CoV-2 (a protein necessary for the virus to enter human cells), 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 that binds to the human cell membrane)
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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