

## **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 that will be given this time is made by Pfizer. The fourth dose of the vaccine is intended to prevent severe cases of COVID-19 virus infection.

According to studies conducted overseas, during the period of the Omicron variant, the efficacy of the fourth dose of this 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	Comirnaty 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	0.3 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 this 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 for which the following apply. Be sure to tell the doctor during the pre-vaccination consultation if you think any of the following apply for you.

- People with obvious 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 other than those described above who have conditions that make it inappropriate for them to receive the vaccine
- (\*1) Obvious fever is usually defined as 37.5°C or higher. However, this does not necessarily apply to cases in which it is judged as a fever in light of the normal body temperature, even if the temperature is below 37.5°C.
- (\*2) Anaphylaxis and multiple symptoms suggestive of anaphylaxis, including generalized skin and mucous membrane symptoms, wheezing, dyspnea, tachycardia, and hypotension. 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 careful about getting vaccinated**

Those who have any of the following conditions should be cautious about receiving this vaccine. If you think this applies to you, be sure to tell 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, blood disorders, or developmental disorders
- People who received vaccines in the past and experienced symptoms suggesting an allergy such as fever or generalized rash within two days after vaccination
- People who have had convulsions in the past
- People who may be allergic to the ingredients of this vaccine.

If you are pregnant or 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 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 including anaphylaxis in the past, or those who have felt sick or fainted, etc.), and if you feel unwell, please contact your doctor immediately. (This makes it possible to respond to sudden 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. on the same day.

### Side Effects

- The principal side effects include pain in the injected area, headache, joint and muscle pain, tiredness, chills, and fever. Rare and serious side effects include shock or anaphylaxis. Because this vaccine is a new type of vaccine, there is a possibility that it may cause symptoms that have not been clarified so far. If you notice any concerning symptoms after vaccination, consult your vaccinating doctor or family doctor.
- Although extremely rare, cases of suspected myocarditis or pericarditis have been reported after vaccination with the first, second or third vaccination doses. 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.
- Swollen lymph nodes, mainly in the armpit, were reported more frequently (around 5%) after the third vaccination compared to the first and second vaccinations. Symptoms are usually mild and recovery is usually within a few days, but if the swelling is severe or protracted, please seek medical attention.
- 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 (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 as a result of the vaccine from the COVID-19 vaccine, relief (medical expenses, disability pension benefits, etc.) is also available under the Immunization Act. Please consult with the municipality where your residence is located regarding the procedures required for application.

### About the COVID-19 infection

When an infection caused by SARS-CoV-2 develops, symptoms similar to those of a common cold are seen, such as fever and cough. While many people recover from the disease with mild symptoms, in severe cases, pneumonia symptoms such as breathing difficulties worsen and may even lead to death.

### Characteristics of the COVID-19 vaccine (vaccine manufactured by Pfizer) to be administered this time

This drug is a messenger RNA (mRNA) vaccine, and it is a formulation in which 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	◇ Tozinameran (mRNA encoding the full-length spike protein that binds to the human cell membrane)
Additives	◇ ALC-0315: [(4-hydroxybutyl)azanediyl]bis(hexane-6,1-diyl)bis(2-hexyldecanoate) ◇ ALC-0159: 2-[[polyethylene glycol]-2000]-N,N-ditetradecylacetamide ◇ DSPC: 1,2-Distearoyl-sn-glycero-3-phosphocholine ◇ Cholesterol ◇ Potassium chloride ◇ Monobasic potassium phosphate ◇ Sodium chloride ◇ Dibasic sodium phosphate dihydrate ◇ 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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