For the Pfizer bivalent vaccine (BA.1/BA.4-5) (May 2023)

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 that will be given this time is the updated (bivalent) booster (ancestral [original] strain and Omicron strain [BA.1 or BA.4-5]) made by Pfizer. The 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 55 and older that one month after receiving the BA.1 bivalent booster shot, 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. Also, the BA.4-5 bivalent booster shot, through non-clinical trials, has been confirmed to induce neutralizing antibodies against original strain, Delta strain and Omicron strain (BA.1, BA.2, BA.4/BA.5, etc.). Thus, it is expected to provide wide-ranging prevention against various mutating strains.

Sales name	Comirnaty RTU 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	0.3 mL per dose, total of 1 dose

- You can receive this vaccine regardless of which type of vaccine you received for your last dose, but it cannot be used for primary series.
- Receiving a booster dose of this vaccine will not completely prevent infection. You should continue to take appropriate infection prevention measures.

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℃ 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℃.

(*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 their last vaccination cannot receive a booster dose using a vaccine containing the same ingredients.

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.

(Continue to the reverse side)

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.

If you have had hypersensitivity or allergic reactions to drugs in the past, be sure to inform the doctor during the pre-vaccination consultation.

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.
- Please refrain from strenuous exercise on the day of the procedure.

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 and pericarditis have been reported. 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.
- Although extremely rare, Guillain-Barré syndrome has been reported after mRNA vaccination. If you experience symptoms such as weakness or numbness in your limbs after vaccination, please visit a medical institution 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 (updated [bivalent] booster [BA.1/BA.4-5] 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 (a protein necessary for the virus to enter human cells), of SARS-CoV-2 (ancestral [original] strain and Omicron strain [BA.1 or BA.4-5]) 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 of the ancestral [original] strain) ✧ Riltozinameran or Famtozinameran (each mRNA encoding the full-length spike protein of the Omicron strain [BA.1 or BA.4-5])
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 ✧ Trometamol ✧ Trometamol hydrochloride ✧ Sucrose

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

MHLW COVID-19 vaccine Search

If you are unable to view the website, please contact your local municipality.