

## Instructions for the COVID-19 vaccination Booster shots (third 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. This vaccine is intended for people aged 18 years and older.

### Effectiveness of the vaccine and administration method

The vaccine to be given this time is manufactured by Takeda, to which Novavax has transferred its manufacturing technologies. The vaccine prevents the onset of COVID-19.

Although the data are from before the Omicron variant became prevalent, clinical trials conducted on subjects aged 18 years and over showed that neutralizing antibody values 28 days after an additional dose of the vaccine were approximately four times higher than those 14 days after the second dose of the vaccine, indicating that a certain level of efficacy can be expected. At present, there are limited findings regarding cases where a vaccine other than this vaccine was administered as the initial (first and second) vaccination doses and then this vaccine was administered as a booster shot (mixed vaccination); however, studies conducted overseas have reported significant increases in antibody values even with mixed vaccinations, though it should be noted that the intervals between vaccinations differ from those approved by the pharmaceutical regulatory bodies in Japan. In addition, while findings regarding the Omicron variant are limited, there have been reports of increased neutralizing antibody values after three doses of the vaccine.

Sales name	Nuvaxovid® 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 second vaccination) *Intramuscular injection
Inoculation target	People aged 18 years and older
Inoculation amount	0.5 mL per dose, total of 1 dose

- The interval before receiving the third dose of the vaccine in accordance with the Immunization Act is at least six months after the completion of the second dose of the vaccine.
- This vaccine can be administered regardless of the type of vaccine used for the first or second doses.
- A booster shot of this vaccine does not completely prevent the onset of symptoms. You should 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 have observed these symptoms after the first or second vaccination doses may not receive a booster shot 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.

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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 obstetrician/gynecologist, you can still be vaccinated if the examining doctor has determined that vaccination is suitable.

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.

**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. If you feel unwell after vaccination, try not to exert yourself, refrain from taking a bath, etc., and see if your condition improves.
- 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. If you notice any concerning symptoms after vaccination, consult your vaccinating doctor or family doctor.

**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.

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**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 Takeda) to be administered this time**

The vaccine is a recombinant protein vaccine, a nanoparticle formulation of recombinant protein made from the gene for the SARS-CoV-2 spike protein (a protein necessary for the virus to enter human cells), with an adjuvant added to promote immune activation. When the recombinant spike protein is taken into human cells through inoculation with this vaccine, 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	◇ SARS-CoV-2 rS (recombinant spike protein of SARS-CoV-2)
Additives	◇ Matrix-A *) ◇ Matrix-C *) ◇ Sodium phosphate dibasic heptahydrate ◇ Sodium dihydrogen phosphate monohydrate ◇ Sodium chloride ◇ Polysorbate 80 ◇ pH adjusters

\*) Additives include cholesterol, phosphatidylcholine, disodium hydrogen phosphate dihydrate, potassium dihydrogen phosphate, potassium chloride and sodium chloride.

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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