Instructions for the COVID-19 vaccination

- O As a general rule, this vaccine should be used for people aged 40 years and older.
- ⊕ However, if you are unable to be vaccinated due to allergies to substances contained in other COVID-19 vaccines, and you specifically wish to receive the AstraZeneca vaccine, you can receive this vaccination even if you are under 40 years of age, as long as you are at least 18 years of age.
- There have been reports from overseas of cases, albeit extremely rare, of demyelinating disorders such as thrombosis with thrombocytopenia, capillary leak syndrome, and Guillain-Barré syndrome. Please understand and consider the risks and benefits of vaccination, and make your own decision before getting vaccinated.

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 manufactured by AstraZeneca. This vaccine prevents the onset of COVID-19.

It has been found that fewer people who have received the vaccine have developed COVID-19 than those who have not received it. (Clinical trials have confirmed its effectiveness in preventing the onset of disease to be approximately 70%.)

Sales name	Vaxzevria® intramuscular injection
Efficiency and effects	Prevention of infectious disease caused by SARS-CoV-2
Vaccination frequency and interval	Two times (usually 4–12 weeks apart) *Intramuscular injection
Inoculation target	In principle, people aged 40 years and older
Inoculation amount	0.5 mL per dose, total of two doses

- Following regulatory approval, a second vaccination is usually received 4–12 weeks after the first jab. However, in order to ensure maximum efficacy, it is best to leave an interval of at least eight weeks between vaccinations. Also, if a period of more than 12 weeks has elapsed after your first vaccination, please get your second vaccination as soon as possible.
- Regarding the target age for vaccination, under regulatory approval this vaccine has been confirmed to be effective and safe for people aged at least 18 years. At this time, however, based on the status of recommended use in other countries and reports on risks and benefits for each age range, only those aged 40 years and older are eligible to receive it, as a general rule.
- If you received this vaccine for your first dose, your second dose should be the same vaccine in principle.
- Clinical trials have confirmed that sufficient immunity is not achieved until about 15 days after the second dose of this vaccine has been administered. Also, please be aware that vaccination cannot completely prevent infection. 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 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 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 experienced venous or arterial thrombosis with thrombocytopenia after SARS-CoV-2 vaccination
- People with a history of capillary leak syndrome
- 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 reading 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 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 2 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. 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.
- You can go about your daily 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, headaches, joint and muscle pain, weariness, fatigue, chills, fever, and so on. In clinical trials, these symptoms tend to occur more frequently after the first vaccination than the second vaccination. Although rare, serious side effects can include shock and 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.
- There have been reports from overseas of cases, albeit extremely rare, of demyelinating disorders such as thrombosis with thrombocytopenia (*1), capillary leak syndrome (*2), and Guillain-Barré syndrome (*3). If you experience any of the following symptoms after vaccination, please visit a medical institution immediately.
 - (*1) Symptoms including persistent severe headache, blurred vision, shortness of breath, confusion, cramps, chest pain, swelling or pain in the legs, persistent abdominal pain, internal bleeding (bruising) in areas other than the injected area, etc. Most of these symptoms usually occur within 28 days after vaccination, and more often after the first vaccination than after the second vaccination.
 - (*2) Symptoms include swelling of the limbs, low blood pressure, etc.
 - (*3) Impairment of movement such as difficulty in exerting power to the limbs, sensory impairment such as numbness, urination/defecation disorders, and visual impairment such as blurred vision.

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-like symptoms such as breathing difficulties can develop, and may even lead to death.

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

This drug is a viral vector vaccine. In this formulation, the gene encoding the amino acid sequence of the SARS-CoV-2 spike protein (a protein necessary for the virus to enter human cells) has been incorporated into a simian adenovirus (an adenovirus, or cold virus, that has been processed to prevent it from proliferating). When this gene is taken into human cells following vaccination with this drug, viral spike proteins are produced in the cells based on the gene, 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	♦ Coronavirus (SARS-CoV-2) vaccine (recombinant simian adenovirus vector)
ingredient	(Note: Simian adenovirus incorporating a gene encoding the amino acid sequence of the SARS-CoV-2
	spike protein)
Additives	♦ L-Histidine
	♦ L-Histidine hydrochloride monohydrate
	♦ Sodium chloride
	♦ Magnesium chloride
	♦ Disodium edetate hydrate
	♦ Sucrose
	♦ Dehydrated ethanol
	♦ Polysorbate 80

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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