

Explanation of the COVID-19 Vaccine

COVID-19 Vaccination

This vaccination is part of the national and local government vaccination program for the novel coronavirus (officially known as SARS-CoV-2, or COVID-19). The cost of this vaccination is fully covered by the government, and it will be provided to anyone who wishes to receive it, free of charge. This vaccine is for people 16 and older.

Vaccine Effects and Method of Administration

This vaccine is made by Pfizer. It will prevent further COVID-19 infections from occurring.

It has been found that people who have received the vaccine are less likely to develop COVID-19 infections than those who have not received the vaccine. (Approximately 95% of patients who receive the vaccine have been reported to experience a protective effect.)

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| Product Name | Comirnaty® intramuscular injection |
| Efficacy and Effects | Prevention of SARS-CoV-2 infection |
| Number of Injections and Period Between | Two injections (ordinarily 3 weeks apart), as injections into the muscle |
| Vaccine Eligibility | For patients 16 or older (efficacy and safety still unknown for people younger than 16) |
| Doses | 2 doses of 0.3 mL each |

- After the first injection, you must also receive a second injection, usually after three weeks. (If more than 3 weeks have passed since your first injection of the vaccine, try to receive the second injection as soon as possible.)
- After the first injection, make sure that the second injection is the same type of vaccine as the first one.
- This vaccine is believed to provide adequate immunization starting approximately seven days after the second injection. The efficacy of this drug in preventing infections currently unknown. Make sure to take appropriate measures to prevent the spread of disease, regardless of vaccination.

Who Is Unable to Receive the Vaccine?

The following categories of people cannot receive this vaccine. If you fall under one of these categories, be sure to inform the doctor during your pre-vaccination diagnosis.

- People who have an obvious fever*¹
- People who have a severe acute illness
- People who have a history of severe hypersensitivity*² to a component of the vaccine
- People whose condition is not appropriate to receive the vaccine for any other reason

*¹ An “obvious fever” generally means a body temperature of 37.5°C or higher. However, it can also mean a temperature below 37.5°C if that temperature would be considered a fever compared to your normal body temperature.

*² Anaphylaxis and symptoms that suggest anaphylaxis, such as body-wide skin and mucous membrane symptoms, wheezing, breathing difficulties, rapid heartbeat, and hypotension.

Who Should Use Caution in Receiving the Vaccine?

The following categories of people should use caution in receiving this vaccine. If you fall under one of these categories, be sure to inform the doctor during your pre-vaccination diagnosis.

- People receiving anticoagulation, or who have a blood platelet deficiency or a blood clotting disorder
- People who have a previous diagnosis of immunodeficiency, or who have a relative with congenital immunodeficiency
- People who have underlying diseases such as heart disease, kidney disease, liver disease, blood disease, or a developmental disorder
- People who, after receiving a vaccine in the past, had have allergic symptoms such as fever or a generalized rash within two days after vaccination
- People who have had convulsions in the past
- People who have a risk of an allergic reaction to a component of this vaccine

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If you are pregnant, might be pregnant, or are breastfeeding, be sure to tell the doctor at your pre-vaccination diagnosis. This product contains additives that have not previously been used in vaccines. If you have ever had hypersensitivity or an allergic reactions to any drug, please tell the doctor at your pre-vaccination diagnosis.

Precautions after Receiving the Vaccine

- After receiving the vaccine injection, please wait at the facility for at least 15 minutes (or, if you have ever experienced severe allergic symptoms, such as anaphylaxis, or have ever felt unwell or fainted after receiving a vaccine, please wait for at least 30 minutes). If you feel unwell, contact a doctor immediately. (Sudden adverse reactions can be handled.)
- Keep the injection site clean. It is fine to shower and bathe on the same day you receive the vaccine, but try not to rub or scrub the injection site.
- Avoid vigorous activity on the day you receive the vaccine.

Adverse Reactions

The most common adverse reactions and side effects of this injection include pain in the injection site, headache, joint and muscle pain, fatigue, chills, and fever. Rare major adverse reactions include shock and anaphylaxis. Because this is a new type of vaccine, it is possible that previously-unknown symptoms may develop. If you are worried about symptoms that have developed after vaccination, consult the vaccination medical staff, or your primary care doctor.

Relief System for Injury to Health with Vaccination

In extremely rare cases, preventative vaccines can cause harm to health (illness or residual disability). Because these cases are rare, but cannot be fully prevented, a relief system has been established.

If the COVID-19 vaccine causes harm to health, financial relief (medical expenses, disability pension, etc.) will be provided under the Immunization Act. For more details on how to apply for this relief system, please consult the municipality where the address registered on your residence certificate (*juminhyo*) is located.

COVID-19 Infections

Infections caused by the SARS-CoV-2 virus develop into fever, cough, and other symptoms resembling the common cold. While many people recover after only relatively mild sickness, severe cases can worsen into pneumonia symptoms such as breathing difficulty, or even death.

Characteristics of the COVID-19 Vaccine (Vaccine made by Pfizer)

This is a messenger RNA (mRNA) vaccine. The mRNA, which is encapsulated in a lipid membrane, serves as the blueprint for the spike protein of the SARS-CoV-2 virus (the virus needs this protein in order to enter human cells). Injecting this vaccine causes this mRNA to be absorbed by human cells, and cells produce the viral spike proteins based on this mRNA. This causes the body to then produce neutralizing antibodies for this spike protein, and causes a cellular immune response. This sequence of events is believed to prevent infection with SARS-CoV-2.

This product contains the following ingredients.

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| Active Ingredient | ◇ Tozinameran (mRNA encoding a full-length spike protein that binds to the human plasma membrane) |
| Additives | ◇ ALC-0315: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate ester) ◇ ALC-0159: 2-((polyethylene glycol)-2000)-N,N-ditetradecyl acetamide ◇ DSPC: 1,2-dystearoyl-sn-glycero-3-phosphocholine ◇ Cholesterol ◇ Potassium chloride ◇ Potassium dihydrogen phosphate ◇ Sodium chloride ◇ Disodium hydrogen phosphate dihydrate ◇ Purified sucrose |

For more information on the COVID-19 vaccine, please refer to the Ministry of Health, Labour and Welfare website.

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