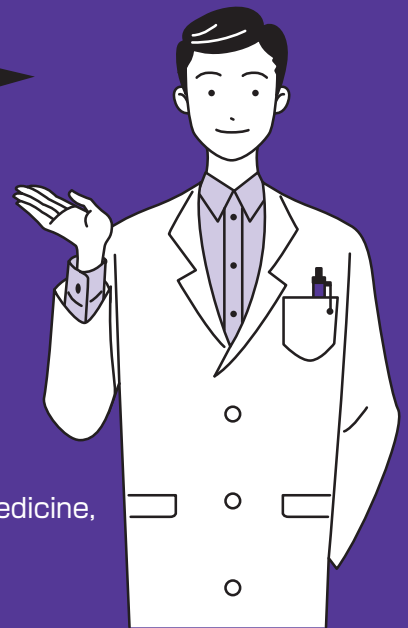




## COVID-19 Vaccine

# COMIRNATY

- Information for persons receiving  
the vaccine and their families -



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COVID-19 is an infectious disease caused by a coronavirus called SARS-CoV-2. It presents symptoms very similar to the common cold, such as a fever and cough. Most persons with COVID-19 have mild symptoms and can recover from COVID-19. However, in some cases, the symptoms progress to severe dyspnea (difficulty breathing) and pneumonia, leading to death.

This information leaflet has been prepared for persons who are planning to receive the COVID-19 vaccine (COMIRNATY, hereinafter referred to as "this vaccine"), for persons who have already been vaccinated, and for their families. This information leaflet explains about this vaccine. Please check this information leaflet, together with the information provided by your local government.

This vaccine has been specially approved(\*). As there is only limited information on the prevention of COVID-19 and side effects of the vaccine, the doctor in charge of vaccination will explain about this vaccine before your vaccination.

(\*) What is special approval?

Under this system, the Minister of Health, Labour and Welfare (MHLW Minister) can approve the emergency use of drugs, in order to prevent the spread of diseases that may have a serious impact on the lives and health of the persons in Japan. In this case, the MHLW Minister is authorized to grant approval after hearing the opinions of experts, even if the drugs do not meet the usual requirements for approval. However, this system can be used only under the condition that this vaccine has already been used in foreign countries for the prevention of the target disease.

Two doses of this vaccine are required.

Receive the second dose 3 weeks after the first dose. To schedule the date of the second dose, consult, for example, the medical institution where you received the first dose.

(If more than 3 weeks have passed since the first dose, please receive the second dose as soon as possible.)



## About this vaccination project

✓ This vaccination is carried out as part of the COVID-19 vaccination project by the Japanese central and local government.

✓ The full cost of this vaccination is covered by public funds. Therefore, this vaccine is available for everyone at no cost.

✓ This vaccine is intended for persons 12 years or older.

**Before receiving this vaccine, persons who are eligible for vaccination OR their guardians are required to give consent to receiving the vaccination in writing (using the Vaccine Screening Questionnaire) after an explanation has been provided about the efficacy and safety of this vaccine, possible side effects of this vaccine, and the Relief System for Injury to Health with Vaccination, during the pre-vaccination screening.**

✓ The following persons are eligible for priority vaccination. Persons will be invited to receive this vaccination in the order of priority.

**1. Healthcare professionals and other persons who frequently come into contact with patients with COVID-19 or suspected patients**



**2. Elderly persons**



**3. Persons with underlying medical conditions and persons working at facilities for the elderly**




**Fully covered by public funds  
Available for everyone at no cost**

**2-dose series  
separated by 3 weeks**

✓ For detailed information on the vaccination centers (for example, medical institutions) for this vaccine and, for example, what to bring with you, please check the information provided by your local government. If you have any questions, please contact your local government.



## Characteristics of this vaccine

- ✓ This vaccine is a messenger RNA (mRNA)-type vaccine. The mRNA vaccines inject part of the code that tells the body how to make viral proteins. Based on this information, the human body makes part of the viral proteins, followed by production of antibodies against the proteins. This gives the body the tools (immunity) to defend against the virus.
- ✓ This vaccine prevents COVID-19, by utilizing our body's immune system, which attacks foreign substances in the body.
- ✓ **Two doses of this vaccine are required. Receive the second dose 3 weeks after the first dose.** 

(If more than 3 weeks have passed since the first dose, please receive the second dose as soon as possible.)

## Efficacy of this vaccine



### Prevention of COVID-19

- This vaccine prevents the development of COVID-19.

- Even after the vaccination, it is still necessary to practice the basic strategies for infection

prevention (for example, wear a mask, avoid closed spaces, avoid crowded places, avoid close-contact settings, ensure ventilation, wash your hands, follow cough etiquette). (The effect of this vaccine in preventing transmission has not been evaluated.)



**Adequate immunity from this vaccination can be expected after about 7 days from the second dose.**

## Safety of this vaccine (side effects)

Be careful of your physical condition after vaccination (particularly for several days immediately after vaccination).

If you have any of the following symptoms, or if you notice unusual changes or abnormalities in your physical condition, contact the doctor or nurse at the vaccination center (for example, medical institution) where you received this vaccine, or your family doctor.

### Possible severe symptoms (incidence unknown)



#### Shock, anaphylaxis

[Clinical symptoms, their timing and duration]

Shock and anaphylaxis should be suspected, if the following symptoms occur **immediately after vaccination, sometimes within 5 minutes and usually within 30 minutes after vaccination.**

- Skin symptoms: for example, itching of the skin, urticaria, erythema, redness of the skin
- Gastrointestinal symptoms: for example, abdominal pain, nausea
- Visual symptoms: visual abnormalities
- Respiratory symptoms: for example, hoarseness of voice, sneezing, itchy throat, breathing difficulties
- Shock symptoms: for example, looking pale, clouding of consciousness

After receiving this vaccine, you will be asked to stay for a while at the vaccination center (for example, medical institution) where you received it. If you develop these symptoms, please **immediately** tell the doctor, nurse or other health care providers of the vaccination center (for example, medical institution).

### Possible physical symptoms

(symptoms that appeared in 10% or more of persons who received the vaccine)



- Pain and swelling at the injection site
- Diarrhea
- Muscle and joint pain
- Headache
- Tiredness, chills, fever

[Clinical symptoms, their timing and duration]

- In most persons who reported pain at the injection site, the pain began on the day of vaccination and lasted for about 2 days. Most other symptoms appeared on the day after of vaccination, and lasted for about 1 day.
- Many of these symptoms occurred more frequently after the second dose than the first, and more frequently in non-elderly persons than in the elderly.
- These symptoms usually resolve within a few days. If you are taking antipyretic anti-inflammatory analgesics (drugs for fever, pain and inflammation) for your illness, please consult your doctor or pharmacist. In addition, if you think you might have severe symptoms, such as severe pain/swelling and high fever, consult a doctor.

## Persons who **CANNOT** receive this vaccine

Persons who have any of the following conditions cannot receive this vaccination. If any of the following applies to you, please tell your doctor at the consultation before vaccination.

- ① Persons who have an obvious fever.
- ② Persons who have a serious acute illness.
- ③ Persons who have a history of severe hypersensitivity to the ingredients of this vaccine.
- ④ Persons who have any other condition which makes them unsuitable for this vaccination.

## Persons to whom this vaccination should be given with caution

Caution must be taken when persons with any of the following conditions receive this vaccination. If any of the following applies to you, please tell your doctor at the consultation before vaccination.

- ① Persons who are receiving anticoagulant therapy, or who have thrombocytopenia or coagulation disorders
- ② Persons who have been diagnosed with immunodeficiency in the past, or whose close blood relatives have congenital immunodeficiency
- ③ Persons who have underlying medical conditions, such as disease of the heart, kidney, liver or blood and developmental disorders
- ④ Persons who have developed symptoms suspected to be allergies, such as fever and skin rash all over the body, within 2 days after receiving a vaccination in the past
- ⑤ Persons who had convulsions in the past
- ⑥ Persons who may have allergies to the ingredients of this vaccine
- ⑦ Persons who have kidney dysfunction
- ⑧ Persons who have liver dysfunction

If you are pregnant, may be pregnant, or are breast-feeding, please tell your doctor at the consultation before vaccination. The efficacy and safety of this vaccine for children younger than 12 years old have not been confirmed yet.

Elderly persons should tell the doctor about their health condition at the consultation before vaccination.

## Precautions when receiving this vaccine

Please take the following precautions when receiving this vaccine.

- ① Two doses of this vaccine are required.
- ② Receive the second dose 3 weeks after the first dose. (If more than 3 weeks have passed since the first dose, please receive the second dose as soon as possible.)
- ③ If you received this vaccine for the first dose, please receive this vaccine for the second dose as well.

## What to do after receiving this vaccine

- ✓ After receiving this vaccine, you will be asked to stay for a while at the vaccination center (for example, medical institution) where you received it. If you have any abnormalities in your physical condition, please immediately tell the doctor, nurse or other health care providers. (Sudden side effects can be managed.)
- ✓ Even after the vaccination, it is still necessary to practice the basic prevention strategies for infection prevention (for example, wear a mask, avoid closed spaces, avoid crowded places, avoid close-contact settings, ensure ventilation, wash your hands, follow cough etiquette). (The effect of this vaccine in preventing transmission has not been evaluated.)
- ✓ Please keep the injection site clean.
- ✓ You can take a bath on the day of vaccination, but should not rub the injection site.
- ✓ Please avoid excessive exercise on the day of vaccination.

## Frequently Asked Questions about this vaccine

### Q1. Will we still need to practice the infection prevention measures once we get the COVID-19 vaccine?

A1

The intent of this vaccine is to prevent the development of COVID-19. It is still necessary to practice the basic strategies for infection prevention (for example, wear a mask, avoid closed spaces, avoid crowded places, avoid close-contact settings, ensure ventilation, wash your hands, follow cough etiquette) even after the vaccination. (The effect of the vaccine in preventing transmission has not been evaluated.)

### Q2. What should I be careful about before and after receiving the vaccine?

A2

#### Before getting the vaccine:

As a general rule, get vaccinated when you are in good physical condition. Talk with your doctor if you feel something is not right, feel something unusual in your physical condition, or experience any discomfort; if you have had a drug allergy, or have food allergies or allergic diseases; if you are nervous about getting vaccines in general, or have a fear of needles and pain.



**A2**

### **After receiving the vaccine:**

In rare cases, a temporary loss of consciousness (fainting) occurs triggered by anxiety and pain of vaccination. After receiving the vaccine, take a rest, for example, by sitting on a chair with a backrest for a while.

In addition, vaccination may rarely lead to severe allergic reactions, such as shock and anaphylaxis. If you have had allergic reactions with other drugs, have food allergies or allergic diseases, you should be observed carefully after vaccination. Please talk to your doctor so that you can stay within the vaccination center (for example, medical institution) where you received this vaccine for a while. By staying at the medical institution, these symptoms, if any, can be managed.

Although causality with the vaccine is unknown, cases of myocarditis and pericarditis occurring after vaccination have been reported. If you have symptoms suggestive of myocarditis or pericarditis, such as chest pain, palpitations, swelling, dyspnea (difficulty breathing, shortness of breath), and tachypnea (hard breathing, rapid breathing), please contact your doctor immediately.

### **Q3. What should I do if the interval between the first and second doses of this vaccine is more than 3 weeks?**

**A3**

Get your second dose as soon as possible.

### **Q4. Regarding the injection of the genetic information that tells the body how to make viral proteins, I am worried that this injection may cause changes in my body in the future. Is that possible?**

**A4**

Messenger RNA (mRNA) is broken down over time, from several minutes to several days. In addition, mRNA is not taken up into human genetic information (DNA). Our body has a mechanism to make mRNA from DNA. In this mechanism, the information flows only one way, from DNA to mRNA. There is no opposite flow, and therefore DNA cannot be made from mRNA. For these reasons, it is believed that the information from the injected mRNA cannot remain in the body for long. In addition, the mRNA is not taken up into the genetic information of sperms and ova(eggs) of humans.

### **Q5. Should children and infants get this vaccine?**

**A5**

This vaccine is intended for persons who are 12 years or older. The efficacy and safety of this vaccine for children younger than 12 years old have not been confirmed.

### **Q6. I am pregnant, or may be pregnant. Should I get this vaccine?**

**A6**

Please talk to your doctor. Get the vaccine only if the benefits of the vaccination are considered to outweigh the risks.

### **Q7. Should breast-feeding mothers get this vaccine?**

**A7**

Please talk to your doctor. Get the vaccine only if the benefits of the vaccination and breast-feeding outweigh the risks.

**Q8. I had allergic reactions to other vaccines, drugs, food and cosmetics in the past. Is it okay for me to receive this vaccine?**

**A8**

Please describe all your allergy information in the Vaccine Screening Questionnaire in as much detail as you can. With the Questionnaire, talk to your family doctor in advance, or speak to your doctor on the day of vaccination.

**Q9. How effective is the vaccine?**

**A9**

In persons who received 2 doses of this vaccine 21 days apart, the efficacy (effect in preventing COVID-19) of the vaccine was about 95.0% at least 7 days after the second dose.

The median period of follow-up of this population evaluated for efficacy was about 2 months after the second dose. This vaccine is still undergoing clinical studies, and more information will be available in the future.

**Q10. Are there any concerns about side effects of the vaccine?**

**A10**

Vaccination may cause side effects. If you have any symptoms of concern or any changes in your physical condition, please contact your doctor immediately. If you are harmed by the vaccination, the Relief System for Injury to Health with Vaccination, run by the Japanese central government, is available. Please consult your local government.

**Q11. Regarding COVID-19 and vaccination against the coronavirus, how can I check the information?**

**A11**

Information on COVID-19 and vaccination against the coronavirus is available on the Ministry of Health, Labour and Welfare website (<https://www.mhlw.go.jp/>).

**Contact information for this vaccine**



Information on this vaccine is available on our specific website, "Pfizer's COVID-19 Vaccine Website for Recipients and their Families". Please access this website from the 2D Barcode on the left or the URL below.

<https://www.pfizer-covid19-vaccinated.jp>

**BIONTECH**



Marketing Authorisation  
Holder: BioNTech  
Manufacturing GmbH

The Pfizer BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.