

# For NUVAXOVID®※ Recipients and Caregivers

This brochure contains information to help you understand the risks and benefits of NUVAXOVID®, which you or your caregiver may receive.

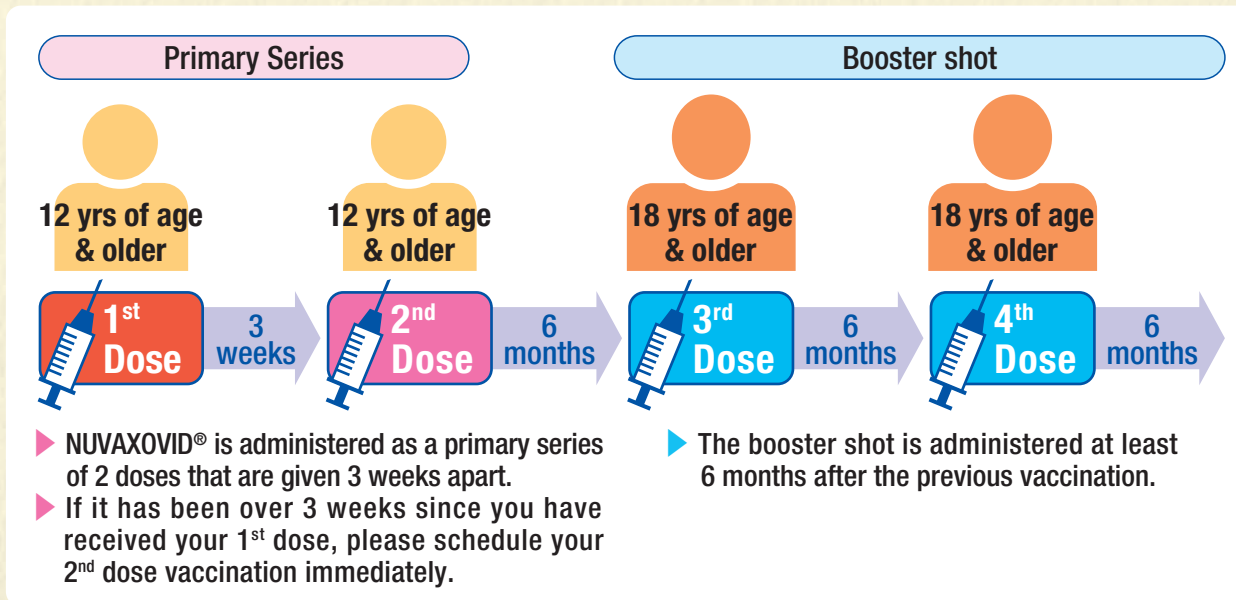
Please use this brochure in addition to the information provided by your local municipality.

※NUVAXOVID®: NUVAXOVID COVID-19 Vaccine, Adjuvanted

\* This brochure is for NUVAXOVID® recipients and the contents are based on Japanese law and the approved matters of NUVAXOVID® in Japan. While every effort is made to ensure the accuracy of translation, Takeda Pharmaceutical Company Limited assumes no liability for damage or loss caused by any error, inaccuracy, or misunderstanding with regard to this translation. If you have any questions about the notice or your treatment, please consult with your doctor.

## NUVAXOVID® is a vaccine that may prevent COVID-19.

### ● Immunization schedule is as follows:



- You should continue to take basic infection prevention measures (wear masks, avoid the three Cs[closed places, crowded places, close-contact settings], wash hands, have coughing manners) even after you have received the vaccine.
- As NUVAXOVID® may cause side effects (fever, tiredness, pain etc), you should make plans of the day of and the day after your vaccination accordingly.

If you have received 1st dose of NUVAXOVID®, you should receive a 2nd dose of NUVAXOVID® to complete the vaccination series.

Please schedule your 2nd dose vaccination with your local municipality or vaccinating doctor.

2nd dose Vaccination Date:

YYYY / MM / DD    AM / PM    [ ] : [ ]

2nd dose Vaccination Location:

[ ]

Please schedule your 2nd dose vaccination at the time of your 1st dose vaccination.

Make sure to write down or make a note on your cell phone of your 2nd dose vaccination schedule.



# IMPORTANT SAFETY INFORMATION

## BEFORE you receive NUVAXOVID®



### What you should mention to your vaccinating doctor BEFORE you receive NUVAXOVID®

Please check  
the  boxes

#### ● 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 symptoms of 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 another condition making it inappropriate for them to receive the vaccine

\*1: An obvious symptom of fever is usually defined as a temperature of 37.5°C or higher. However, this standard does not necessarily apply if fever has been diagnosed in comparison to 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, hypotension, etc.

#### ● People who need to be cautious about getting vaccinated:

Those to whom any of the following circumstances apply should be cautious about receiving this vaccine. If you think any of the following circumstances apply to you, be sure to inform 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 or blood disorders, or developmental disorders
- People who, after receiving vaccines in the past, have experienced symptoms indicative of an allergy, such as fever or generalized rash, within two days of vaccination
- People who have experienced convulsions in the past
- People who may be allergic to the ingredients of this vaccine

If you are pregnant, may be pregnant, or are breast-feeding, be sure to inform the doctor during the pre-vaccination consultation.

#### ● Please consult with your vaccinating doctor if:

- You feel different than usual or do not feel well
- You feel anxious about vaccines, needles or pain
- You have allergies, food allergies or have had allergic reaction to medication
- You have fear of vaccines

# IMPORTANT SAFETY INFORMATION

## AFTER you receive NUVAXOVID®

**Please stay at the facility where you received the vaccine for 15-30 minutes after vaccination.**

There is a remote chance that NUVAXOVID® could cause severe shock or anaphylaxis within a few minutes to 30 minutes after vaccination.

Also, vagal response may be triggered by pain or anxiety from the vaccination.

For this reason, please sit on a chair with a back and relax for 15-30 minutes at the place where you received your vaccine.

Please notify your vaccinating doctor or nurse immediately if you experience any concerning symptoms or any of the following symptoms:

### Signs of shock or anaphylaxis reaction:

- Cold sweating, lightheadedness
- Turning pale
- Feelings of having a fast-beating, difficulty breathing
- Itching, bad rash all over your body
- Dizziness, fainting
- Scratchy throat
- Cold feet and hands



### Signs of vagal response:

- Dizziness on standing up
- Turning pale (sometime fainting)

※ **Please be sure to take basic infection prevention measures while waiting:**

- ▶ Wear a mask
- ▶ Keep social distance
- ▶ Refrain from talking

If you feel any of the conditions mentioned above or notice any concerning symptoms after you leave the vaccination site, please contact your vaccinating doctor or your family doctor.

- Side effects on the back page of this brochure may occur. If you experience high fever or convulsion, please seek medical care immediately.
- Please keep the injected area 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 your vaccination.
- You should continue to take basic infection prevention measures (wear masks, avoid the three Cs[closed places, crowded places, close-contact settings], wash hands, have coughing manners) even after you have received the vaccine as the effectiveness against transmission is unknown.



## Q1 What is NUVAXOVID®?

A1

NUVAXOVID® contains a recombinant form of the SARS-CoV-2 spike protein. This spike protein is a foreign object to our body thus, when we receive the vaccine, our immune system is activated to attack and remove this spike protein. NUVAXOVID® also contains ingredients that support the immune system. By receiving the vaccine, we can protect our body from being infected with the COVID-19 virus.

## Q2 Why do we need a booster shot?

A2

Even after you have received the primary series (1<sup>st</sup> and 2<sup>nd</sup> dose) of the vaccine, you may still be infected with the COVID-19 virus. There are many reasons for this but decrease in the antibody level with time is considered as one. A booster shot after primary series gives your immune system additional strength.

Please visit the Ministry of Health, Labor and Welfare website (<https://www.mhlw.go.jp/stf/covid-19/booster.html>) for more information.

Q3

## Do we still need to take infection prevention measures after we receive NUVAXOVID®?

A3

NUVAXOVID® may prevent COVID-19 but we still do not know how the vaccine may help prevent the spread of COVID-19 from vaccine recipients to others. While vaccination is still in progress, there will be a crowd of vaccine recipients and non-vaccine recipients in the society. Thus, we would like to ask you to continue to take infection prevention measures such as avoid the 3 Cs (closed places, crowded places, close-contact settings), wear a mask, wash hands with soap and use alcohol sanitizers.

Q4

## What do need to be aware of before and after we receive NUVAXOVID®?

A4

### Before you receive NUVAXOVID®:

Please be sure to receive the vaccine when you are in good condition. Please notify your vaccinating doctor if you have any concerns regarding your condition, have had allergic reaction to medication in the past, have food allergies or allergies, feel anxious about needles or pain, have fear of vaccines.

### After you receive NUVAXOVID®:

There is a remote chance that you may faint due to anxiety or pain with the vaccination. To avoid fallig down (sometimes people who faint can fall down and hurt themselves), please be sure to be seated for about 30 minutes after the vaccination. In addition, the vaccine may cause severe allergic reaction such as shock or anaphylaxis. Please make sure to wait at the facility for a while as this makes it possible to respond to any sudden onset of side effects.

Q5

## What if I have had allergic reaction to other vaccines, medication, food or makeup in the past?

A5

Please consult with your family doctor or write down in your screening questionnaire and notify your vaccinating doctor at the pre-vaccination consultation (Please write down everything that have caused allergic reactions).

Q6

## What if I am or may be pregnant?

A6

Please discuss your options with your doctor and receive the vaccine only if you have determined that the benefits of the vaccination outweighs the risks.

## **Q7** What if I am breastfeeding?

**A7**

Please discuss your options with your doctor and take into account the benefits of the vaccination and breastfeeding and consider whether to continue or discontinue breastfeeding. We do not know how much of the ingredients or the antibody to the ingredients of the vaccine will transfer into breastmilk.

## **Q8** Can children or infants receive NUVAXOVID®?

**A8**

People aged 12 years and older may receive this vaccine for primary series (Efficacy and safety of primary series for people under 12 years of age are not yet clear).  
Booster dose is only for people 18 years of age and older (Efficacy and safety of booster dose for people under 18 years of age are not yet clear).

**Q9**

## **Q9** What if it has been over 3 weeks since I have received the 1<sup>st</sup> dose of the primary series?

**A9**

Please schedule your 2<sup>nd</sup> dose vaccination as soon as possible.

**Q10**

## **Q10** What are the risks of NUVAXOVID®?

**A10**

There is a chance that this vaccine may cause side effects. If you experience any concerning symptoms or feel different than usual, please seek medical attention right away. In case of health damage resulting from the COVID-19 vaccine, relief benefits (such as medical expenses, disability pension benefits etc.) are available under the Immunization Act. Please consult with the municipality where you reside in regard to the procedures required for the application.

**Q11**

## **Q11** Where can I find more information on COVID-19 and COVID-19 vaccines?

**A11**

Please visit the Ministry of Health, Labor and Welfare website ([https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000164708\\_00079.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000164708_00079.html)) for more information. Also contact your local municipality for details of the COVID-19 vaccination.

**Q12**

## **Q12** Should teenagers and people in the twenties, especially men not receive the vaccine as there is a higher risk of myocarditis and pericarditis?

**A12**

It has been reported that the COVID-19 vaccines used in Japan may prevent COVID-19 and severe COVID-19. As there is an increase in the number of COVID-19 cases among younger people in Japan as in the rest of the world, we would like to ask you to consider receiving the vaccine. However, it is your decision whether you receive the vaccine or not. Please be sure to understand the benefits and risks of the vaccine in making your decision.



## Side Effects that may occur after you receive NUVAXOVID®

### ● Injection site reactions:

It has been reported that 60% of the 1<sup>st</sup> dose vaccine recipients, and 80% of the 2<sup>nd</sup> and 3<sup>rd</sup> dose vaccine recipients have experienced some kind of injection site reactions. Symptoms vary but may include the following:

**pain/tenderness, swelling, redness of the injected area**

### ● General side effects:

It has been reported that 50% of the 1<sup>st</sup> dose vaccine recipients, and 70% of the 2<sup>nd</sup> and 3<sup>rd</sup> dose vaccine recipients have experienced some kind of general side effects. Symptoms vary but may include the following:

**headache, vomiting (nausea), tiredness, fatigue, muscle pain, joint pain, hand and feet pain, shivering, fever**

Symptoms may be severe after the 2<sup>nd</sup> or 3<sup>rd</sup> vaccination. Most symptoms go away after 1-3 days after vaccination however if you experience high fever or convulsions, please contact your healthcare provider.

Symptoms occur mostly after 1-2 days after vaccination but sometimes occur after 7 days after vaccination. Symptoms tend to occur more in younger (vs. older) people and female (vs. male).

**These may not be all the possible side effects of NUVAXOVID®.**

**You should monitor your health conditions at least for a few days after vaccination. If you notice any concerning symptoms, please ask your family doctor for medical advice.**

\*In the case of health damage resulting from the COVID-19 vaccine, relief benefits (such as medical expenses, disability pension benefits) are available under the Immunization Act. Please consult with the municipality where you reside in regard to the procedures required for application.

Medical Institution



Takeda Pharmaceutical Company Limited