

Side effects may occur after the vaccination.

Figures in parentheses <> represent the frequency of the side effect (based on the package insert).

Major side effects

Symptoms around the injection site

- Pain<63%>
- Warmth <18%>
- Skin bruising (Skin discoloration) <18%>
- Itching <13%>

Systemic symptoms

- Fatigue<52%>
- Headache<51%>
- Fatigue (Weariness)<44%>
- Muscle pain <44%>
- Feverishness sensation <34%>
- Chills <31%>
- Joint pain <27%>
- Nausea <21%>

● Most of the side effects listed above will occur on the day following the date of vaccination and disappear within one to three days of onset.

If you experience any side effects after the vaccination, such as pain at the injection site, muscle pain or fever, you can use an analgesic/antipyretic (acetaminophen, loxoprofen, etc.). If your symptoms do not improve and you continue to experience pain or a high fever, please seek medical attention.

Shock and anaphylaxis may occur.

Severe allergic reactions, called anaphylaxis, such as hives, difficulty breathing, or blood pressure reduction, and angioedema (swelling in the face and throat caused by changes in vessels) may occur suddenly.

There have been reports of thrombosis accompanied by thrombocytopenia occurring very rarely.

Special attention should be paid to the following symptoms, in particular, four to 28 days after the vaccination: severe headache, persistent headache, blurred vision, shortness of breath, distraction, convulsive seizures, chest pain, leg swelling and pain, persistent abdominal pain, unusual skin bruising (skin discoloration), and petechial internal bleeding beyond the site of vaccination. Cerebral venous thrombosis (clot formation within cerebral veins) associated with thrombocytopenia and other serious cases have also been reported.

● **Although a causal relationship has not been established, very rare instances of the following have been reported:**

- Neurological disease, which causes numbness, sensory disturbance (tactile and pinprick sense, loss of sensation, etc.), and motor disturbance (loss of strength, difficulty walking).
- Capillary leak syndrome, which causes rapid swelling of your arms and legs and a sudden drop in blood pressure.

If you have any physical troubles as listed above or if your physical condition is different from usual after the vaccination, please seek medical attention immediately.

Announcement of the Relief System for Injury to Health with Vaccination

Should you suffer from any health hazards due to this vaccination, treatment costs may be paid under the Relief System for Injury to Health with Vaccination.

For more information, please visit the website of the Ministry of Health, Labour and Welfare.

予防接種 救済

Search

*This web site is only available in Japanese

Please check the latest information on the vaccine on the AstraZeneca website.

AstraZeneca website on the COVID-19 vaccine



in Japanese

<https://www.azcovid-19.jp/>



in English

<https://www.azcovid-19.com/>

AstraZeneca K.K.

Meiji Seika Pharma Co., Ltd.

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Risk Management Plan (RMP)

To Those Who Will Receive

 **Vaxzevria™**

a COVID-19 Vaccine
for Intramuscular Injection,
and Their Family Members



Vaxzevria™ is designed to prevent the onset of COVID-19.

The vaccine has obtained a fast-track approval as a viral vector vaccine. Since it has been developed to enable people to receive COVID-19 vaccination as early as possible, we have limited information on it.

The vaccine requires two doses to be fully effective.

The second dose must be administered 4 to 12 weeks after the first dose.

1st dose

4 to 12 weeks

2nd dose

- You are recommended to receive the second dose **at least eight weeks** after the first dose to gain reach its maximum effect.
- If you cannot receive a vaccine as scheduled, please consult a vaccination physician.
- In principle, the second dose should be of the same vaccine as the first dose.

Under the Immunization Act, in principle, people who are 40 years old or older are eligible for the vaccine.

(If needed, people between the ages of 18 and 40 can also receive the vaccine).

- Please be sure to read this document before and after receiving the AstraZeneca COVID-19 vaccine.
- If you have any questions, please consult a vaccination physician or your primary care physician.

Cautions Before Receiving the Vaccination



If the following cases apply to you, you must not receive a vaccine!

- You obviously have a fever.
- You have a severe acute disease (infectious disease, stroke, heart disease, etc.).
- You have experienced a severe hypersensitivity*¹ reaction to any of the components of this vaccine.
- You have suffered from thrombosis or thrombocytopenia after receiving a COVID-19 vaccine.
- You have previously suffered from capillary leak syndrome*².

Aside from the above, you may be unable to receive the vaccine if a physician judges your condition is not appropriate for the vaccination.

*1 Severe hypersensitivity refers to a condition in which hives, abdominal pain, vomiting, difficulty breathing, and/or other symptoms occur simultaneously or suddenly.

*2 For anaphylaxis, please see the reverse side of this sheet.

If the following cases apply to you, consult a physician before receiving a vaccine.

- You have been diagnosed with an immune deficiency or have a close relative with a congenital immunodeficiency disease.
- You have an underlying disease, including heart disease, kidney disease, liver disease, blood disease, or a growth disturbance.
- You have developed a fever and have had symptoms suggestive of allergies within two days after vaccination.
- You have had a convulsion.
- You are or may be pregnant.
- You are breastfeeding.
- You have other health concerns.

○ The safety and effectiveness of the vaccine for those under the age of 18 have not been established.



Cautions After Receiving the Vaccination



Keep calm for approximately 15 to 30 minutes after receiving the vaccine.

You may suffer from side effects such as anaphylaxis* and lose consciousness due to tension and pain. Sit and observe your physical condition at the facility where you received the vaccine for approximately 15 to 30 minutes. If you have a worrisome symptom, seek medical attention.

* For anaphylaxis, please see the reverse side of this sheet.

- Leave the bandage on the injection site as it is for approximately 30 minutes after the vaccination. When taking off the bandage in the facility, dispose of it in a dedicated disposal container (trash can). When taking off the bandage at home, put it in a plastic bag together with the used mask and other items and dispose of it in a trash can.



Do not rub the injection site.

Be careful to keep the injection site clean and not to rub it. You may take a bath on the day of the vaccination.

Avoid strenuous exercise.

You may return to your normal life after receiving the vaccine. However, avoid strenuous exercise.



Continue to take preventive measures against COVID-19 on a daily basis even after receiving the vaccine.



It is important to continue to take preventive measures against COVID-19 on a daily basis, including wearing a mask and washing/sanitizing your hands. In addition, take care to avoid the 3Cs (Closed spaces, Crowded places and Close-contact settings).

- The effectiveness of this vaccine for the prevention of infection has not been established because it is designed to prevent the onset of COVID-19.

Frequent Q&A about vaccination



Q What is a viral vector vaccine?

A A viral vector vaccine is a vaccine in which some genes of the COVID-19 virus are inserted into the vectors (carriers) of a virus that is non-pathogenic to humans. Although inoculation with this vaccine prevents the onset of COVID-19, it does not lead to the growth of COVID-19 viruses in the body.

Q Can I receive a vaccine if I am on a drug?

A You may receive a vaccine even if you are on a drug. However, careful consideration is necessary to determine whether you may receive a vaccine in some cases depending on the disease you are suffering from. Please consult your primary care physician.

Q What should I do if I cannot receive the second dose within 12 weeks after the first dose?

A You are advised to receive the second dose as promptly as possible.