

VACCINATION INFORMATION SHEET NOVAVAX / NUVAXOVID XBB.1.5 COVID-19 VACCINE

The Novavax/Nuvaxovid XBB.1.5 COVID-19 vaccine is unregistered with HSA for use in Singapore, but it is being provided in Singapore under the Special Access Route (SAR). You are receiving this vaccine as the second dose of your primary vaccination series as you have opted to do so.

1. What is the Novavax / Nuvaxovid XBB.1.5 COVID-19 vaccine?

The Novavax/Nuvaxovid XBB.1.5 COVID-19 vaccine protects against COVID-19. The vaccine contains purified copies of a protein found on the COVID-19 virus (SARS-CoV-2 recombinant spike protein) corresponding to that of the Omicron XBB.1.5 variant. It is used to stimulate the body to develop protection against the actual COVID-19 virus.

The primary series of the Novavax/Nuvaxovid vaccine consists of 2 doses taken at the recommended interval of 8 weeks or at least 21 days apart.

2. What does it mean for the vaccine to be supplied under the Special Access Route (SAR)?

The Novavax / Nuvaxovid XBB.1.5 COVID-19 vaccine's safety, quality and efficacy have not been evaluated for supply in Singapore by HSA. Novavax is in the process of filing for local regulatory approval for the Novavax/Nuvaxovid XBB.1.5 COVID-19 vaccine. The said vaccine is currently being provided under the SAR, which is a process for the import and supply of unregistered medicines to facilitate access for unmet medical needs. For more information on the SAR, you may refer to HSA's website at <https://www.hsa.gov.sg/therapeutic-products/register/special-access-routes/import-for-patients>.

3. What are the risks and benefits of receiving the Novavax/Nuvaxovid XBB.1.5 COVID-19 vaccine?

The Novavax/Nuvaxovid XBB.1.5 COVID-19 vaccine is currently not registered for use in Singapore. The vaccine has successfully obtained full approval in the European Union and emergency approval in the United States. These jurisdictions have assessed that the vaccine is able to generate an immune response to the COVID-19 virus and is expected to provide protection against COVID-19. These jurisdictions also expect the safety profile of the Novavax/Nuvaxovid XBB.1.5 COVID-19 vaccine to be similar to that of the original Novavax/Nuvaxovid vaccine.

4. What are the alternatives to receiving the Novavax/Nuvaxovid XBB.1.5 COVID-19 vaccine for my second dose of the primary vaccination series?

You may receive a dose of the Pfizer-BioNTech/Comirnaty or the Moderna/Spikevax XBB.1.5 vaccine instead, to complete your primary vaccination series. If you are medically ineligible for these mRNA vaccines, you can take two doses of the Sinovac-CoronaVac vaccine to complete your primary vaccination series, which is available under the National Vaccination Programme (NVP) until 30 September 2024.

5. Who should receive the vaccine? Who should not receive the vaccine?

You must be 12 years or older to receive the Novavax / Nuvaxovid XBB.1.5 COVID-19 vaccine.

You should **NOT** receive the Novavax / Nuvaxovid XBB.1.5 COVID-19 vaccine if you had an allergic reaction (including anaphylaxis) (1) to a prior dose of the original Novavax/Nuvaxovid vaccine, or (2) to any ingredients in the original Novavax/Nuvaxovid vaccine.

Tell your doctor or nurse before getting the Novavax / Nuvaxovid XBB.1.5 COVID-19 vaccine if you:

- had a fever in the past 24 hours;
- have active cancer treatment, organ/stem cell transplantation, or are immunocompromised;
- have a low platelet count, bleeding disorder, or taking blood thinning medications; or

- had COVID-19 infection before, or had previously received a COVID-19 vaccine.

Most people with the above conditions or situations can receive the Novavax / Nuvaxovid XBB.1.5 COVID-19 vaccine, but the doctor or nurse may provide additional advice.

6. How is the Novavax / Nuvaxovid XBB.1.5 COVID-19 vaccine administered?

This vaccine is administered as an injection into the muscle of your upper arm.

7. What are the ingredients in the Novavax / Nuvaxovid XBB.1.5 COVID-19 vaccine?

The Novavax/Nuvaxovid XBB.1.5 COVID-19 vaccine includes the following ingredients: recombinant spike (rS) protein from the SARS-CoV-2 Omicron variant lineage XBB.1.5; matrix-M1 adjuvant; phosphatidylcholine; potassium dihydrogen phosphate; potassium chloride; disodium hydrogen phosphate dihydrate; disodium hydrogen phosphate heptahydrate; sodium dihydrogen phosphate monohydrate; sodium chloride; polysorbate 80; sodium hydroxide; hydrochloric acid.

8. What are the possible side effects of the vaccine? How do I manage the side effects?

Like other vaccines and medications, side effects can happen. Most side effects are mild or moderate, and usually get better within a few days. The table below lists some common side effects that have been reported with the Novavax / Nuvaxovid COVID-19 vaccines, and guidance on how to manage them.

Side Effects	How to Manage
Pain, redness, swelling at the injection site	Those with fever are advised to self-isolate at home until the fever subsides. Paracetamol 1 to 2 tablets every 6 hours for adults or dosed according to the child's weight as needed.
Fever, chills	
Headache, muscle pain, joint pain	
Tiredness	Rest

- See a doctor if side effects persist or get worse.
- See a doctor to get tested for COVID-19 if you develop cough, sore throat, or runny nose, since you don't develop full protection until at least 7 days after completing the second dose.
- Very rarely, this vaccine may cause a severe allergic reaction or anaphylaxis. Symptoms include difficulty breathing, swelling of your face/throat/eyes/lips, fast heartbeat, dizziness/weakness, or rash.
- If you experience these, seek medical attention at once. Call 995 or go to the nearest A&E immediately.
- If you experience side effects after vaccination which are not listed above, please consult your doctor.

9. Any other advice?

Advice for different groups of vaccine recipients:

- If you are on blood thinning medicines, press firmly on the injection site for 5 minutes.
- If you are on active cancer treatment, recent organ/stem cell transplantation or are on aggressive immunotherapy, please consult your specialist to discuss if you can receive the Novavax/Nuvaxovid XBB.1.5 COVID-19 vaccine.
- Pregnant women and those planning to get pregnant should get vaccinated. Vaccination carries significant benefits for pregnant women and women trying to conceive. There is no evidence that vaccination is harmful in pregnancy.

Before vaccination:

- Continue to take your medications as usual, and do not stop them just for the vaccination.
- Avoid dehydration or skipping meals, to reduce risk of fainting after vaccination.
- If you have a fever or are acutely ill, you should re-schedule your vaccination.

After vaccination:

To reduce the risk of side effects after vaccination, it is advisable for:

- Men aged 12-29 to avoid strenuous physical activity or intense exercise for 1 week after each dose.

10. How do I report side effects?

If you experience severe or unusual side effects, see your doctor, who will be able to advise you and report the side effects to HSA. You may also report side effects directly to HSA on a form by scanning the **QR code**:



11. If I suffer a serious side effect, will I be eligible for the Vaccine Injury Financial Assistance Programme (VIFAP)?

Yes. If you experience a serious side effect which is assessed by a doctor to be related to the Novavax/Nuvaxovid XBB.1.5 COVID-19 vaccine, you can apply for VIFAP as the Novavax/Nuvaxovid XBB.1.5 COVID-19 vaccine is offered under the National Vaccination Programme (NVP).

The content of this information sheet was updated on 1/3/2024. For the latest COVID-19 vaccine consumer information, please refer to the HSA website at <https://www.hsa.gov.sg/covid-19-information-and-advisories>