Covid-19 Vaccine

Important Information about the Novavax COVID19 vaccine, Nuvaxovid

Version 1

21 February 2022

This is a large print leaflet. The leaflet will be updated as new information becomes available. For a printed copy of the most recent version, contact NCBI by emailing **library@ncbi.ie**

About this leaflet

This leaflet tells you about the Novavax COVID-19 coronavirus vaccine, Nuvaxovoid.

It tells you about:

- What COVID-19 is
- what the COVID-19 vaccine is
- who should get the vaccine
- why is it important to get the vaccine
- COVID-19 vaccine, booster and additional doses
- who should not get it and who should delay getting it
- vaccine safety and side effects
- where you can get more information.

Please read this leaflet carefully. You can also talk to a healthcare professional, like your GP – Doctor – or Pharmacist, about the vaccine.

What is COVID-19

COVID-19 is an illness that can affect the lungs and airways, and sometimes other parts of the body. It's caused by a virus called coronavirus.

It is highly infectious. It spreads through the air through droplets produced when people cough or sneeze, or when they touch surfaces where the droplets have landed and then touch their eyes, nose or mouth.

COVID-19 can cause serious illness, hospitalisation and even death.

The most common symptoms of COVID-19 are:

- a fever – high temperature of 38 degrees Celsius or above – including having chills
- dry cough
- fatigue

You may not have all of these symptoms or you may just feel generally less well than usual. It can take up to 14 days for symptoms to show. They can be similar to symptoms of cold or flu.

If you have any symptoms of COVID-19, self-isolate – stay in your room – and visit **www.hse.ie/covid19** for advice.

What is the COVID-19 vaccine?

A vaccine is a substance that should improve immunity – protection – to a particular disease. COVID-19 vaccines protect you from serious illness with COVID-19. If people are vaccinated, it should also reduce the numbers who become seriously ill or even die from COVID-19 in our community.

Vaccines teach your immune system how to protect you from diseases. It is much safer for your immune system to learn how to protect you through vaccination than by contracting COVID-19.

Who should get the vaccine?

Find out who can get a COVID-19 vaccine at
hse.ie/covid19vaccine

While it is up to you to decide to get the vaccine, the HSE, the World Health Organization and the Department of Health strongly recommend that you do so as soon as it is offered to you.
You will need to read this leaflet and the manufacturer's Patient Information Leaflet before you get your vaccine.

You can find the manufacturer's Patient Information Leaflet on **www.hse.ie/covid19vaccinePIL and it is strongly recommended that you read this leaflet.**

You can also talk to a healthcare professional in advance. If you decide to get the vaccine, you will give your informed consent which will be recorded.

The HSE is offering the vaccine free of charge.

How many doses of the COVID-19 vaccine do I need for my first round of vaccines?

When we say 'first round of COVID-19 vaccination' we mean your dose 1 and dose 2 if you got AstraZeneca, Moderna, Pfizer or Novavax. Or your single dose if you got the Janssen vaccine.

mRNA vaccines – Pfizer or Moderna – are the recommended vaccines for first round of vaccinations. However, some people may not be able to get an mRNA vaccine – e.g. they are allergic to the vaccine– or have chosen not to get one. In such cases, Nuvaxovid can be considered.

For people who have never had any COVID-19 vaccines

- You need 2 doses of this vaccine, 21 days apart.

For people who have not completed their first round of COVID-19 vaccines:

- If you have not completed your first round of COVID-19 vaccines, – ie you have only had one dose of Pfizer, Moderna or Astrazenca COVID-19 vaccines– you can get Nuvaxovid for your second dose 28 days later.

- People can choose this option because it has been advised by the National Immunisation Advisory Committee – NIAC – in Ireland. It is not yet approved – licensed – by the European Medicines Agency – EMA. At the moment, the EMA has only approved the use of two doses of the same vaccine for your first round of vaccinations.

What are the recommendations on an additional dose for people with a weak immune system?

People who have their first round of COVID-19 vaccines with an mRNA – Pfizer or Moderna – or viral vector vaccine – Astrazeneca or Janssen:

- If you had a weak immune system at the time of your first round of COVID-19 vaccination, you should have been offered an additional dose of mRNA vaccines to give you better protection.
- mRNA vaccines – Pfizer or Moderna – are the recommended vaccines for additional doses. However, some people may not be able to get an mRNA vaccine –e.g. they have had a severe allergic reaction– or have chosen not to get one.
- In such cases, Nuvaxovid can be considered for an additional dose in those aged 18 years and over. People can choose this option because it has been advised by NIAC in Ireland. It is not yet approved – licensed –by the EMA. At the moment, the EMA has approved the use of two doses of Novaxovid for your first round of vaccinations.
- You should get an additional dose at least 2 months after finishing a COVID-19 vaccine course.

- You will still need a booster dose after your additional dose.

People who have Nuvaxovid for their first round of COVID-19 vaccines:

- At this time no additional dose is recommended for people with a weak immune system who have receive this vaccine for their first round of COVID-19 vaccines.

What are the recommendations on a booster dose?

People who have their first round of COVID-19 vaccines with an mRNA – Pfizer or Moderna – or viral vector vaccine – Astrazeneca or Janssen:

- You should get a booster dose because the protection you get from your initial course of vaccination may weaken with time. Some people are at high risk of severe infection, for example older people and people with underlying health conditions. We hope that a booster dose will give you better protection against COVID-19.
- mRNA vaccines – Pfizer or Moderna – are the recommended vaccines for boosters. However, some people may not be able to get an mRNA vaccine e.g. they have had a severe allergic reaction– or have chosen not to get one.

- In such cases, Nuvaxovid can be considered for a booster dose in those aged 18 years and over. People can choose this option because it has been advised by NIAC in Ireland. It is not yet approved – licensed – by the EMA. At this time, the EMA has approved the use of two doses of Novaxovid for your first round of vaccinations.
- You should get a booster dose at least 5 months after finishing a course of COVID-19 vaccines.

People who have Nuvaxovid for their first round of COVID-19 vaccines:

- At this time no booster dose is recommended for people who have receive this vaccine for their first round of COVID-19 vaccines.

Why is it important to get the COVID-19 vaccine?

Getting a COVID-19 vaccine should reduce your risk of getting COVID-19 and protect you from serious complications of the illness. Our aim in offering the vaccine to the population is to protect people and reduce the illness and deaths caused by this virus.

I already had COVID-19, so do I need to get the vaccine?

Yes. Even if you have already had COVID-19, you could still get it again.

The vaccine will reduce your risk of getting COVID-19 again. Even if you do get COVID-19 again, the vaccine can reduce the seriousness of your symptoms.

I have COVID-19 now, should I get the vaccine?

You should delay getting vaccinated until you recover from COVID-19. From the time you test positive –or symptoms started– you should wait:

- 4 weeks if you are due to get your first round – first or second dose – of COVID-19 vaccination
- 3 months if you are due to get a booster dose or additional dose – if you have a weak immune system.

Can I get this vaccine at the same time as other vaccines?

You can get the Nuvaxovid vaccine at the same time as the flu vaccine. However, you should leave at least two weeks between this vaccine and any other vaccine.

Getting the vaccine

Who is my vaccinator?

Your vaccinator is the person who gives you your vaccine. They are trained by the HSE to give COVID-19 vaccines.

Can the COVID-19 vaccine give you COVID-19?

No. The COVID-19 vaccine cannot give you COVID-19. It is possible to have caught COVID-19 before getting your vaccine and not realise you have the symptoms until after your vaccination appointment.

If you have any symptoms of COVID-19, or if you have a fever which starts more than 2 days after your vaccine, or lasts longer than 2 days, self-isolate – stay in your room – and visit www.hse.ie/covid19 for advice.

Should I get the COVID-19 vaccine if I have a high temperature?

You should delay getting the vaccine if you have a fever – temperature of 38 degrees Celsius or above, until you feel better.

Should I get the vaccine if pregnant, trying to get pregnant or breastfeeding?

Most pregnant women who get the virus – and are not vaccinated – get mild to moderate symptoms. They give birth as planned and the risk of passing on COVID-19 to their baby is low. However, you are more likely to get very unwell and need treatment in intensive care than a woman who is not pregnant. The virus may also cause complications for your baby like premature delivery, miscarriage or stillbirth.

For pregnant women, mRNA COVID-19 vaccines – Pfizer and Moderna – are the recommended vaccine and can be given at any stage of pregnancy. Millions of pregnant women have received the mRNA COVID-19 vaccines worldwide. Studies have shown no serious side effects so far.

However, if you are pregnant and have been advised by your doctor that you cannot receive an mRNA vaccine or you do not wish to have an mRNA vaccine, Nuvaxovid can be considered after a discussion with a healthcare professional – such as a doctor, midwife or vaccinator – about the risks and benefits for you. We have less information on the use of this vaccine in pregnant women.

You can read more at **www.hse.ie/covid19vaccine**

You can get this vaccine if you are breastfeeding or trying to get pregnant.

What vaccine am I being offered?

The vaccine we are offering you is called Nuvaxovid, manufactured by Novavax.

The vaccine contains a version of a protein – the spike protein – found on the surface of virus that causes COVID-19. It also contains an 'adjuvant' – ingredient – to help strengthen the immune responses – antibodies – to the vaccine.

By getting this vaccine your body makes antibodies that help fight the infection if the COVID-19 virus enters your body in the future.

This leaflet has important information about the vaccine you are being offered. Please read it. You can also find it on **www.hse.ie/covid19vaccine**

Are there some people who should not get the COVID-19 vaccine?

Yes. You should not get the COVID-19 vaccine Nuvaxovid if:

- you have had a severe allergic reaction to any of the ingredients in the vaccine –including polysorbate 80. Read the manufacturer's Patient Information Leaflet to see the list of ingredients. Please note COVID-19 vaccines Janssen and Astrazeneca –Vaxzevria – also contain Polysorbate 80.
- you have had a severe allergic reaction to a previous dose of the vaccine.

Talk to your Doctor before getting the COVID-19 vaccine if you:

- have had a severe allergic reaction – anaphylaxis – in the past, including to any other vaccine or medication.

Most people will be able to safely get the vaccine. The person giving you the vaccine will be happy to answer any questions you have at your appointment for the vaccine.

They will also give you a vaccine record card showing the name and batch number of the vaccine you have been given.

Is the vaccine safe?

The HSE only uses vaccines when they meet the required standards of safety and effectiveness.

While the work to develop COVID-19 vaccines has moved much faster than usual, the vaccine we are offering you has gone through all the usual steps needed to develop and approve a safe and effective vaccine.

In order to be approved for use, the COVID-19 vaccine went through all the clinical trials and safety checks all other licensed medicines go through, following international standards of safety. The vaccine we are offering you is called Nuvaxovid, manufactured by Novavax.

It has:

- been tested with thousands of people as part of clinical trials
- met strict standards of safety, quality and effectiveness, and been approved and licensed by regulators. For Ireland, the regulator is the European Medicines Agency – EMA – visit **www.ema.europa.eu** for more information.

Studies on people who got a booster dose haven't shown any serious side effects but we have less information on the safety of the booster and additional doses of this vaccine.

How is the COVID-19 vaccine given?

The COVID-19 vaccine is given as an injection into your upper arm. It will only take a few minutes.

What are the side effects of the vaccine?

Like all medicines, vaccines can cause side effects. Most of these are mild to moderate, short-term, and not everyone gets them.

More than 1 in 10 people will have these very common side effects:

- Feeling tired
- Feeling generally unwell
- Headache
- Nausea or Vomiting
- Muscle pain
- Joint pain
- Tenderness or Pain in your arm where you have had the vaccine injection

Up to 1 in 10 people will have these **common** side effects:

- Fever – Temperature of 38 degrees Celsius or above
- Chills
- Pain in extremities
- Redness or swelling where the vaccine was given

Up to 1 in 100 people will have these uncommon side effects:

- swelling of the lymph glands
- high blood pressure lasting for a few days after vaccination
- a rash
- redness of the skin
- generalised itchiness
- itchiness where the vaccine was given
- hives

Some side effects are seen more often after the second dose. Serious side effects, like a severe allergic reaction, are extremely rare with COVID-19 vaccines in general. Your vaccinator is trained to treat very rare serious allergic reactions.

The COVID-19 vaccine has gone through the same clinical trials and safety checks as all other licensed vaccines, however the vaccine is new and long-term side effect information is limited.

As more people in Ireland and around the world get this vaccine, more information on side effects may become available. The HSE will update this information regularly on our website, and if necessary, will update the information leaflets given to people at their vaccination.

After Getting Your Vaccine

We are giving you a record of your vaccination today. **Please keep the record card safe.**

What might happen in the next few days?

Some people who got the vaccine that you got today may get some of the side effects listed above. Most of these are mild to moderate and short-lived.

Fever after the vaccine

It's quite common to develop a fever after a vaccination. Usually, this happens within 2 days – 48 hours – of getting the vaccine, and it goes away within 2 days.

You are more likely to get a fever after your second dose of the vaccine.

If you feel uncomfortable, take paracetamol or ibuprofen as directed on the box or leaflet. However if your fever lasts more than 48 hours or if you are still concerned, please seek medical advice. Do not take ibuprofen if you are pregnant.

How long does it take the vaccine to work?

After having both doses of the COVID-19 vaccine, most people will have immunity. This means they will be protected against serious illness with COVID-19.

It takes 7 days after getting the second dose for it to work.

There is a chance you might still get COVID-19, even if you have the vaccine.

Does the vaccine work in everyone?

Worldwide, vaccines save at least 2 to three million lives each year, and protect many more from lifelong illnesses. Billions of people worldwide have now received COVID-19 vaccines.

There's strong, reliable evidence that COVID-19 vaccines greatly reduce your risk of getting COVID-19. They're highly effective at preventing deaths and serious illness with COVID-19.

If you have a weakened immune system, there is no extra risk in taking the vaccine, but it may not work as well for you.

When I get the vaccine, does that mean I won't spread COVID-19 to others?

We do not know yet if having the vaccine stops you spreading the COVID-19 virus to others. You should continue to follow the current public health advice for vaccinated individuals to stop the spread of the virus.

Thank you for protecting yourself and others.

How long does immunity last from the vaccine?

We do not know yet how long immunity will last after your first round of vaccines with Nuvaxovid or as a booster – if you got a different COVID-19 vaccine for your first round.
Clinical trials are ongoing to find this out.

More information

For more information, read the manufacturer's Patient Information Leaflet. This will be printed for you on the day you get your vaccine, or you can find it on **www.hse.ie/covid19vaccinePIL**

You can also talk to a health professional, like your GP – Doctor, Pharmacist or healthcare team.

You can also visit the HSE website at
www.hse.ie/covid19vaccine or call HSELive on 1800 700 700

For more information on the COVID-19 vaccine, including materials in other formats and translation support, visit
www.hse.ie/covid19vaccinematerials
We strongly recommend you read this leaflet.

How do I report side effects?

As with all vaccines, you can report suspected side effects to the Health Products Regulatory Authority – HPRA.

The HPRA is the regulatory authority in the Republic of Ireland for medicines, medical devices and other health products.

As part of its role in the safety monitoring of medicines, the HPRA operates a system through which healthcare professionals or members of the public can report any suspected adverse reactions – side effects– associated with medicines and vaccines which have occurred in Ireland.

The HPRA strongly encourages reporting of suspected adverse reactions –side effects– associated with COVID-19 vaccines to support continuous monitoring of their safe and effective use. To report a suspected adverse reaction to the COVID-19 vaccine, please visit **www.hpra.ie/report**

You can also ask your Doctor or a family member to report this for you. As much information as is known should be provided, and where possible, the vaccine batch number should be included.

The HPRA cannot provide clinical advice on individual cases. Members of the public should contact their healthcare professional – their Doctor or Pharmacist – with any medical concerns they may have.

Your personal information

In order to administer the vaccine safely and to record all the necessary information to monitor and manage the vaccine, the HSE will be processing your personal information. All information processed by the HSE will be in accordance to the general laws and in particular the General Data Protection Regulation – GDPR – which came into force in 2018.

The processing of your data will be lawful and fair. It will only be processed for the specific purpose to manage the vaccinations. The principle of Data Minimisation has been applied. This means that only data that is necessary to identify you, book your appointment, record your vaccination and monitor its effects is being recorded.

You have the following rights as a data subject under the GDPR in respect of your personal data that are processed.

- Request information on and access to your personal data – commonly known as a 'data subject access request'–. This enables you to receive a copy of the personal data we hold about you and to check that we are lawfully processing it.

- Request correction of the personal data that we hold about you. This enables you to have any incomplete or inaccurate information we hold about you corrected.

- Request erasure of your personal data. This enables you to ask us to delete or remove personal data where there is no good reason for us continuing to process it. You also have the right to ask us to delete or remove your personal information where you have exercised your right to object to processing.

- Object to processing of your personal data.

More information is available at **www.hse.ie/eng/gdpr**

Published by HSE on 21 February 2022

For the most up-to-date information visit **www.hse.ie**