COVID-19 VACCINE

COVID-19 vaccines

Information about your Nuvaxovid vaccine

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About this booklet

This booklet provides information about your COVID-19 vaccine.

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Your vaccinator can answer any questions you might have after reading this booklet.

About your COVID-19 vaccine

COVID-19 vaccines are the best way to protect yourself from COVID-19. The vaccines provided by the HSE provide the best available protection against the serious complications of COVID-19 and reduce the risk of hospitalisation and death.

The National Immunisation Advisory Committee (NIAC) recommend that mRNA vaccines should be given. The updated Comirnaty (Pfizer) vaccine is the available recommended mRNA vaccine used in Ireland's COVID-19 vaccination programme. For those who cannot receive or would prefer not to receive an mRNA vaccine, NIAC recommend the most up to date Nuvaxovid vaccine available.

This booklet provides information about Nuvaxovid vaccine. Nuvaxovid is approved for use in people aged 12 years and older. Some sections of this booklet contain information relevant for everyone who NIAC recommend should get a COVID-19 vaccine. However, Nuvaxovid can only be given to those aged 12 years and older.

Who is recommended to get a COVID-19 vaccine?

People who are at risk of severe illness from COVID-19 are recommended to get a COVID-19 vaccine. For most people who are at risk of severe illness, a COVID-19 vaccine is recommended once a year. If you are in a very high-risk group, the protection from vaccination weakens more quickly and therefore to get more protection, a COVID-19 vaccine is recommended twice a year.

You should get a COVID-19 vaccine once a year if you are:

- Aged 60 to 79 years
- Aged 6 months and older with a medical condition that puts you at higher risk of complications from COVID-19

You should get a COVID-19 vaccine twice a year if you are:

- Aged 80 years and older
- Aged 18 years and older living in a long-term care facility for older adults
- Aged 6 months and older with immunocompromise (a weak immune system) that puts you at higher risk of complications from COVID-19

If you are a healthcare worker and you are in any of the groups listed above, you should follow the same advice.

If you are pregnant and you have a weak immune system or a medical condition that puts you at higher risk of complications from COVID-19, then you should get one dose of a COVID-19 vaccine during your pregnancy.

If you are a healthcare worker or if you are pregnant or if you are aged over 18 years and you are not in any of the groups listed above, you can get a COVID-19 vaccine once a year if you choose to, following discussion with your healthcare provider.

If you have been vaccinated before, you should wait at least 3 months after your last COVID-19 vaccine or your last COVID-19 infection before getting vaccinated.

For more information on when your next COVID-19 vaccine is due, visit **www.hse.ie** or call our team in HSE Live on **1800 700 700** or speak to your healthcare provider.

What if I've never had a COVID-19 vaccine?

If you have never had a COVID-19 vaccine and you are in a risk group (as listed above), then you are recommended to get a COVID-19 vaccine. If you have never had a COVID-19 vaccine and you are not in a risk group, (as listed above) you can get a vaccine if you choose to get one, following a

discussion with a healthcare provider. Anyone with immunocompromise (a weak immune system) may need more than one vaccine dose. You should speak to your healthcare provider for further advice about the number of vaccines needed and the best time to get vaccinated. If you have never had a COVID-19 vaccine and you get a COVID-19 infection, you should wait at least 4 weeks after your infection (either when your symptoms began or when you tested positive) before getting vaccinated.

Recommended vaccines

The latest updated Comirnaty mRNA vaccine manufactured by Pfizer is the COVID-19 vaccine that is recommended by NIAC.

For those who cannot receive or would prefer not to receive an mRNA vaccine the Nuvaxovid vaccine is recommended by NIAC.

In Europe, Nuvaxovid is approved by the European Medicines Agency (EMA).

In the United States, Nuvaxovid is approved by the Federal Drug Administration (FDA).

Important:

Advice from the European Medicines Agency (EMA) and the National Immunisation Advisory Committee (NIAC) may vary at times. When this happens, we follow NIAC guidance in Ireland.

Pregnancy and breastfeeding

If you are pregnant and you are in a risk group, for example if you have a weak immune system or a medical condition that puts you at higher risk of complications from COVID-19, one dose of a COVID-19 vaccine during your pregnancy is recommended. Some people with a weak immune system may be recommended to get a second COVID-19 vaccine during their pregnancy.

If you are not in a risk group, you can choose to get a COVID-19 vaccine if you wish, following a discussion with your healthcare provider.

mRNA COVID-19 vaccines are the recommended vaccines in pregnancy, we have less information on the use of Nuvaxovid in pregnancy. If you are pregnant and you are recommended to get a COVID-19 vaccine or you are choosing to have a COVID-19 vaccine, an mRNA vaccine is recommended for you.

However, if you have been advised by your doctor that you cannot have an mRNA vaccine, the Nuvaxovid vaccine can be considered. You should first discuss this with your treating healthcare professional, such as a doctor or midwife about the risks and benefits of the vaccine for you.

If you are pregnant, you should wait at least 6 months since your previous COVID-19 vaccine or infection before being vaccinated. You can have the COVID-19 vaccine at any stage of pregnancy, but the best time is between 20 and 34 weeks of pregnancy. COVID-19 vaccination is safe in pregnancy.

It is safe to have a COVID-19 vaccine if you are breastfeeding.

COVID-19 and children

Nuvaxovid vaccine is approved for use in people aged 12 years and older. The vast majority of children who get COVID-19 have very mild symptoms.

COVID-19 can cause serious illness, hospitalisation or death in children, but this is very rare.

Rarely, COVID-19 can cause a condition called Multisystem Inflammatory Syndrome in Children (MIS-C).The condition can cause inflammation of different organs (e.g., the heart). Most children who get MIS-C have no underlying medical condition. Most children with MIS-C recover after time in hospital or intensive care.

Sometimes, symptoms connected to COVID-19 can continue for some weeks or months. This is called 'long COVID'. The risk of this condition is lower in children compared to adults.

Children aged 6 months and older with certain medical conditions and children with weak immune systems are at higher risk of severe illness and hospitalisation if they get COVID-19, and they are recommended to get a COVID-19 vaccine either once or twice a year.

Consent for your child to be vaccinated

A parent or legal guardian will be asked to give consent for their child to be vaccinated.

Young people aged 16 years or older are legally entitled to consent for themselves

Your decision to give consent for the vaccine or not will be respected.

What to expect after your COVID-19 vaccine

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

Serious side effects, like a severe allergic reaction, are extremely rare. Your vaccinator is trained to treat very rare serious allergic reactions.

The side effects can be different for each vaccine, and you should read this booklet and the manufacturer's patient information leaflet for the vaccine you get. You will be given a copy of the manufacturer's patient information leaflet on the day you get your vaccine.

In the next section, we give you the known side effects of the COVID-19 vaccine detailed in this booklet and tell you how common or rare they are. We also highlight who should not get vaccinated. You can find further information on **www.hse.ie**.

Vaccine side effects and when not to get vaccinated

On the following pages, we tell you about the possible side effects and when not to get vaccinated. We categorise side effects from very common to extremely rare.

- Very common – more than 1 in 10 people
- Common – up to 1 in 10 people
- Uncommon – up to 1 in 100 people
- Rare – up to 1 in 1,000 people
- Very rare – up to 1 in 10,000 people
- Extremely rare – it is not known yet how many people who get this vaccine will experience these side effects, but they are thought to be extremely rare

You should look out for side effects in the hours and days after your vaccine.

Side effects

Side effects of the Nuvaxovid COVID-19 vaccine

The possible side effects and how often they occur are listed below, followed by information on when not to take this vaccine. If in any doubt, always ask a trusted healthcare professional.

Possible side effects	
Very common More than 1 in 10 people	• headache • nausea or vomiting • muscle pain • joint pain • tenderness or pain in your arm where you have had the vaccine injection • feeling tired • feeling generally unwell
Common Up to 1 in 10 people	• redness or swelling where the vaccine was given • fever (temperature of 38 degrees Celsius or above) • pain in extremities
Uncommon Up to 1 in 100 people	• swelling of the lymph glands • high blood pressure lasting for a few days after vaccination • chills • a rash • redness of the skin • generalised itchiness • itchiness where the vaccine was given • hives
Rare Up to 1 in 1,000 people	• warmth where the vaccine was given

Extremely rare Frequency not known yet	• a severe allergic reaction (anaphylaxis) • myocarditis or pericarditis (this means inflammation of the heart muscle or the lining of the heart muscle) • unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia) • decreased feeling or sensitivity, especially in the skin (hypoaesthesia)

Myocarditis and pericarditis are inflammatory heart conditions. Myocarditis and pericarditis are extremely rare side effects of Nuvaxovid vaccines.

Most people with myocarditis or pericarditis get better on their own or with supportive treatment but would need care in hospital. This could include needing to go to intensive care. We don't yet know if there are any long-term problems because of these side effects.

Symptoms of myocarditis and pericarditis

Get medical help if you get any of these symptoms after you get this vaccine:

- breathlessness
- palpitations – a forceful heartbeat that may be irregular
- chest pain

When not to get vaccinated

You should NOT get the Nuvaxovid COVID-19 vaccine if:

- You have had a severe allergic reaction to any of the ingredients in the vaccine including polysorbate 80 (SmPC). Read the manufacturer's patient information leaflet to see the list of ingredients.
- You have been told by your doctor that you should not have a Nuvaxovid vaccine for medical reasons.

Talk to your doctor before getting this COVID-19 vaccine if you:

- Are currently feeling very unwell.
- Had myocarditis or pericarditis - inflammation of the heart muscle or lining of the heart - after any previous COVID-19 vaccine.
- Had a severe allergic reaction – anaphylaxis – in the past, including to any other vaccine or medication.

If you recently received the mpox vaccine – Imvanex or JYNNEOS – you need to wait 4 weeks before you get a COVID-19 vaccine because of the possible risk of myocarditis.

What to do if you have fever or aches and pains after vaccination

If you have a fever (temperature of 38 degrees Celsius or higher) or aches and pains, you can take paracetamol or ibuprofen to help. However, if your fever lasts more than 48 hours or if you are still concerned, please seek medical advice.

If you are pregnant and you have a fever or aches and pains after vaccination, you can take paracetamol. Do not take ibuprofen or aspirin to treat a fever or aches and pains after vaccination in pregnancy.

Time needed for vaccines to work

It takes some time after getting your vaccine, up to 14 days, for your immune system to respond and give you protection from the serious complications of COVID-19.

There's strong, reliable evidence that COVID-19 vaccines are highly effective at preventing serious illness and death from COVID-19.

How to report side effects

If you think you have had a side effect after receiving a vaccine, you can report it to the Health Products Regulatory Authority (HPRA) at **www.hpra.ie**.

Your doctor, nurse, pharmacist or a family member can also report the side effect to the HPRA.

Your personal information

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 with 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 of managing the vaccinations. The HSE applies the principle of data minimisation. This means that only data that is necessary to identify you, book your appointment, record your vaccination and monitor its effects is being recorded.

As a data subject under the GDPR in respect of your personal data that are processed, you have the right to:

- 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**.

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Further information on the vaccine you are receiving is available here:

Please note that for the 2025/2026 winter vaccination programme, the HSE vaccine supplies of Nuvaxovid (Novavax) have come from United States. Therefore, this link will direct you to the FDA website.

Please also note that any side effects following vaccination should continue to be reported to the HPRA (www.hpra.ie)

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

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