



COVID-19 vaccines

Information about your Pfizer, or Novavax vaccine

Version 1

04 April 2024

This is a large print leaflet. The leaflet will be updated as new information becomes available. For a large print copy of the most recent version, contact Vision Ireland Library by emailing: **library@vi.ie**

About this booklet

This booklet provides general information about your COVID-19 vaccine. There are separate information booklets about the Pfizer vaccine for children aged five to 11 and 12 to 15 years available at **www.hse.ie**

It's available online for you to read before you get your vaccine and you will be given this booklet when you go to get your vaccine.

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

Please keep this booklet, as you may need to refer back to it. If you want this booklet in another format such as Easy Read, Braille, Audio, Irish Sign Language or you want a translated version, visit www.hse.ie/covid19vaccinematerials

About your COVID-19 vaccine

COVID-19 vaccines are the best way to protect yourself from COVID-19. Since the vaccines were introduced, we have seen fewer people with serious illness and fewer deaths from the virus in Ireland.

Getting a COVID-19 vaccine should reduce your risk of getting COVID-19 and protect you from serious complications. The HSE is vaccinating people in Ireland to protect them and to continue to reduce the number of people with serious illness and the number of deaths.

This booklet has information about the main vaccines in Ireland's COVID-19 vaccination programme: **Pfizer**, and **Novavax**.

In Ireland, COVID-19 vaccines BidPrevtyn Beta, AstraZeneca – also called Vaxzevria – and Janssen – also called Jcovden – and Spikevax (also called Moderna) are no longer used, but you can find information on them on **www.hse.ie**

Vaccines, boosters and additional doses

When we refer to vaccine – or vaccines – in this booklet, we mean:

- a primary course – first or second dose
- an additional dose – offered to people with a weak immune system and/or
- a booster dose

Primary course

A primary course is recommended for all people aged 12 years and older.

A primary course is:

- a first and second dose, 4 weeks apart for those aged 6 months and older with a weak immune system
- a single dose for those aged 5 years and older

Additional dose

An additional dose is offered to people with a weak immune system.

Booster doses

The protection you got from your previous vaccines or the protection you got from a COVID-19 infection may weaken over time. Boosters increase your protection from COVID-19.

You may wish to consider getting your booster to protect others too – for example, if you are a carer or you live with someone at high risk of COVID-19, such as someone with a weak immune system.

For more information on when your next COVID-19 vaccine is due visit **www.hse.ie** or call our team in HSELive on: **1800 700 700**.

Adapted vaccines

The Comirnaty vaccines that you will be offered are adapted vaccines. Adapted Comirnaty vaccines contain mRNA to protect against variant strains of Covid-19. They are expected to give wider protection against Covid-19 variants than the original vaccine.

Adapted vaccines are recommended by the National Immunisation Advisory Committee and approved by the European Medicines Agency.

The Novavax vaccine currently offered is also an adapted COVID-19 vaccine.

The vaccines are either:

- Comirnaty Omricon XBB.1.5 – Pfizer vaccine
- Nuvaxovid XBB.1.5– Novavax vaccine

These vaccines contain mRNA to protect against the original strain of COVID-19 as well as the COVID-19 variant strains BA.1 or BA.4-5. They are expected to give wider protection against COVID-19 variants than the previous vaccines.

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.

Vaccine approval, safety and monitoring

The HSE only uses vaccines when they meet the required standards of safety and effectiveness and after the European Medicines Agency EMA has licensed them.

COVID-19 vaccines have gone through the same clinical trials and safety checks as all other licensed vaccines, however the vaccines are still quite new and the information on the long-term side effects is limited.

We have less information on the safety of the second and subsequent COVID-19 boosters. However, many countries have given their populations multiple doses of COVID-19 vaccines. Studies show that there have not been any unexpected safety concerns so far for people who have received multiple boosters.

It is expected that the safety of the adapted vaccines will be similar to the previous vaccines. Safety of the vaccines will continue to be monitored by the EMA.

It is your choice to get the vaccine. The HSE, the World Health Organization WHO and the Department of Health strongly recommend that you get your vaccine when it is offered to you.

The Health Products Regulatory Authority HPRA and the European Medicines Agency EMA monitor COVID-19 vaccines for safety and effectiveness. We tell you more about the HPRA on page [28](#).

In Ireland, the National Immunisation Advisory Committee NIAC gives advice on vaccine policy to the Department of Health and the HSE implements the department's policy.

Pregnancy and breastfeeding

You should get your COVID-19 vaccine if you're:

- pregnant
- trying for a baby or might get pregnant
- breastfeeding

Most pregnant people who get the virus, even if they haven't had a COVID-19 vaccine, get mild to moderate symptoms. They give birth as planned and the risk of passing COVID-19 to their baby is low.

However, if you are pregnant you are more likely to get seriously ill and need treatment in intensive care. The virus may also cause complications for your baby.

Children under the age of one are at higher risk of hospitalisation and severe illness from COVID-19. Young babies whose mothers were vaccinated in pregnancy, were less likely to need hospital care with COVID-19.

There is no evidence that COVID-19 vaccines affect fertility in men or women. You don't have to delay getting pregnant after your COVID-19 vaccine.

It is safe to get your COVID-19 vaccine at the same time as the other vaccines you're offered in pregnancy.

If you are pregnant, you will likely be offered a **Pfizer** vaccine. This is an mRNA type vaccine – a vaccine that tell your body how to make antibodies that help fight the COVID-19 virus.

However, if you have been advised by your doctor that you cannot receive an mRNA vaccine – the **Novavax** vaccine 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 **Novavax** vaccine in pregnant women. You can find more information on **www.hse.ie**

If you have not had your primary course, it may be given at any stage in pregnancy.

If you're pregnant a COVID-19 booster is recommended once in pregnancy if it is more than 6 months since you had a COVID-19 vaccine or infection. This booster can be given at any stage in pregnancy but it is recommended between 20 – 34 weeks. You can get it earlier if its been more than 12 months since your previous COVID-19 vaccine or infection.

If you have any questions you can talk to a trusted healthcare professional.

In pregnancy, you only need one COVID-19 booster. However, if you are pregnant and have a weak immune system you may get your second booster at least 6 months after your last COVID-19 vaccine or infection – at any stage in pregnancy.

COVID-19 and children

The vast majority of children who get COVID-19 have very mild symptoms or no symptoms at all.

COVID-19 can cause serious illness, hospitalisation or death in children, but this is very rare. Although the risk of hospitalisation and serious disease is very low in children, it is higher in younger children.

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.

The risk of a children being hospitalised because of COVID-19 is very low, and the risk of any children needing intensive car treatment is extremely low.

Children with certain health conditions are at higher risk of severe illness and hospitalisation if they get COVID-19. However, over half of children in hospital with COVID-19 may not have any underlying health conditions.

Rarely, COVID-19 can cause a condition called Multisystem Inflammatory Syndrome in children (MIS-C).

The condition causes pneumonia, inflammation of the heart and difficulty breathing. Most children with MIS-C recover after time in hospital or intensive care but some children have lasting side effects and a very small number can die.

Consent for your child to be vaccinated

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

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

The following might be useful in being informed about your choices:

Consider your child having the vaccine if:

- Your child has an underlying medical condition that puts them at high risk of severe COVID-19.
- Your child lives with a child or an adult who is at high risk of severe COVID-19.
- You want to increase protection for your child against the extremely rare possibility of severe COVID-19, Multisystem Inflammatory Syndrome or “long COVID”.

Consider your child not having the vaccine, or waiting until more information is available if:

- You do not want to risk the very rare side effect of myocarditis and pericarditis from vaccination.
- You want to wait for more information to become available about the risk of Multisystem Inflammatory Syndrome and of COVID-19 in children.

- You want to wait for more information to be available about the long term effects of the vaccines in children and young people.

Benefits of the vaccine:

- Protection from COVID-19
- Protection for children who have health conditions that put them at high risk of severe COVID-19.
- Protection for healthy children from severe COVID-19 – although this is very rare in this age group. The risk of a child being hospitalised because of COVID-19 is very low, and the risk of any child needing intensive care treatment is extremely low.
- Protection from COVID-19 and complications from COVID-19 such as “long COVID” and Multisystem Inflammatory Syndrome in children.
- May help prevent the spread of COVID-19 to others. This is especially important if children and young people are living with a sibling or an adult who is at risk of severe COVID-19.

Risks of the vaccine:

- Short term side effects like a sore arm, fever or tiredness.

- About 1 in 100,000 people have a severe side effect, like an allergic reaction to the vaccine.
- Very rarely some people develop inflammation of the heart and the outer lining of the heart after vaccination.
- We don't yet have information about longer term effects of COVID-19 vaccines in children.

Recommended vaccines by age

All COVID-19 vaccines give you good protection from severe illness with COVID-19 when you have:

- your primary course and
- any additional and/or booster doses recommended for you

The National Immunisation Advisory Committee NIAC advises that you can get any COVID-19 mRNA vaccine – **Pfizer** – for a primary course and any booster doses, even if you had a different vaccine before.

Advice by age group:

If you are:

- 6 months and over, you will be offered **Pfizer** vaccine for COVID-19

If you can't have an mRNA vaccine, you may be offered the **Novavax** vaccine. **Novavax** is approved for use for people who are 12 and over.

What to expect after your COVID-19 vaccine

Like all medicines, vaccines can cause **side effects**. Most of these are mild to moderate, 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. The manufacturer's leaflet is available on **www.hse.ie** or we can print a copy for you on the day you get your vaccine.

In the next section, we give you the known side effects of the two COVID-19 vaccines detailed in this booklet, and tell you how common or rare they are. We also highlight who should

not take each vaccine. You can find further information on **www.hse.ie**

More information becomes available all the time. The information on **www.hse.ie** is updated more frequently, as new studies are published.

The two vaccines – their side effects and when not to take a particular vaccine

On the following pages, we tell you about the possible side effects and when not to take a particular vaccine. 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.

While different vaccines will have side effects in common, you should pay attention to the side effects listed for the vaccine that you get. The name and colour of the vaccine is on the

record card that your vaccinator will give you and on the pages in this booklet. You should look out for side effects in the hours and days after your vaccine.

COVID-19 vaccine Pfizer – also called Comirnaty

The possible side effects and how often they occur are listed below, followed by 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

- feeling tired
- tenderness or swelling where you have had the vaccine injection
- headache
- muscle pain
- joint pain
- diarrhoea
- fever – temperature of 38 degrees Celsius or above – or chills
- redness where the vaccine was given
- irritability
- decreased appetite
- drowsiness

Common

Up to 1 in 10 people

- nausea
- vomiting
- redness where the vaccine was given
- swelling of the lymph glands. This is more common after a booster dose.
- rash

Uncommon

Up to 1 in 100 people

- itchiness where the vaccine was given
- dizziness
- generalised itchiness
- allergic reactions like hives or rash
- sleeplessness
- excessive sweating
- night sweats
- decreased appetite
- lack of energy, lethargy or feeling unwell
- pain in the arm you got the vaccine in

Rare

Up to 1 in 1,000 people

- temporary drooping on one side of the face
- allergic reactions like hives or swelling of the face

Very rare

Up to 1 in 10,000 people

- myocarditis and pericarditis. This means inflammation of the heart muscle or the lining of the heart muscle. See the next page for symptoms.

Extremely rare

Frequency not known yet

- a severe allergic reaction
- Erythema Multiforme – a skin reaction that causes red spots or patches on the skin that may look like a target or “bulls-eye” with a dark red centre surrounded by paler red rings
- swelling of the face if you have facial fillers
- extensive swelling of the arm – or leg – where the vaccine was given
- tingling or prickling sensation, or loss of sensation in some part of the body
- heavy periods

Symptoms of myocarditis and pericarditis

Myocarditis and pericarditis are inflammatory conditions of the heart. The risk of these conditions is higher in younger men. These conditions are more likely to occur after the second dose and mostly happen within 14 days of getting the vaccine.

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

You should NOT get the COVID-19 vaccine Pfizer

Comirnaty if:

- you have had a severe allergic reaction to any of the ingredients in the vaccine, including polyethylene glycol or PEG. Read the manufacturer's Patient Information Leaflet to see the list of ingredients
- you have had a severe allergic reaction to a previous dose of the **Pfizer** vaccine or the **Moderna** Spikevax COVID-19 vaccine
- you have had a severe allergic reaction after Trometamol – one of the contents in contrast dye used in MRI radiological studies

- you have been told by a Doctor that you should not have the **Moderna** Spikevax COVID-19 vaccine or the **Pfizer** COVID-19 vaccine for medical reasons

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

- had a severe allergic reaction – anaphylaxis – in the past, including to any other vaccine or medication
- had myocarditis and pericarditis – inflammation of the heart muscle or lining of the heart – after a previous dose of COVID-19 vaccines

For children who have previously had Multisystem Inflammatory Syndrome – MIS-C– they can get the COVID-19 vaccine once they have recovered and at least 90 days after they were diagnosed, whichever is longer.

If you recently received the MPOX – formerly known as Monkeypox – vaccine – Imvanex or Jynneos – you need to wait 4 weeks before you get a COVID-19 vaccine because of the unknown risk of myocarditis.

COVID-19 vaccine Novavax – also called

Nuvaxovid

The possible side effects and how often they occur are listed below, followed by 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

- 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

Common

Up to 1 in 10 people

- fever – temperature of 38 degrees Celsius or above
- pain in extremities
- redness or swelling where the vaccine was given

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

- warmth where the vaccine was given

Extremely rare

Frequency not known yet

- anaphylaxis – a severe allergic reaction
- tingling or prickling sensation, or loss of sensation in some part of the body
- myocarditis and pericarditis – inflammation of the heart muscle or the lining of the heart muscle. See the next page for symptoms.

Symptoms of myocarditis and pericarditis

Myocarditis and pericarditis are inflammatory conditions of the heart. Even though the risk of these conditions is very low, you should know the signs to look for. These symptoms can develop within a few days after getting the vaccine and have primarily occurred within 14 days.

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

You should NOT get the COVID-19 vaccine Novavax

Nuvoxoid 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 vaccine Vaxzevria also contain Polysorbate 80.
- have had a severe allergic reaction to a previous dose of the vaccine.

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

- had myocarditis and pericarditis – inflammation of the lining of the heart – after a previous dose of COVID-19 vaccines
- have had a severe allergic reaction – anaphylaxis – in the past, including to any other vaccine or medication

If you recently received the MPOX – formerly known as Monkeypox – vaccine – Imvanex or Jynneos – you need to wait 4 weeks before you get a COVID-19 vaccine because of the unknown risk of myocarditis.

What to do if you have fever or aches and pains

If you have a fever 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.

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 COVID-19.

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

You should also follow the latest public health advice on protecting yourself and others at **www.hse.ie**

How to report side effects

We are learning about COVID-19 vaccines. If you experience a side effect after your COVID-19 vaccine, we ask you to report it to the Health Products Regulatory Authority HPRA.

The HPRA is the regulatory authority in Ireland for medicines, medical devices and other health products. Please visit www.hpra.ie/report to report a side effect of a COVID-19 vaccine. You can also ask your Doctor or a family member to report a side effect for you.

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 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

Where to find more information

www.hse.ie has detailed COVID-19 information from our experts on:

- The vaccines available and who can get them
- How to get vaccinated
- Getting your vaccine after having the disease
- Vaccine doses recommended for you
- Deciding on vaccination for children
- Symptoms and testing
- Advice to protect yourself and others

For more information about the vaccine you are being given, you can read the manufacturer's Patient Information Leaflet. This is printed for you on the day you get your vaccine, or you can find it on www.hse.ie/covid19vaccinePIL

If you have any questions about the vaccine, you can talk to a health professional, like your vaccinator, Doctor, Pharmacist or healthcare team.

You can also call HSELive on Freephone **1800 700 700**. Our team are here to help Monday to Friday 8am to 8pm or Saturday and Sunday 9am to 5pm.

Published by HSE April 2024

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



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Government of Ireland