



COVID-19 vaccines

Information about your Pfizer, VidPrevtyn Beta or Novavax vaccine

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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 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 three main vaccines in Ireland's COVID-19 vaccination programme for people aged 16 and over: **Pfizer**, **VidPrevtyn Beta** and **Novavax**.

In Ireland, COVID-19 vaccines AstraZeneca – also called Vaxzevria – and Janssen – also called Jcovden – 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 30 and older, and for those aged 12-29 with a weak immune system
- a first and second dose, eight weeks apart for those aged a 12-29. There is a separate information booklet for children aged 12 – 15 years

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.

At least one booster is recommended for all adults aged 18 years and older. After this, autumn boosters are recommended for some people.

An autumn booster will be offered if you are:

- 50 and older
- five or older with a weak immune system
- five to 49 with a condition that puts you at high risk of serious illness from COVID-19
- a healthcare worker

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**.

People aged 18-49 who are up to date with their vaccines – primary course and first booster – can get an autumn booster following discussion with a healthcare professional.

If you are due to get a flu vaccine, you can get any COVID-19 vaccine at the same time.

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.

Four adapted mRNA COVID-19 vaccines have also been recommended for use as booster doses by the National Immunisation Advisory Committee NIAC in Ireland, following approval by the European Medicines Agency EMA.

The vaccines are:

- Comirnaty BA.1 – Pfizer vaccine
- Comirnaty BA.4-5 – Pfizer vaccine
- Spikevax BA.1 – Moderna vaccine
- Spikevax BA.4-5 – Moderna 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.

If an adapted vaccine is not available, the original vaccines can be given.

If you are receiving your first round of vaccines, you will be offered the adapted vaccine, Comirnaty BA.4-5 – Pfizer vaccine – or one of the original vaccines.

VidPrevtyn Beta is based on the beta variant of COVID-19. It can be used to protect against COVID-19 only as a booster in adults aged 18 and older who have already received an mRNA COVID-19 vaccine or adenoviral vector COVID-19 vaccine – such as Vaxzevria or Jcovden.

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.

Second or subsequent boosters of mRNA vaccines have not been approved by the EMA. However, the EMA and the European Centre for Disease Control ECDC have issued advice that a second booster of an mRNA COVID-19 vaccine can be given to those aged 18 or over and for people aged 16 and over with health conditions that put them at high risk of disease as a second booster will give them better protection.

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. All the mRNA adapted vaccines contain Trometamol which means you cannot have these if you have had anaphylaxis – severe allergic reaction – to Trometamol.

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 29.

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 1 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.

In addition, as there is limited clinical data available, NIAC does not recommend the routine use of **VidPrevtyn Beta** in

pregnancy. Administration of **VidPrevtyn Beta** during pregnancy should only be considered on a case by case basis, in consultation with a relevant specialist when the potential benefits outweigh any potential risks.

We have less information on the use of **Novavax** and **VidPrevtyn Beta** vaccines in pregnant women. You can find more information on **www.hse.ie**

The adapted Covid-19 vaccines can be given as a booster in pregnancy. If you have not had your primary course, the 2 doses may be given at any stage of pregnancy.

If you have not had your primary course, the 2 doses may be given at any stage in pregnancy.

If you're pregnant and you have never had a COVID-19 booster:

- your first booster vaccine is recommended at least 4 months since your last COVID-19 vaccine dose or confirmed COVID-19 infection.
- you can get your first booster at any stage in pregnancy.

If you had your first booster before you were pregnant:

- you should get another booster 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 recommended between 20-34 weeks. You can get it earlier if it's 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 1 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.

Recommended vaccines by age

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

- your first round of vaccines 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** – as a booster dose, including the adapted vaccines, even if you had a different vaccine before.

Advice by age group:

If you are:

- five 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, or at times the **VidPrevtyn Beta** vaccine. **Novavax** is approved for use for people who are 12 and over. **VidPrevtyn Beta** is approved for use as a booster for people who are 18 and over.

There is separate advice about vaccines for children on www.hse.ie

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 three 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 three 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

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.

Uncommon

Up to 1 in 100 people

- itchiness where the vaccine was given
- dizziness
- generalised itchiness
- a 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. Even though the risk of these conditions is very low, you should know the signs to look for. Myocarditis and pericarditis are more common in men under the age of 30 after their

second primary vaccine dose. The risk of these side effects appears to be lower after the first booster.

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 VidPrevtyn Beta

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

- pain where you had the vaccine injection
- headache
- muscle pain
- joint pain
- feeling generally unwell
- chills

Common

Up to 1 in 10 people

- redness or swelling where you had the injection
- fever – temperature of 38 degrees Celsius or above
- feeling tired
- nausea
- diarrhoea

Uncommon

Up to 1 in 100 people

- itchiness where you had the injection
- bruising where you had the injection
- warmth where you had the injection
- swollen lymph glands

You should NOT get the COVID-19 vaccine VidiPrevtyn

Beta if:

- you have had a severe allergic reaction – anaphylaxis – to any of the ingredients in the vaccine – including polysorbate 20 or octylphenol ethoxylate. 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 this vaccine.

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.

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
- chills
- 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
- a rash
- redness of the skin
- generalised itchiness
- itchiness where the vaccine was given
- hives

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**](http://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.

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



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