



COVID-19 vaccines

for people aged 16 and over

Information about your Pfizer, Moderna or Janssen vaccine

Version 1

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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. It is for people aged 16 and over.

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**, **Moderna** and **Janssen**.

There are separate information booklets about vaccines for children aged five to 11 and 12 to 15 years available at **www.hse.ie**

If you are being offered the Novavax vaccine, also called Nuvaxovid, there is a separate information booklet available for you.

In Ireland, COVID-19 vaccine AstraZeneca, also called Vaxzevria, is no longer used, but you can find information on it on **www.hse.ie**

Vaccines, boosters and additional doses

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

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

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. In particular, the risk of rare side effects after a booster dose is not yet known.

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.

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** or a **Moderna** vaccine. These are both mRNA type vaccines – vaccines that tell your body how to make antibodies that help fight the COVID-19 virus. You can find more information on **www.hse.ie**

You will only be offered the **Moderna** vaccine in Ireland if you are aged 30 and over.

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

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** or **Moderna** – as a booster dose, even if you had a different vaccine before.

Advice by age group:

If you are:

- 16 to 30, you will be offered **Pfizer** vaccine for COVID-19
- 30 or over you will be offered **Pfizer** vaccine or **Moderna** vaccine for COVID-19
- under 50, **Janssen** is not recommended

If you can't have an mRNA vaccine, you may be offered **Janssen** or Novavax. There is separate advice for Novavax and you can read about it on **www.hse.ie**

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

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.

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

Uncommon

Up to 1 in 100 people

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

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.

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 had myocarditis – inflammation of the heart – after a previous dose of the **Pfizer** vaccine or the **Moderna** Spikevax COVID-19 vaccine
- 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 pericarditis – inflammation of the lining of the heart – after a previous dose of the **Pfizer** vaccine or the **Moderna** Spikevax COVID-19 vaccine

COVID-19 vaccine Moderna – also called Spikevax

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 had the vaccine injection – redness can also occur here, sometimes 9 to 11 days after vaccination
- headache
- swollen lymph glands – usually under your arm where you had the injection
- muscle pain
- joint pain
- nausea or vomiting
- fever – temperature of 38 degrees Celsius or above – or chills

Common

Up to 1 in 10 people

- diarrhoea
- rash
- rash or hives where you had the vaccine injection – sometimes 9 to 11 days after vaccination

Uncommon

Up to 1 in 100 people

- itchiness where the vaccine was given
- dizziness
- tummy pain

Rare

Up to 1 in 1,000 people

- Bell's palsy – temporary drooping on one side of the face
- swelling of your face if you have facial fillers
- tingling or prickling sensation, or loss of sensation in some part of the body

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 or hypersensitivity reactions
- develop 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
- flare-ups of capillary leak syndrome, see below 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.

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

Symptoms of capillary leak syndrome

Capillary leak syndrome causes fluid to leak from small blood vessels. There is a possible risk of flare-ups in people with a history of capillary leak syndrome. Even though the risk of the condition is extremely low, you should know the signs to watch for.

Get urgent medical help if you get any of these symptoms after the **Moderna** vaccine:

- rapid swelling of the limbs (arms and legs)
- sudden weight gain

You may also feel faint due to low blood pressure.

People usually reported capillary leak syndrome within the first few days of getting this vaccine. Watch out for these symptoms in the days after your vaccination.

You should NOT get the COVID-19 vaccine Moderna Spikevax 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 **Moderna** vaccine or the **Pfizer** Comirnaty vaccine
- you have had a severe allergic reaction after Trometamol, one of the contents in contrast dye used in MRI radiological studies
- you had myocarditis – inflammation of the heart – after a previous dose of the **Moderna** vaccine or the **Pfizer** Comirnaty COVID-19 vaccine
- you are under the age of 30
- you have been told by a Doctor that you should not have the **Pfizer** Comirnaty vaccine or the **Moderna** Spikevax COVID-19 vaccine for medical reasons

People under the age of 30 who received a previous dose of **Moderna** Spikevax COVID-19 vaccine should receive the **Pfizer** Comirnaty COVID-19 vaccine as a second or subsequent dose.

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 pericarditis – inflammation of the lining of the heart – after a previous dose of this vaccine or the **Pfizer** Comirnaty vaccine COVID-19 vaccine
- have a history of capillary leak syndrome

COVID-19 vaccine Janssen

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
- pain where you had the vaccine injection
- headache
- muscle pain
- nausea

Common

Up to 1 in 10 people

- redness or swelling where you had the injection
- joint pain
- cough
- fever – temperature of 38 degrees Celsius or above – or chills

Uncommon

Up to 1 in 100 people

- back pain
- lack of energy
- feeling unwell
- muscle weakness
- pain in the limbs
- pain in the throat
- a rash
- sneezing
- excessive sweating
- a tremor
- diarrhoea
- unusual feeling in the skin, such as tingling or a crawling feeling – paraesthesia
- dizziness

Rare

Up to 1 in 1,000 people

- hives and hypersensitivity
- reduced sensation in a part of the body – hypoesthesia
- swollen lymph glands
- vomiting
- persistent ringing in the ears – tinnitus

- blood clots in the deep veins, such as deep vein thrombosis and pulmonary embolisms

Very rare

Up to 1 in 10,000 people

- very unusual blood clots with low platelets – see next page for symptoms
- Guillain-Barré Syndrome – a condition that affects the nerves in the body – see page 25 for symptoms

Extremely rare

Frequency not known yet

- a severe allergic reaction
- very low levels of blood platelets – immune thrombocytopenia
- a condition that causes fluid to leak from small blood vessels – capillary leak syndrome, see page 24 for symptoms
- inflammation of the spinal cord – transverse myelitis
- cutaneous small vessel vasculitis – inflammation of blood vessels in the skin

Symptoms of very rare and unusual blood clots

Even though the risk of blood clots with low platelets is extremely low, you should know the signs to watch for.

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

- breathlessness
- pain in the chest or stomach
- swelling or coldness in a leg
- severe or worsening headache, blurred vision, confusion or seizures
- persistent bleeding under the skin where there was no previous injury
- multiple small bruises, reddish or purplish spots, or blood blisters under the skin

People reported very rare blood clots with low platelets within 14 days of getting this vaccine. Watch out for these symptoms in the weeks after your vaccination.

Symptoms of capillary leak syndrome

Capillary leak syndrome causes fluid to leak from small blood vessels. Even though the risk of the condition is extremely low, you should know the signs to watch for.

Get urgent medical help if you get any of these symptoms after the **Janssen** vaccine:

- rapid swelling of the limbs – arms and legs
- sudden weight gain

You may also feel faint due to low blood pressure.

People usually reported capillary leak syndrome within 4 days of getting this vaccine. Watch out for these symptoms in the days after your vaccination.

Symptoms of Guillain-Barré Syndrome – GBS

Guillain-Barré Syndrome is a condition that affects the nerves in the body. It causes nerve inflammation and can result in pain, numbness, muscle weakness and difficulty walking.

Get urgent medical attention if you:

- have double vision or difficulty moving your eyes
- have difficulty swallowing, speaking or chewing
- have coordination problems, feel unsteady or have difficulty walking
- feel weakness and paralysis in your arms, legs, chest or face
- have tingling sensations in your hands or feet
- have problems with bladder control and bowel function

You should NOT get the COVID-19 vaccine Janssen 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.
- you have had a severe allergic reaction to a previous dose of this vaccine or the COVID-19 AstraZeneca vaccine Vaxzevria
- you had blood clots with low platelets after a previous dose of the COVID-19 AstraZeneca vaccine Vaxzevria
- you have a history of capillary leak syndrome, see page 24 for symptoms
- you have been told by a Doctor that you should not have the COVID-19 AstraZeneca vaccine Vaxzevria 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 thrombocytopenia – abnormally low level of platelets – in the past

You will need your platelet levels monitored after this vaccine if you have a history of immune thrombocytopenia.

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.

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



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