



COVID-19
VACCINE

COVID-19 vaccines

Information about your
Comirnaty (**Pfizer**) vaccine

Version 4
September 2025

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. This booklet contains information about the updated Comirnaty (Pfizer) vaccine, which is the available recommended mRNA vaccine used in Ireland's COVID-19 vaccination programme.

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 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,

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) or children aged 6 months to 4 years who have never had a COVID-19 vaccine before 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 before getting vaccinated.

Recommended vaccines

You will be offered the latest updated Comirnaty mRNA vaccine manufactured by Pfizer.

The latest updated Comirnaty vaccines provide the best available protection against the circulating strains of COVID-19.

Updated Comirnaty mRNA vaccines are recommended by the National Immunisation Advisory Committee (NIAC) and approved by the European Medicines Agency (EMA).

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, then you should get one dose of a COVID-19 vaccine during your pregnancy. 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.

If you are pregnant, you should wait 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

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.

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.

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, but a very small number can die.

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.

Consent for your child to be vaccinated

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

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. The manufacturer's leaflet is available on **www.hse.ie**, or we can give you a copy 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

The name 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.

Side effects

Side effects of the Comirnaty (Pfizer) 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	• feeling tired • tenderness (in children aged 6 months to 23 months) or pain and 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 (in children aged 6 months to 11 years) • irritability (in children aged 6 months to 23 months) • decreased appetite (in children aged 6 months to 23 months) • drowsiness (in children aged 6 months to 23 months)
Common Up to 1 in 10 people	• nausea • vomiting • redness where the vaccine was given • swelling of the lymph glands • rash (in children aged 6 months to 23 months)

Uncommon Up to 1 in 100 people	• itchiness where the vaccine was given • dizziness • generalised itchiness • allergic reactions like hives or a rash or swelling in the face • 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
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

Myocarditis and pericarditis are inflammatory heart conditions. The risk of these very rare conditions is higher in younger men.

These conditions are more likely to occur after the second dose of the vaccine. They have mostly been seen within 14 days of getting the vaccine.

Two European studies have estimated the risk of myocarditis after the second dose of the vaccine:

- One additional case for every 38,000 men aged 12 to 29 (within 7 days)
- One additional case for every 17,500 men aged 16 to 24 (within 28 days)

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 Comirnaty (Pfizer) COVID-19 vaccine 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 an mRNA COVID-19 vaccine, e.g., Comirnaty (Pfizer) or Spikevax (Moderna) vaccines.
- 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 an mRNA COVID-19 vaccine, e.g., Comirnaty (Pfizer) or Spikevax (Moderna) vaccines, 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.
- Have a condition called mastocytosis.
- Are currently feeling very unwell.

Children who have previously had Multisystem Inflammatory Syndrome – MIS-C – 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 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

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.

You should also follow public health advice on protecting yourself and others that is available at **www.hse.ie**.

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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You can also find links to the patient information leaflets for the COVID-19 vaccine on the HSE website. Scan the QR code to read the information.



Published by HSE September 2025
For the most up-to-date information visit **www.hse.ie**

Order Code: HNI01602