



COVID-19
VACCINE

COVID-19 vaccines

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

Version 3
March 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.

Primary course and booster doses

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

- A primary course – first dose. Some children aged 6 months to 4 years may need a second dose for their primary course. People with a weak immune system will need a second dose for their primary course and some may need a third dose.

- Booster doses may be recommended for some people based on their age or medical history.

COVID-19 vaccines give you the best available protection from severe illness when you have:

- your primary course and
- any booster vaccines that are recommended for you.

Primary course

A primary course of a COVID-19 vaccine is recommended for:

- Those aged 60 years and older.
- Those aged 18-59 years living in long term care facilities for older adults.
- Those aged 6 months-59 years with:
 - » immunocompromise (a weak immune system) associated with a suboptimal response to vaccination.
 - » with medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death.
- Health and care workers.
- Pregnant adolescents and adults.

For those aged 6 months-59 years who are healthy, a primary course of a COVID-19 vaccine is not routinely recommended. However, you can access a primary course of a COVID-19 vaccine, if appropriate based on discussions with your health care provider (e.g., GP, pharmacist or HSE vaccinator).

A primary course is:

- A single dose for those age 5 years and older.
- For those age 6 months to 4 years.
 - » A first and second dose, 4 weeks apart, if they have not had COVID-19 infection before.
 - » A single dose, if they have had COVID-19 infection before.
- A first and second dose, 4 weeks apart, for those age 6 months and older with a weak immune system.
- A third dose may be offered to people with a weak immune system, 8 weeks after the second dose following instruction from a relevant specialist doctor.

Booster doses

The protection you got from your previous vaccines or the protection you got from a COVID-19 infection may weaken over time. Booster doses increase your protection from serious complications of COVID-19.

After the primary course, booster doses are recommended for some people. 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**.

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 and approved by the European Medicines Agency.

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

You should get a COVID-19 vaccine if you are pregnant.

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

If you are trying for a baby or might get pregnant, and if you are in a group recommended or receive a COVID-19 vaccine, you do not need to delay having your vaccine.

In pregnancy, most 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 get COVID-19 when 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, are less likely to need hospital care with COVID-19.

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 are recommended to receive an updated Comirnaty mRNA vaccine.

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

If you're pregnant, a booster dose of a COVID -19 vaccine is recommended once in pregnancy if it is more than 6 months since you had a COVID-19 vaccine or infection. This booster dose can be given at any stage in pregnancy but is 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 one dose of COVID-19 vaccine. However, if you are pregnant and have a weak immune system you may get a second dose at least 6 months after your last COVID-19 vaccine or infection.

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 child being hospitalised because of COVID-19 is very low, and the risk of any child needing intensive care treatment is extremely low.

Children with certain medical conditions or children with weak immune systems are at higher risk of severe illness and hospitalisation if they get COVID-19.

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 and a very small number can die.

A primary COVID-19 vaccination course is recommended for children aged 6 months and older who have a weak immune system or a medical condition that puts them at higher risk of severe illness from COVID-19. Booster doses may be recommended at different times of the year for children who are at higher risk of severe illness.

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.

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 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 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	<ul style="list-style-type: none"> ● 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	<ul style="list-style-type: none"> • nausea • vomiting • redness where the vaccine was given • swelling of the lymph glands. This is more common after a booster dose. • Rash (in children aged 6 months to 23 months)
Uncommon Up to 1 in 100 people	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • temporary drooping on one side of the face
Very rare Up to 1 in 10,000 people	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 primary course of the vaccine. They have mostly been seen within 14 days of getting the vaccine. The risk of myocarditis is lower after a booster dose.

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)

Available data shows myocarditis and pericarditis after a primary course in children ages 5 to 11 years is very rare and less than in ages 12 to 17 years.

Most people get better on their own or with supportive treatment, but would need care in hospital. 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
- if you are currently feeling very unwell

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 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 (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 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 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**



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Published by HSE March 2025

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information visit **www.hse.ie**

Order Code: HNI01602



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