



**COVID-19
VACCINE**
Public Health
Advice

COVID-19 Vaccine

Important Information about
the Pfizer/BioNTech vaccine,
Comirnaty

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Rialtas na hÉireann
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About this leaflet

This leaflet tells you about the COVID-19 (coronavirus) vaccine.

It tells you about:

- what COVID-19 is
- what the COVID-19 vaccine is
- who should get the vaccine
- why it is important to get the vaccine
- about COVID-19 vaccine booster doses
- who should not get it and who should delay getting it
- vaccine safety and side effects
- where you can get more information

Please read this leaflet carefully. You can also talk to a healthcare professional, like your GP (Doctor) or Pharmacist, about the vaccine.



What is COVID-19?

COVID-19 is an illness that can affect your lungs and airways, and sometimes other parts of your body. It's caused by a virus called coronavirus.

It is highly infectious. It spreads through the air through droplets produced when people cough or sneeze, or when they touch surfaces where the droplets have landed and then touch their eyes, nose or mouth.

COVID-19 can cause serious illness, hospitalisation and even death.

The most common symptoms of COVID-19 are:

- a fever (high temperature of 38 degrees Celsius or above) - including having chills
- dry cough
- fatigue

You may not have all of these symptoms or you may just feel generally less well than usual. It can take up to 14 days for symptoms to show. They can be similar to symptoms of cold or flu.

If you have any symptoms of COVID-19, self-isolate (stay in your room) and visit **www.hse.ie/covid19** for advice.

What is the COVID-19 vaccine?

A vaccine is a substance that should improve immunity (protection) to a particular disease. COVID-19 vaccines protect you from serious illness with COVID-19. If people are vaccinated, it should also reduce the numbers who become seriously ill or even die from COVID-19 in our community.

Vaccines teach your immune system how to protect you from diseases. It is much safer for your immune system to learn how to protect you through vaccination than by getting COVID-19.

Who should get the vaccine?

Find out who can get a COVID-19 vaccine at

www.hse.ie/covid19vaccine

While it is up to you to decide to get the vaccine, the HSE, the World Health Organization and the Department of Health strongly recommend that you do so as soon as it is offered to you.

You will need to read this leaflet and the manufacturer's Patient Information Leaflet before you get your vaccine. You can find the manufacturer's Patient Information Leaflet on

www.hse.ie/covid19vaccinePIL

You can also talk to a healthcare professional in advance. If you decide to get the vaccine, you will give your consent which will be recorded.

The HSE is offering the vaccine free of charge.

How many doses of the COVID-19 vaccine do I need?

You need 2 doses of this vaccine, 21 to 28 days apart, for protection from serious illness.

If you have a weak immune system you may need an additional dose of COVID-19 vaccine, at least 2 months after your second dose.

Everyone aged 16 and over is recommended a booster dose.

Why would I need a booster dose of vaccine?

You should get a booster dose when it's offered to you because the protection you get from your initial course of vaccination may weaken with time. Some people are at high risk of severe infection, for example older people and people with underlying health conditions.

We hope that a booster dose will give you better protection against COVID-19.

When should I get a booster dose?

You should get a booster dose at least 3 months after finishing a course of COVID-19 vaccines. Some people might get a booster dose at least 2 months after finishing the course.

Why is it important to get the COVID-19 vaccine?

Getting a COVID-19 vaccine should reduce your risk of getting COVID-19 and protect you from serious complications of the illness. Our aim in offering the vaccine to the population is to protect people and reduce the illness and deaths caused by this virus.

I already had COVID-19, so do I need to get the vaccine?

Yes. Even if you have already had COVID-19, you could still get it again.

The vaccine will reduce your risk of getting COVID-19 again. Even if you do get COVID-19 again, the vaccine can reduce the seriousness of your symptoms.

I have COVID-19 now, should I get the vaccine?

No. You should delay getting vaccinated until you recover from COVID-19.

Do this for:

- at least 4 weeks after you first notice symptoms or
- 4 weeks since you tested positive for COVID-19

Can I get a booster dose after having COVID-19?

If you have had COVID-19 since you were vaccinated, wait for 6 months before you get a booster dose or an additional dose.

Can I get this vaccine at the same time as other vaccines?

Yes, you can get a COVID-19 vaccine at the same time as any other vaccines that you need.

What are the recommendations on boosters and additional doses?

The European Medicines Agency (EMA) license vaccines in Europe. The National Immunisation Advisory Committee (NIAC) makes recommendations for Ireland based on local data and evidence.

EMA and NIAC advice may vary at times. Where EMA advice differs from NIAC, we follow NIAC guidance in Ireland.

For people aged 12 and over who are immunocompromised, the EMA has approved an additional dose of the same mRNA vaccine you already had, 28 days after the second dose. NIAC advise that any mRNA vaccine can be given, regardless of which vaccine you have received, at least 2 months after the last COVID-19 vaccine.

For anyone over 18, EMA has approved a booster dose of the same mRNA vaccine you already had 6 months after the second dose. NIAC has recommended that anyone over 16 can have any mRNA vaccine, regardless of which vaccine you had, at least 3 months after your last vaccine dose.

Getting the vaccine

Who is my vaccinator?

Your vaccinator is the person who gives you your vaccine. They are trained by the HSE to give COVID-19 vaccines.

Can the COVID-19 vaccine give you COVID-19?

No. The COVID-19 vaccine cannot give you COVID-19. It is possible to have caught COVID-19 before getting your vaccine and not realise you have the symptoms until after your vaccination appointment.

If you have any symptoms of COVID-19, or if you have a fever which starts more than 2 days after your vaccine, or lasts longer than 2 days, self-isolate (stay in your room) and visit www.hse.ie/covid19 for advice.

Should I get the COVID-19 vaccine if I have a high temperature?

No. You should delay getting the vaccine if you have a fever (temperature of 38 degrees Celsius or above), until you feel better.

Should I get the vaccine if pregnant, trying to get pregnant or breastfeeding?

You should get a COVID-19 vaccine to protect yourself from the virus if you're:

- pregnant
- trying for a baby or might get pregnant in the future
- breastfeeding

Most pregnant women who get the virus get mild to moderate symptoms. They give birth as planned and the risk of passing on COVID-19 to their baby is low.

However, you are more likely to get very unwell and need treatment in intensive care than a woman who is not pregnant. The virus may also cause complications for your baby.

If you're pregnant, you should get a booster dose when it's offered to you.

COVID-19 vaccines are still new and we're still learning about them. You can read more at www.hse.ie/covid19vaccine

What vaccine am I being offered?

The vaccine we are offering you is called Comirnaty, manufactured by Pfizer/BioNTech. This mRNA vaccine teaches your body how to make a protein that will trigger an immune response, without using the live virus that causes COVID-19.

Your body then makes antibodies that help fight the infection if the COVID-19 virus enters your body in the future.

You can have this vaccine as a booster dose, even if you already got a different vaccine.

This leaflet has important information about the vaccine you are being offered. Please read it. You can also find it on www.hse.ie/covid19vaccine

Is the vaccine safe?

The HSE only uses vaccines when they meet the required standards of safety and effectiveness.

While the work to develop COVID-19 vaccines has moved much faster than usual, the vaccine we are offering you has gone through all the usual steps needed to develop and approve a safe and effective vaccine.

In order to be approved for use, the COVID-19 vaccine went through all the clinical trials and safety checks all other licensed medicines go through, following international standards of safety.

The vaccine we are offering you is called Comirnaty, manufactured by Pfizer/BioNTech. It has:

- ✓ been tested with thousands of people as part of clinical trials
- ✓ met strict standards of safety, quality and effectiveness, and been approved and licensed by regulators. For Ireland, the regulator is the European Medicines Agency (EMA) – visit www.ema.europa.eu for more information

Is a booster dose safe?

Studies on people who got a booster dose haven't shown any serious side effects but we have less information on the safety of the booster and additional doses. A number of countries are giving boosters and additional doses.



How is the COVID-19 vaccine given?

The COVID-19 vaccine is given as an injection into your upper arm. It will only take a few minutes.

What are the side effects of the vaccine?

Like all medicines, vaccines can cause side effects. Most of these are mild to moderate, short-term, and not everyone gets them.

More than 1 in 10 people may experience:

- feeling tired
- tenderness or swelling in your arm where you have had the vaccine injection
- headache
- muscle pain
- joint pain
- diarrhoea
- fever (temperature of 38 degrees Celsius or above)

More than 1 in 100 people may develop nausea, vomiting or redness where the vaccine was given.

More than 1 in 1,000 people will develop itchiness where the vaccine was given, generalised itchiness, a rash, swelling of the lymph glands, sleeplessness, excessive sweating, night sweats, decreased appetite, lack of energy or lethargy.

Bell's palsy is a rare side effect seen in more than 1 in 10,000 people.

Rarely, people who have had facial fillers may develop swelling of their face. This is seen in more than 1 in 10,000 people.

Serious side effects, like a severe allergic reaction, are extremely rare and are seen in approximately 1 in 100,000 people. Your vaccinator is trained to treat very rare serious allergic reactions.

Extremely rarely, people may 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.

Very rarely, people may develop myocarditis and pericarditis after getting the Pfizer/BioNTech vaccine. 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 and mostly happen within 14 days of getting the vaccine.

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

- 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).

The risk of myocarditis or other rare side effects after a booster dose is not yet known.

The COVID-19 vaccine has gone through the same clinical trials and safety checks as all other licensed vaccines, however the vaccine is new and long-term side effect information is limited.

As more people in Ireland and around the world get this vaccine, more information on side effects may become available. The HSE will update this information regularly on our website, and if necessary, will update the information leaflets given to people at their vaccination.

Fever after the vaccine

It's quite common to develop a fever after a vaccination. Usually, this happens within 2 days (48 hours) of getting the vaccine, and it goes away within 2 days.

You are more likely to get a fever after your second dose of the vaccine.

If you feel uncomfortable, take paracetamol or ibuprofen as directed on the box or leaflet. If you are concerned, please seek medical advice.

Symptoms of myocarditis and pericarditis

Myocarditis and pericarditis are conditions that cause inflammation of the heart. Even though the risk of these conditions is very low, you should know the signs to look out for. Get medical help if you get any of these symptoms after your Pfizer/BioNTech vaccine:

- breathlessness
- palpitations (a forceful heartbeat that may be irregular)
- chest pain

Are there some people who should not get the COVID-19 vaccine?

Yes. You should not get the Pfizer/BioNTech 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 the 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/BioNTech COVID-19 vaccine.
- ✗ you had myocarditis after a previous dose of this vaccine or the Moderna (SpikeVax) COVID-19 vaccine.

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

- have had an severe allergic reaction (anaphylaxis) in the past, including to any other vaccine or medication.
- had pericarditis after a previous dose of this vaccine or the Moderna (SpikeVax) COVID-19 vaccine.

Most people will be able to safely get the vaccine. The person giving you the vaccine will be happy to answer any questions you have at your appointment for the vaccine.

They will also give you an aftercare advice leaflet, and a vaccine record card showing the name and batch number of the vaccine you have been given.

How long does it take the vaccine to work?

After having both doses of the COVID-19 vaccine, most people will have immunity. This means they will be protected against serious illness with COVID-19.

It takes 7 days after getting the second dose for it to work.

There is a chance you might still get COVID-19, even if you have the vaccine.

Does the vaccine work in everyone?

Worldwide, vaccines save at least 2 to 3 million lives each year, and protect many more from lifelong illnesses. Billions of people have now received COVID-19 vaccines all over the world.

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

If you have a weakened immune system, there is no extra risk in taking the vaccine but it may not work as well for you and you may need an additional dose of the COVID-19 vaccine for the best possible protection.

When I get the vaccine, does that mean I won't spread COVID-19 to others?

We do not know yet if having the vaccine stops you spreading the COVID-19 virus to others. You should continue to follow public health advice on how to stop the spread of the virus.

In particular, you still need to:

- wear a face covering where advised
- wash your hands regularly
- stay at home if you have any symptoms of COVID-19

Thank you for protecting yourself and others.

How long does immunity last from the vaccine?

Boosters are recommended to extend the protection of COVID-19 vaccines. We do not know yet how long immunity will last after boosters. Clinical trials are ongoing to find this out.

More information

For more information, read the manufacturer's Patient Information Leaflet. This will be printed for you on the day you get your vaccine, or you can find it on **www.hse.ie/covid19vaccinePIL**

You can also talk to a health professional, like your GP (Doctor), Pharmacist or healthcare team.

You can also visit the HSE website at **www.hse.ie/covid19vaccine** or call HSELive on **1800 700 700**

For more information on the COVID-19 vaccine, including materials in other formats and translation support, visit

www.hse.ie/covid19vaccinematerials

How do I report side effects?

As with all vaccines, you can report suspected side effects to the Health Products Regulatory Authority (HPRA).

The HPRA is the regulatory authority in the Republic of Ireland for medicines, medical devices and other health products. As part of its role in the safety monitoring of medicines, the HPRA operates a system through which healthcare professionals or members of the public can report any suspected adverse reactions (side effects) associated with medicines and vaccines which have occurred in Ireland.

The HPRA strongly encourages reporting of suspected adverse reactions (side effects) associated with COVID-19 vaccines to support continuous monitoring of their safe and effective use. To report a suspected adverse reaction to the COVID-19 vaccine, please visit **www.hpra.ie/report**

You can also ask your Doctor or a family member to report this for you. As much information as is known should be provided, and where possible, the vaccine batch number should be included.

The HPRA cannot provide clinical advice on individual cases. Members of the public should contact their healthcare professional (their Doctor or Pharmacist) with any medical concerns they may have.

Your personal information

In order 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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