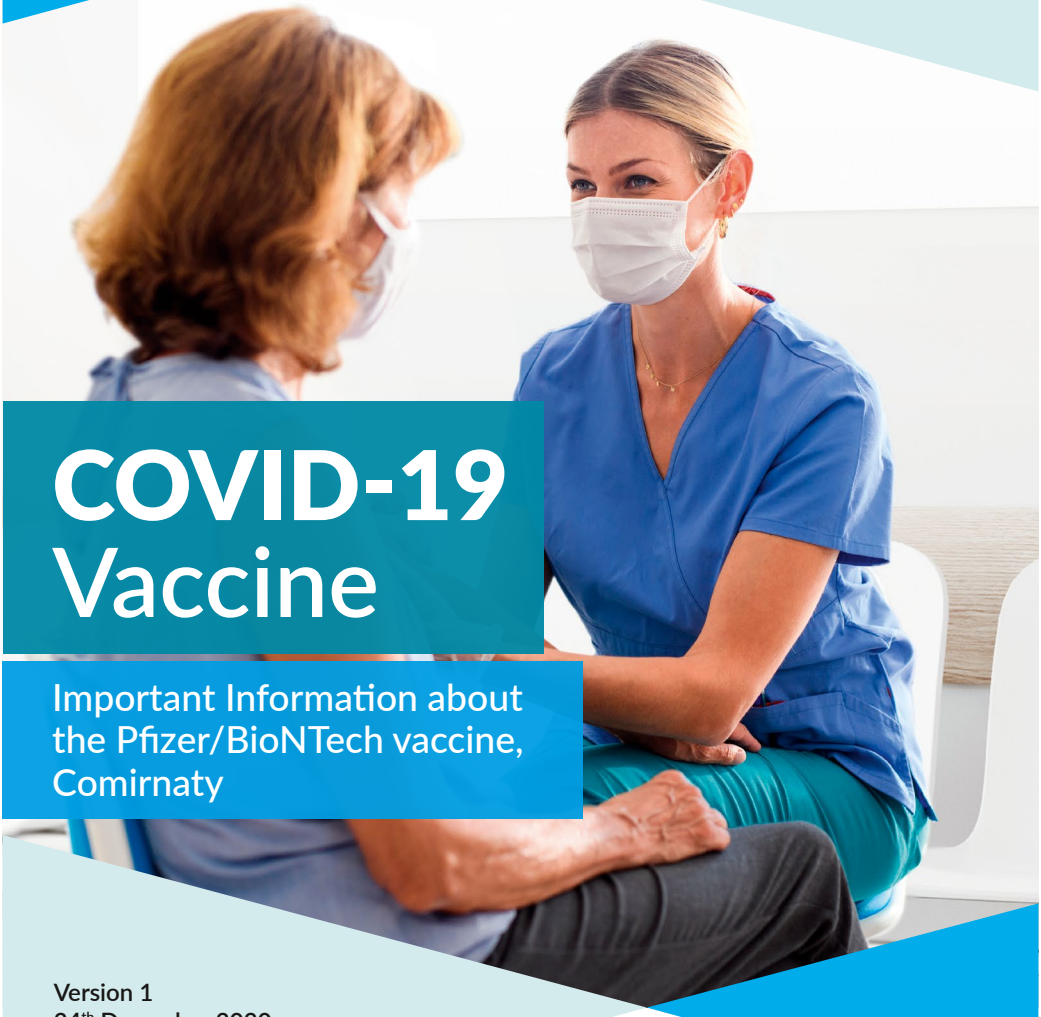
COVID-19 VACCINE
Public Health Advice



COVID-19 Vaccine

Important Information about the Pfizer/BioNTech vaccine, Comirnaty

Version 1
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Rialtas na hÉireann
Government of Ireland

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 will be offered it first, why and where to access it
- why it is important to get the vaccine
- who should not get it and who should delay getting it
- vaccine safety and its side effects
- where you can get more information

Please read this leaflet carefully. You can also talk to a healthcare professional, like your GP 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.

COVID-19 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.

Common symptoms of COVID-19 include:

- a fever (high temperature of 38 degrees Celsius or above)
- a new cough – this can be any kind of cough, not just dry
- shortness of breath or breathing difficulties
- loss or change to your sense of smell or taste – this means you've noticed you cannot smell or taste anything, or they smell or taste differently

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 common symptoms of COVID-19, self-isolate (stay in your room) and phone a GP. They can arrange a COVID-19 test for you.

For more information on COVID-19, please visit **www.HSE.ie/coronavirus** or call HSELive on **1850 24 1850**.

Who is most at risk from COVID-19?

People over 65 and people with certain health conditions have a higher risk of getting seriously ill if they get COVID-19.

Older people living in long-term care facilities also have a greater risk of getting seriously ill if they get COVID-19, as this virus spreads quickly among people living together.

Healthcare workers have a higher risk of being exposed to COVID-19 than others.

What is the COVID-19 vaccine?

A vaccine is a substance that should improve immunity (protection) to a particular disease. The COVID-19 vaccine will offer you protection from 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 are we offering the vaccine to first?

We (the Health Service Executive) are offering the people who are most at risk of COVID-19 the vaccine first. We are offering it to:

- people aged 65 years and older who live in long-term care facilities
- frontline healthcare workers

You can see the full list of priority groups on the website: **www.gov.ie/covid19vaccine**

While it is up to you to decide to get the vaccine, the HSE strongly recommends that you do so as soon as we offer it to you.
The HSE is offering the vaccine free of charge.

You will need to read this leaflet and the Patient Information Leaflet before you get the vaccine. You can find the 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.

Who is my vaccinator?

Your vaccinator is the person who gives you your vaccine. They are a trained health professional working with the HSE, like a nurse, doctor or pharmacist.

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

Getting a COVID-19 vaccine should protect you from the serious complications of COVID-19. 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 four weeks after you first notice symptoms or
- four weeks since you tested positive for COVID-19

Getting the vaccine

Where do I access the vaccine?

If you live in a long-term care facility, you will be offered the vaccine in that facility and get it there.

If you are a frontline healthcare worker, you will be offered the vaccine where you work or close to where you work.

We will tell people in the next priority groups where and when they can access the vaccine as it becomes available more widely.

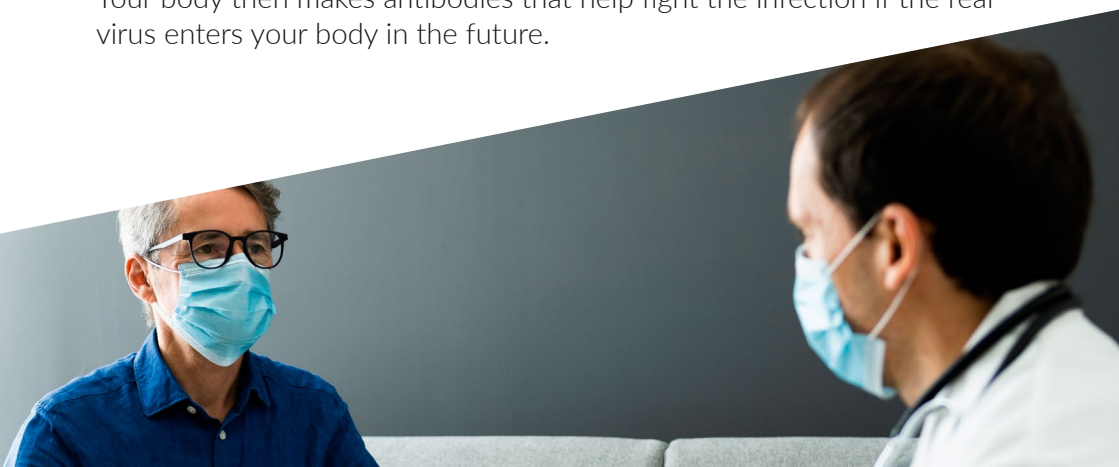
We will let you know through advertising or direct invitation when it's your turn to have the COVID-19 vaccine. It is important not to contact the HSE for a vaccination before then.

What vaccine is available?

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

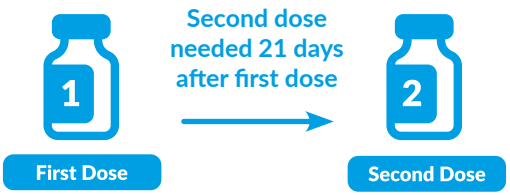
This mRNA vaccine teaches your body how to make a protein that will trigger an immune response, without using the live virus that causes COVID-19.

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



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.



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

You will need two doses of the COVID-19 vaccine to get the best protection. You need to get the second dose 21 days (three full weeks) after the first dose.

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

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 one in 10 people may experience:

- tenderness, swelling and/or redness in your arm where you have had the vaccine injection
- headache
- muscle pain
- fever (temperature of 38 degrees Celsius or above)

More rarely, people develop itchiness where the vaccine was given, swelling of the lymph glands or sleeplessness. These are seen in more than 1 in 1000 people.

Serious side effects to vaccines, like an allergic reaction, are extremely rare, seen in approximately 1 in 100,000 people for all vaccines. Your vaccinator is trained to treat very rare serious allergic reactions.

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 first or second dose of the vaccine.

Fever after the vaccine

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

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 common symptoms of COVID-19, it is important to self-isolate (stay in your room) and arrange a free test to find out if you have COVID-19.

If you have a fever which starts more than two days after you get the vaccine, or lasts longer than two days, you should self-isolate and ask a GP to arrange a COVID-19 test for you.

If you have symptoms after the first dose, you still need to have the second dose. While you may get some protection from the first dose, having the second dose will give you the best protection against the virus.

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

Yes. You should not get the COVID-19 vaccine if:

- ✗ you have had a severe reaction to any of the ingredients in the vaccine. Read the Patient Information Leaflet to see the list of ingredients.
- ✗ you have had a severe reaction to a previous dose of the 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.

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.

Is it safe to get the vaccine if pregnant or breastfeeding?

There's no evidence the COVID-19 vaccine is unsafe if you're pregnant.

The vaccine was not widely tested on pregnant women so the evidence available at this time is limited.

If you are a healthcare worker or in an at-risk group, and you are pregnant, you should talk to your obstetrician or GP about getting the COVID-19 vaccine.

You can get the COVID-19 vaccine if you are breastfeeding.

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 COVID-19.

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

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

Does the vaccine work in everyone?

The vaccine has been tested on people aged 16 and older. The current evidence is that the vaccine protects 95% of people who get it.

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.

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 health care 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.

How long does immunity last from the vaccine?

We do not know yet how long immunity will last. Clinical trials are ongoing to find this out.

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. That is why it is important that we all continue to follow public health advice on how to stop the spread of the virus.

In particular, you still need to:

- follow social distancing guidelines (keep two metres apart from others where possible)
- wear a face covering
- wash your hands regularly

The HSE, Department of Health and the World Health Organization recommends people get the COVID-19 vaccine when it is offered to them.

Thank you for protecting yourself and others.

More information

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

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

You can also visit the HSE website at **www.hse.ie/covid19vaccine**, or call HSElive on **1850 24 1850**.

For more information on the COVID-19 vaccine, including materials in other formats and translation support, visit **HSE.ie/covid19vaccinematerials**

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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