



Covid-19 Vaccine

Important Information about the COVID-19

Vaccine Janssen

Version 7

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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 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
- 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.

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 symptoms of COVID-19, self-isolate – stay in your room – and get a COVID-19 test.

For more information on COVID-19, please visit www.hse.ie/coronavirus or call HSELive on **1800 700 700**.

Who is most at risk from COVID-19?

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

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 should get the vaccine?

You can see the list of groups for vaccination on this website:

www.gov.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.

Vaccines will be given as the supply arrives in Ireland.

When it's your turn, we will let you know how to get your vaccine through advertising or direct invitation. It is important not to contact the HSE for a vaccination before then.

You will need to read this leaflet and the manufacturer's Patient Information Leaflet before you get the 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.

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 four weeks after you first notice symptoms or
- four weeks since you tested positive for COVID-19

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, 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 get a COVID-19 test.

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 or breastfeeding?

The Janssen COVID-19 vaccine is not recommended for pregnant women. You will be offered a different vaccine. Talk to your obstetrician or GP about getting a different COVID-19 vaccine.

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

What vaccine am I being offered?

The vaccine we are offering you is called COVID-19 Vaccine Janssen. The vaccine is manufactured by Janssen.

This viral vector vaccine contains a harmless version of a different virus – the vector. This teaches your body how to make a protein that will trigger an immune response.

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

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 COVID-19 Vaccine Janssen.

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.

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 one dose of this COVID-19 vaccine to get long lasting protection.

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:

- feeling tired
- pain in the arm where they had the vaccine injection
- headache
- muscle pain
- nausea

More than one in 100 people may have redness or swelling where they had the injection, joint pain, cough or a fever – temperature of 38 degrees Celsius or above.

More than one in 1,000 may have back pain, lack of energy, muscle weakness, pain in the limbs, pain in the throat, a rash, sneezing, sweating or a tremor.

More than 1 in 10,000 people may have a red, itchy rash.

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

Very rarely 1 in 300,000 people may develop very unusual blood clots with low platelets. 1 in 10 of these people may die.

The risk of this very rare condition is higher in younger people, especially women.

A very small number of cases of capillary leak syndrome have occurred in people after this vaccine. It is a serious but very rare condition, and can sometimes be fatal.

A very small number of people developed Guillain-Barré Syndrome after this vaccine. The condition can be serious and needs to be treated in hospital.

You can talk to your GP – Doctor – or vaccinator about the risks and benefits of getting this vaccine.

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 when they get 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.

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 very rare blood clots

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

Get urgent medical help if you get any of these symptoms after the COVID-19 Vaccine Janssen:

- 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

The very rare blood clots with low platelets were usually reported within 14 days of getting the COVID-19 Vaccine Janssen. Watch out for these symptoms in the weeks after your vaccination.

Symptoms of very rare 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 out 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.

Capillary leak syndrome was usually reported within 4 days of getting the Janssen 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 chewing
- have coordination problems
- feel unsteady or have difficulty walking feel weakness and paralysis in arms, legs, chest or face
- have tingling sensations in hands or feet
- have problems with bladder control and bowel function

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 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 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 the COVID-19 vaccine if you have had a severe allergic reaction – anaphylaxis – in the past, including to any other vaccine or medication.

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.

I am under 50 years old. Should I get this vaccine?

Either the Pfizer/BioNTech or Moderna COVID-19 vaccine is recommended for people under the age of 50. However, the EMA has approved this vaccine for use in those aged 18 and over.

Talk to your vaccinator, GP (Doctor) or Pharmacist about the risks and benefits for you of getting this vaccine.

If you get this vaccine, it is important to know the symptoms of very rare blood clots so that you know when to get medical help. The symptoms are listed in this leaflet.

How long does it take the vaccine to work?

It takes 14 days for the vaccine 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. Millions 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.

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 guideline – keep two metres apart from others where possible
- wear a face covering
- wash your hands regularly

Thank you for protecting yourself and others.

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.

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



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