Covid-19 Vaccine

Comirnaty, Pfizer BioNTech vaccine for children and young people aged 12-15:

Important information for parents and guardians

Version 3

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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 for children aged 12–15 years.

It tells you about:

- COVID-19 in children aged 12–15
- what the COVID-19 vaccine is
- the benefits of vaccination for children aged 12–15
- the risks of vaccination for children aged 12–15
- vaccine safety and side effects
- where you can get more information

Please read this leaflet carefully. Our aim for this information booklet is to allow you to help make an informed decision about getting the vaccine for your child. You can also talk to a healthcare professional, like your GP – Doctor – or Pharmacist, about the vaccine.

You can also:

- read the manufacturer's Patient Information Leaflet available on **www.hse.ie/covid19vaccinePIL**

- discuss vaccination with your child or read the leaflet with them

- read the further information available on **www.hse.ie**

- read the aftercare leaflet that you get after vaccination

About COVID-19

COVID-19 is an illness that can affect the lungs and airways, and sometimes other parts of the 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.

The most common symptoms of COVID-19 are:

- a fever – high temperature of 38 degrees Celsius or above – including having chills

- dry cough

- fatigue

It can take up to 14 days following exposure to COVID-19 for symptoms to show. The symptoms can be similar to those of a cold or flu. Your child may not have all of these symptoms or they may just feel generally less well than usual.

If your child has any symptoms of COVID-19, they should self-isolate – stay in their 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**.

COVID-19 and children aged 12-15

The majority of children and young people aged 12-15 years who get COVID-19 have very mild symptoms or no symptoms at all. Having COVID-19 at this age can be disruptive as children have to miss school and other people in the home may have to restrict their movements.

COVID-19 can cause serious illness, hospitalisation or death in children, but this is very rare.

Sometimes symptoms connected to COVID-19 can continue for some weeks or months – 'long COVID'.

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

Children and young people with certain health conditions are at higher risk of severe illness. Data from the United States shows that around 7 in 10 children admitted to hospital with COVID-19 have some other underlying conditions.

Extremely rarely, COVID-19 can cause a condition called Multisystem Inflammatory Syndrome in children. The condition causes pneumonia, inflammation of the heart and difficulty breathing and it can cause death.

Most of the reported cases occurred in male children aged 1 to 14.

What is the COVID-19 vaccine?

A vaccine is a substance that should improve immunity – protection – to a particular disease. Vaccines teach the immune system how to protect people from diseases.

The evidence available says that COVID-19 vaccine should offer your child protection from COVID-19. If children are vaccinated, this should also help reduce the numbers who become seriously ill or die from COVID-19 in our community.

What vaccine is my child being offered?

The vaccine your child is being offered is called Comirnaty, Pfizer BioNTech.

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

Your child's body then makes antibodies that help fight the infection if the COVID-19 virus enters their body in the future.

Before vaccination, you will be asked to give consent for your child to get the vaccine and this consent will be recorded.

Why is the vaccine being offered to all children aged 12 to 15?

Our aim in offering the vaccine to the population is to protect people and reduce the illness and deaths caused by this virus.

Getting a COVID-19 vaccine should protect your child and those around them from getting COVID-19. Though serious illness from COVID-19 is rare in this age group, they are even less likely to become seriously ill with COVID-19 if they are vaccinated.

COVID-19 vaccines are very highly recommended by the National Immunisation Advisory Committee – NIAC – for children who
- have a health condition that puts them at high risk of severe illness if they get COVID-19.
- live with a child or adult who is at risk of severe illness if they get COVID-19 e.g. another child with complex medical needs, or an immunocompromised adult

For all children in this age group, the recommendation of NIAC is that the benefits of vaccination are greater than the risks from the vaccine.

The benefits include avoiding getting COVID-19, and extra protection from the rare risks of serious illness from COVID-19. Children who are vaccinated will be less likely to miss school and other activities because of COVID-19.

Is the vaccine effective for children aged 12 to 15 years?

The clinical trial for the Comirnaty, Pfizer BioNTech vaccine showed that it was highly effective at preventing COVID-19 in children this age.

Is the vaccine safe for children aged 12-15 years?

This COVID-19 vaccine is recommended for children aged 12 and over in Ireland by the National Immunisation Advisory Committee.

This vaccine has been tested on thousands of people including over 2000 children and young people aged 12-15 years as part of clinical trials. No additional safety concerns were identified in the clinical trial for children and young people aged 12-15 years.

This vaccine has also 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.

In order to be approved for use, the vaccine went through all the clinical trials and safety checks all other licensed medicines go through, following international standards of safety. Safety monitoring of all COVID-19 vaccines is constantly reviewed by the relevant authorities.

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

We are still learning about the effectiveness and side effects of COVID-19 vaccines in this age group.

All medicines have side effects and you should read about known common and rare side effects of this vaccine in this leaflet before you give consent for your child to be vaccinated.

My child has already had COVID-19, can they get the vaccine?

If your child has had COVID-19 they will likely have some immunity which may last for approximately 9 months.

Even if your child has already had COVID-19, they could still get it again.

The vaccine will reduce the risk of getting COVID-19 infection again.

My child has COVID-19 now, can they get the vaccine?

If your child has had COVID-19, they can be vaccinated from 4 weeks after they first developed symptoms or from their positive COVID-19 test.

Can my child get the COVID-19 vaccine if they have a high temperature?

No. If they have a fever – temperature of 38 degrees Celsius or above, you should delay getting the vaccine until they feel better.

Can the vaccine give my child COVID-19?

No. The COVID-19 vaccine cannot give your child COVID-19.

It is possible to catch COVID-19 before getting the vaccine and not realise they have the symptoms until after the vaccination appointment. If your child has any symptoms of COVID-19, it is important that they self-isolate – stay in their room – and arrange a free test to find out if they have COVID-19.

If your child has a fever which starts more than two days after they get the vaccine, or lasts longer than two days, your child should self-isolate and get a COVID-19 test.

Who is my child's vaccinator?

This is the person who gives them their vaccine. They are trained by the HSE to give COVID-19 vaccines.

How is the COVID-19 vaccine given?

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

How many doses of COVID-19 vaccine will my child need?

They will need 2 doses of the Pfizer/BioNTech vaccine for the best possible protection against COVID-19. Your child will get their second dose 21 to 28 days after the first dose.

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, 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 boys and younger men.

Myocarditis was reported in about 1 in 1,000,000 vaccine doses. However, data from the United States estimates that the risk of myocarditis after the second dose is higher in boys aged 12 to 17. In this age group it occurs in about 1 in 16,000 boys after their second dose. In girls aged 12 to 17 the risk is 1 in 100,000 after their second dose.

Pericarditis was reported in about 1 in 1,000,000 vaccine doses.

These rare heart conditions are more likely to occur after the second dose and mostly happen within 14 days of getting the vaccine. 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.

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 is quite common to develop a fever after vaccination. Usually, this happens within 2 days of getting the vaccine, and it goes away within 2 days. Your child is more likely to get a fever after their second dose of the vaccine.

If your child feels uncomfortable, you should give them paracetamol or ibuprofen as directed on the box or leaflet. If you are concerned about your child, please seek medical advice.

Symptoms of myocarditis and pericarditis

Very rarely, people may develop myocarditis and pericarditis after getting the Comirnaty, Pfizer BioNTech vaccine. Myocarditis and pericarditis are inflammatory heart conditions.

You should know the signs to look out for in your child.

Get medical help if your child gets any of these symptoms after their vaccine:

- breathlessness

- palpitations – a forceful heartbeat that may be irregular

- chest pain

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

Yes. Your child should not get the Comirnaty, Pfizer BioNTech COVID-19 vaccine if:

- your child has 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.

- your child has had a severe allergic reaction to a previous dose of the Pfizer/BioNTech vaccine or the Moderna COVID-19 vaccine.

- your child has been told by a Doctor that they should not have the Moderna COVID-19 vaccine or the Pfizer/BioNTech COVID-19 vaccine.

- your child had myocarditis after a previous dose of this vaccine or the Moderna – Spikevax – COVID-19 vaccine.

You should talk to your child's doctor before getting the COVID-19 vaccine if they:

- had a severe allergic reaction – anaphylaxis – in the past, including to any other vaccine or medication.
- had pericarditis after a previous dose of this Comirnaty, Pfizer BioNTech vaccine or the Moderna – Spikevax – COVID-19 vaccine.

Most children will be able to safely get the vaccine. The person giving your child 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 your child has 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 COVID-19.

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

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

Does the vaccine work in everyone?

The vaccines have been used in millions of people worldwide over the last year. There is strong, reliable evidence that COVID-19 vaccines greatly reduce the risk of getting COVID-19. They are highly effective at preventing deaths and serious illness with COVID-19.

The vaccines do not work the same in each person, and it is possible to still get COVID-19 after being vaccinated. If your child has a weakened immune system, there is no extra risk in taking the vaccine but it may not work as well for your child.

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 my child gets the vaccine, does that mean they won't spread COVID-19 to others?

We do not know yet if having the vaccine stops people 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.

After vaccination your child will be advised to continue to follow public health guidelines for vaccinated people.

Consent for your child to be vaccinated

A parent or legal guardian will be asked to give consent for each child to be vaccinated. This can be given online, after the child is registered for their appointment. It can also be given in person on the day of the vaccination, but only if the parent or legal guardian is present with the child.

Another adult who is not the parent or legal guardian can accompany a child to their vaccination appointment, if the parent or legal guardian has completed the online consent process, in advance.

A child will not be allowed to attend a vaccination centre alone for a vaccine.

Your decision to give consent for the vaccine or not will be respected and the following summary might be useful to you in being informed about your choices.

Benefits of the vaccine

- Protection for children and young people who have health conditions that put them at high risk of severe COVID-19. Data from the United States shows that around 7 in 10 children admitted to hospital with COVID-19 have some other underlying condition.
- Protection for healthy children and young people from severe COVID-19 – although this is very rare in this age group. The risk of a child being hospitalised because of COVID-19 is low, and the risk of any child needing intensive care treatment is extremely low.
- Protection from COVID-19 which can cause children to miss school and other people in the home may have to restrict movements.

- Sometimes symptoms connected to COVID-19 can continue for some weeks or months – 'long COVID'. UK data suggests five in every 1000 children aged 12-16 may experience 'long COVID' after infection.

- May help prevent the spread of COVID-19 to others. This is especially important if children and young people are living with a child or an adult who is at risk of severe COVID-19.

- Protection from the extremely rare complication of Multisystem Inflammatory Syndrome in children. The condition causes pneumonia, inflammation of the heart and difficulty breathing and it can cause death. Most of the cases occurred in male children aged 1-14.

Consider having the vaccine now if:

- Your child has an underlying medical condition that puts them at high risk of severe COVID-19.

- Your child lives with a child or an adult who is at high risk of severe COVID-19.

- You want to protect your child against the very rare possibility of severe COVID-19, Multisystem Inflammatory Syndrome or 'long COVID'.

Risks of the vaccine

- Short term side effects like a sore arm, fever or tiredness.

- About 1 in 100,000 people might have a severe side effect, like an allergic reaction to the vaccine.

- Very rarely some people develop inflammation of the heart – – myocarditis – and the outer lining of the heart – pericarditis– after vaccination. This has been reported in about 1 in 100,000 girls given second doses and in about 1 in 16,000 boys given second doses in those aged 12-17. Most people recover from myocarditis and pericarditis but they may need treatment in hospital.

- We don't yet have information about longer term effects of COVID-19 vaccines in children and young people.

Consider not having the vaccine, or waiting until more information is available, if:

- You do not want to risk the very rare side effect of myocarditis and pericarditis from vaccination.
- You want to wait for more information to become available about the risk of Multisystem Inflammatory Syndrome and of COVID-19 in children and young people.
- You want to wait for more information to be available about the longer term effects of the vaccines in children and young people.

More information

For more information, read the manufacturer's Patient Information Leaflet. This will be printed for you on the day your child gets their 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 child's 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 child's 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 your child, book their appointment, record their vaccination and monitor its effects is being recorded.

You have the following rights under the GDPR in respect of your child's personal data that are processed.

- Request information on and access to your child's personal data – commonly known as a 'data subject access request'. This enables you – the child's parent or legal guardian – to receive a copy of the personal data we hold about your child and to check that we are lawfully processing it.

- Request correction of the personal data that we hold about your child. This enables you to have any incomplete or inaccurate information we hold about your child corrected.

- Request erasure of your child's personal data. This enables you to ask us to delete or remove your child's 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 child's 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**