



COVID-19 Vaccine

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

Important information for parents and guardians

Version 12

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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 to 15.

It tells you about:

- COVID-19 in children aged 12 to 15
- what the COVID-19 vaccine is
- the benefits of vaccination for children aged 12 to 15
- the risks of vaccination for children aged 12 to 15
- vaccine safety and side effects
- what to expect after their COVID-19 vaccine
- giving consent for their COVID-19 vaccine
- 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

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.

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.

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 you should visit www.hse.ie/covid19 for advice.

COVID-19 and children aged 12 to 15

The majority of children and young people aged 12 to 15 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.

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 this condition is lower in children and young adolescents compared to adults.

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.

Rarely, COVID-19 can cause a condition called Multisystem Inflammatory Syndrome in children – MIS-C. 75 per cent of the children who develop MIS-C have no underlying health condition.

The condition causes pneumonia, inflammation of the heart and difficulty breathing. Most children with MIS-C recover after time in hospital or intensive care but some children have lasting side effects and a very small number can die. MIS-C is more rarely seen following omicron infection.

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 serious illness with 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. The Comirnaty vaccines your child is being offered are adapted vaccines. Adapted vaccines contain mRNA to protect against variant strains of Covid-19. They are expected to give wider protection against Covid-19 variants than the original vaccine.

Adapted vaccines are recommended for children aged 12 – 15 years by the National Immunisation Advisory Committee and are approved by the European Medicines Agency – EMA.

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 seriously ill with 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 weak immune system.

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 helping to avoid 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.

Why is a first booster offered to all children aged 12-15?

The protection that your child has from previous vaccinations may weaken over time.

This reduced protection, along with the highly transmissible Omicron variant meant that more children in the 12 to 15 age group needed hospital care in the most recent wave of the pandemic than in previous waves.

We hope that a first booster dose will give better protection against COVID-19 and reduce illness and the need for hospital care in children this age.

Children with a weak immune system are recommended a first booster.

However all children aged 12 to 15 can get a booster dose because:

- The benefits of the vaccine outweigh the risks
- It reduces the risks and complications of COVID-19 – including severe illness, long COVID and MIS-C–
- They are less likely to miss school and other activities which are important for their wider wellbeing
- It may offer better protection against future variants.

Why are some children with a weak immune system being offered an additional dose?

If your child is 12 and over and had a weak immune system when they had their first round of COVID-19 vaccines, they may require an additional dose.

We hope that an additional dose of vaccine will:

- improve their child's immune system's response to the vaccine
- give them better protection against COVID-19
- prevent them from getting seriously ill with COVID-19.

Why are autumn booster doses being offered to some children aged 12-15 with a weak immune system?

Autumn booster doses are recommended for children aged 12-15 who have a weak immune system.

This is because the protection from the vaccines they had previously may weaken with time, meaning:

- they may be more at increased risk of severe disease
- their immune system does not respond as strongly to vaccination

Keeping up to date with their booster doses gives your child extra protection from COVID-19 and helps prevent serious illness from COVID-19.

Why are some children with medical conditions being offered an autumn booster dose?

An autumn booster dose is recommended for children aged 12-15 who have a health condition that puts them at high risk of severe illness if they get COVID-19.

This is because:

- the protection your child got from their previous vaccines or the protection your child got from a COVID-19 infection may weaken over time
- your child may be at higher risk of severe disease if they get COVID-19

Boosters increase your child's protection from COVID-19. Without it, they're more at risk of serious illness if they do get 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 to 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 to 15 years as part of clinical trials. No additional safety concerns were identified in the clinical trial for children and young people aged 12 to 15 years.

It is expected that the safety of the adapted vaccines will be similar to the previous vaccines. Safety of the vaccines will continue to be monitored the European Medicines Agency – EMA.

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.

COVID-19 vaccines have been given to millions of children in many countries.

What do we know about the safety and side effects of boosters or additional doses in children aged 12 to 15?

A number of countries are giving boosters and additional doses in this age group.

There is less information available on the safety of the booster and additional doses.

Myocarditis and pericarditis are inflammatory heart conditions and are very rare risks of mRNA vaccines. These rare side effects are more common in men under the age of 30 years after their second primary vaccine dose. The risk of these side effects appears to be lower after the first booster. The risk of myocarditis may be lower in those aged 12-15 years compared to older adolescents.

It is expected that the safety of the adapted vaccines will be similar to the previous vaccines. Safety of the vaccines will continue to be monitored by the EMA.

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. 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.

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 - or if they have a fever which starts more than 2 days after their vaccine, or lasts longer than 2 days - they should self-isolate – stay in their room – and you should visit [**hse.ie/covid19**](https://www.hse.ie/covid19) for advice.

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

As a precaution, if your child has recently received the MPOX vaccine – previously known as monkeypox vaccine – Imvanex or Jynneos – they need to wait 4 weeks before they get their COVID-19 vaccine because of the unknown risk of myocarditis.

However, your child can get a COVID-19 vaccine at the same time as any other vaccines that they need, including their nasal spray flu vaccine and any school-based vaccinations.

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?

For their first round of COVID-19 vaccines, all children need 2 doses of this vaccine, eight weeks apart, for protection from serious illness.

Children aged 12 to 15 can then get a first booster dose at least 4 months after their first round of COVID-19 vaccine or infection.

If your child has a medical condition that puts them at higher risk of becoming very unwell with COVID-19, they are recommended an autumn booster dose which should be given 9 months after their last COVID-19 vaccine or infection.

However, if your child has a weak immune system they should get their second dose 4 weeks after their first dose. They may need an additional dose of COVID-19 vaccine eight weeks after their second dose. This is then followed by a first booster 4 months after their additional dose or COVID-19 infection.

Children with a weak immune system who have had an additional dose and a first booster dose, are recommended an autumn booster dose. Autumn booster doses should be given 6 months following a previous booster dose or COVID-19 infection.

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

If your child has COVID-19 and they are due to have their first dose of the vaccine, they can be vaccinated from 4 weeks after they first develop symptoms or had a positive COVID-19 test.

If your child has Covid-19 and they are due to have their second dose of the vaccine, they can be vaccinated from 8 weeks after they develop symptoms or had a positive Covid-19 test.

If your child with a weak immune system has had COVID-19 after their second dose and is due to get their additional dose:

- if their COVID-19 infection was more than 7 days after the second vaccine dose, an additional dose is not required. They should go on to get their first booster dose 4 months after infection
- if your child gets a COVID-19 infection within 7 days of their second dose they should get their additional dose 4-8 weeks after infection

If your child is due to get a booster, please read the previous question for information on when your child can get a booster after a COVID-19 infection.

Is an additional dose or booster dose of vaccine licensed by the EMA or NIAC?

Additional doses for some children who have a weak immune system:

- the EMA has approved an additional dose of the same mRNA vaccine, at least 28 days after their second dose
- NIAC, in Ireland, has recommended that they can get the Pfizer vaccine as an additional dose eight weeks after their second dose

First boosters for all children in this age group:

- the EMA approved a first booster dose of the Pfizer vaccine for children in this age group who have previously had Pfizer, at least three months after their last dose
- NIAC, in Ireland, has recommended that children in this age group can get the Pfizer vaccine, as a booster dose regardless of which mRNA vaccine they have received, 4 months after their last COVID-19 dose

Subsequent boosters for some children in this age group:

- NIAC has recommended an autumn booster for children aged 12-15 with a health condition that puts them at high risk of severe illness if they get COVID-19. NIAC has

recommended an autumn booster for some children with a weak immune system.

Do we follow EMA or NIAC advice in Ireland?

- NIAC recommendations can vary from EMA recommendations due to local data and considerations

In Ireland we follow NIAC advice.

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 these **very common** side effects:

- 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 – or chills

Up to 1 in 10 people will have these **common** side effects:

- nausea
- vomiting
- redness where the vaccine was given
- swelling of the lymph glands – more often seen after a booster dose

Up to 1 in 100 people will have these **uncommon** side effects:

- dizziness
- itchiness where the vaccine was given
- generalised itchiness
- a rash
- sleeplessness
- excessive sweating
- night sweats
- decreased appetite
- lack of energy, lethargy or feeling unwell
- pain in the arm you got the vaccine

Up to 1 in 1,000 people will have these **rare** side effects:

- temporary drooping on one side of the face

Up to 1 in 10,000 people will have these **very rare** side effects: myocarditis and pericarditis – means inflammation of the heart muscle or the lining of the heart muscle – see below for symptoms.

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:

- 1 additional case for every 38,000 men aged 12 to 29 – within 7 days.
- 1 additional case for every 17,500 men aged 16 to 24 – within 28 days.

Early data from other countries shows myocarditis is less likely in those aged 12 to 15 than those aged 16 to 24. Early data in

people aged 16 and over indicates that myocarditis is less often reported after the booster dose than the second dose.

Data suggests most cases of myocarditis last only a short while and get better with supportive care; with studies being done to understand the longer term impact.

It's not known yet how many people who get this vaccine will experience these side effects but they are thought to be extremely rare:

- a severe allergic reaction. Your vaccinator is trained to treat serious allergic reactions
- 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 filler
- 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

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 leaflet given to people at their vaccination.

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 had a severe allergic reaction after Trometamol – one of the contents in contrast dye used in MRI radiological studies.
- 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.

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 myocarditis and pericarditis – inflammation of the heart muscle or lining of the heart – after a previous dose of COVID-19 vaccines.

As a precaution, if your child has recently received the MPOX vaccine – Imvanex or Jynneos – they need to wait 4 weeks before they get their COVID-19 vaccine because of the unknown risk of myocarditis.

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.

After Getting the Vaccine

We are giving you a record of your child's vaccination today.

Please keep the record card safe.

What might happen in the next few days?

Some people who got the vaccine that your child got today may get some of the side effects listed above. Most of these are mild to moderate and short lived.

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.

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 billions 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 and they may need an additional dose of the COVID-19 vaccine for the best possible protection.

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.

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.

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 reaction – 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.

Consent for your child to be vaccinated

A parent or legal guardian will be asked to give consent for each child to be vaccinated.

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.
- 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 COVID-19, and complications from COVID-19 such as 'long COVID' and Multisystem Inflammatory Syndrome in children. The risk of 'long COVID' is lower in children and young adolescents compared to adults.
- 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.

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. 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.
- We have less information on the safety of the booster and additional doses in those aged 12 to 15.

Consider your child 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'.

Consider your child 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**

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



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