5a COVID-19

Content last updated: 05 March 2025

In some circumstances, advice in these guidelines may differ from that in the product Summary of Product Characteristics (SmPC). When this occurs, NIAC advises that the recommendations in these guidelines, which are based on current expert advice from NIAC, are followed.

Contents

Key changes

Date of update	Key changes
05 March 2025	Recommendations for COVID-19 booster vaccination in Spring 2025 New Figure (Figure 5a.2) Updated Table 5a.2 Details about vaccines no longer available have been removed

Acronyms used in this chapter

AEFI	adverse event following immunisation
BMI	body mass index
CLS	capillary leak syndrome
COPD	chronic obstructive pulmonary disease
COVID-19	coronavirus disease 2019
CVST	cerebral venous sinus thrombosis
EC	European Commission
EMA	European Medicines Agency
FDA	Food and Drug Administration (US)
GBS	Guillain-Barré syndrome
HCW	healthcare worker
HPRA	Health Products Regulatory Authority
HPV	Human Papillomavirus
IGRA	interferon gamma release assay
INR	international normalised ratio
IM	intramuscular
MERS	Middle East respiratory syndrome
MHRA	Medicines and Health Products Regulatory Agency (UK)

MIS-C	multisystem inflammatory syndrome in children
mRNA	messenger RNA
NA	neutralising antibody
NIAC	National Immunisation Advisory Committee
NIO	National Immunisation Office
PCR	polymerase chain reaction
PEG	polyethylene glycol
S antigen	spike antigen
SARS	severe acute respiratory syndrome
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SmPC	Summary of Product Characteristics
TST	tuberculin sensitivity test
TTS	thrombosis with thrombocytopenia syndrome
VOC	variants of concern
WHO	World Health Organization

5a.1 Introduction

Seven coronaviruses cause disease in humans. Four of these generally cause minor respiratory illnesses. Three coronaviruses – Middle East respiratory syndrome coronavirus (MERS-CoV), severe acute respiratory syndrome coronavirus (SARS-CoV), and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) cause more severe disease. The disease caused by SARS-CoV-2 is termed COVID-19.

As with most RNA viruses, mutations occur, and multiple variant strains of SARS-CoV-2 have been identified. Variants are subject to monitoring with regard to their growth potential or mutation profile which could impact vaccine effectiveness.

5a.2 Epidemiology

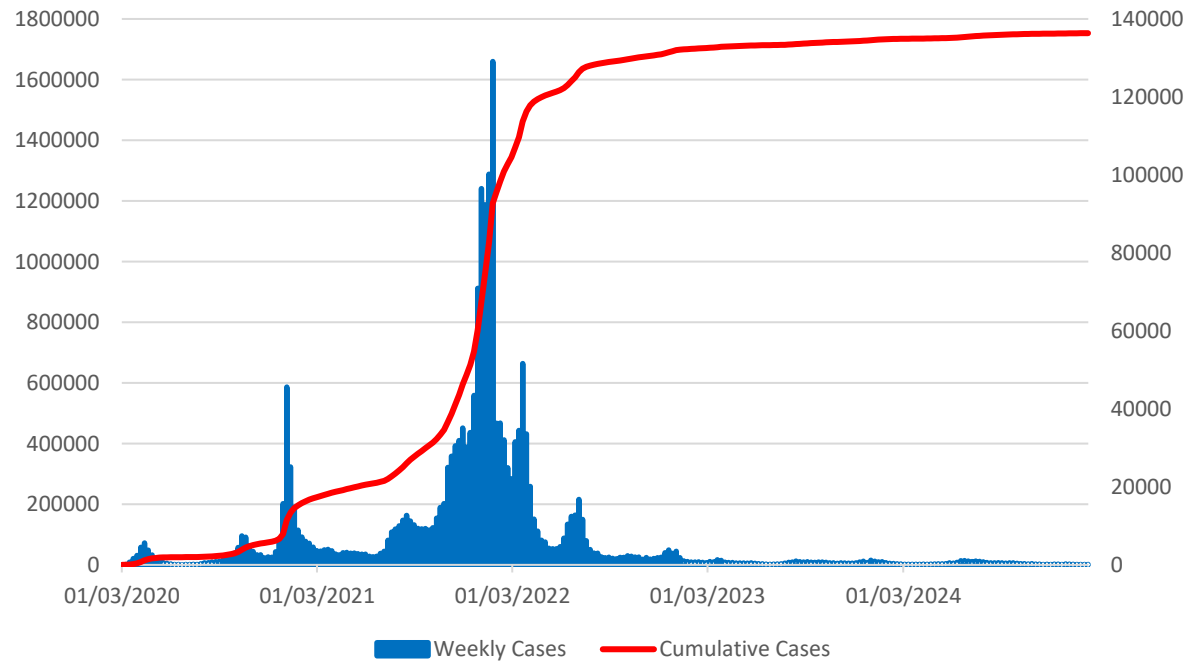
Note: Refer to www.hpsc.ie for the most up-to-date information on COVID-19 epidemiology.

In December 2019, SARS-CoV-2 was identified in humans in Wuhan, China. The disease it causes is called Coronavirus disease 2019 (COVID-19). On 11 March 2020, the World Health Organization (WHO) declared the outbreak a pandemic.

By 20 August 2023, over 769 million confirmed cases and over 6.9 million deaths have been reported globally. In Ireland, the first laboratory confirmed case of COVID-19 was reported on 29 February 2020. Since then, there have been five waves, peaking in April and October 2020, January 2021, January and July 2022.

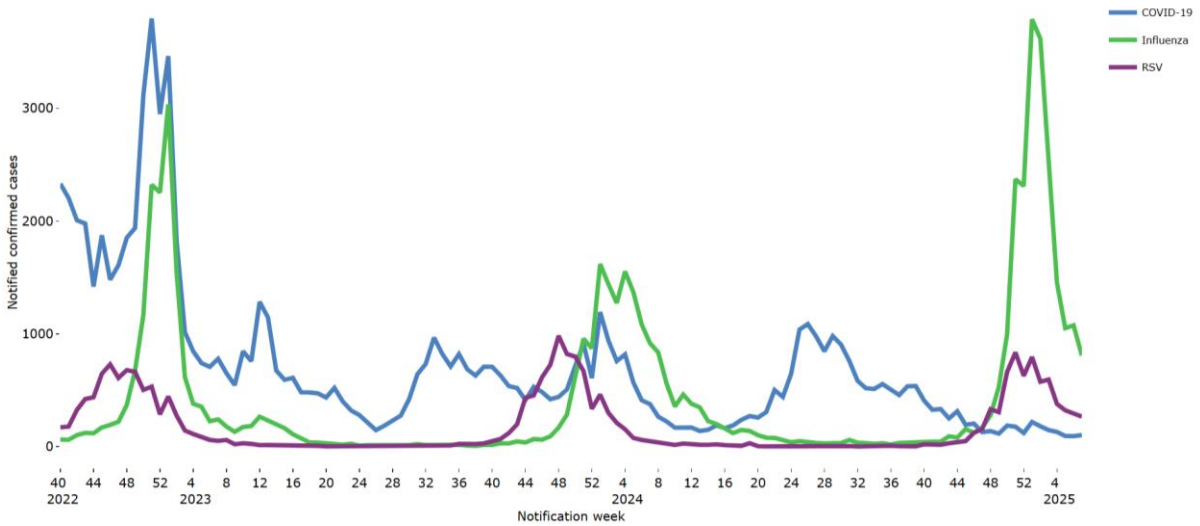
Up to 15 February 2025, approximately 1.8 million PCR confirmed COVID-19 cases and 9,540 deaths have been notified in Ireland (Figure 5a.1).

Figure 5a.1 Number and cumulative number of confirmed COVID-19 cases notified in Ireland by notification date to midnight 15 February 2025



Source: HPSC

Figure 5a.2 Number of confirmed COVID-19, influenza and RSV cases notified from week 40 of 2022 to week 5 of 2025



Source: HPSC

COVID-19 notifications do not show the same seasonality as influenza or RSV in Ireland (Figure 5a.2).

The highest proportion of hospitalisations and deaths has been in those aged 65

years and older. An underlying medical condition was present in most of those admitted to ICU.

Outbreaks continue to occur among patients and staff in hospitals and in long stay care facilities.

The lowest proportion of hospitalisations and deaths has been in those under 15 years of age.

The main medical conditions associated with increased risk of hospitalisation are listed in Table 5a.3.

Transmission

Estimates for the basic reproductive number (R0) of SARS-CoV-2 ranged from 2-8 before the widespread use of vaccines, masks and social distancing. It also varies depending on the predominant circulating strain. The R0 in confined settings may be at the higher end of this range.

Transmission occurs mainly to those who have been indoors and within two metres of someone with COVID-19 for a cumulative total of at least 15 minutes over a 24-hour period. Factors that increase the risk of infection include presence in an enclosed space with inadequate ventilation if an infectious person is shouting, singing, or exercising.

Most transmission occurs in household and community settings. Young children are less likely to transmit infection than adolescents or adults. SARS-CoV-2 virus can survive on surfaces for a few days, depending on the surface and environmental conditions.

Incubation period: typically 2-5 days (range 1-14 days or longer).

Infectious period: from two days before symptom onset, peaking within five days of symptoms onset. Viable virus is not usually detectable for more than 12 days after symptom onset.

5a.3 Effects of COVID-19

5a.3.1 Symptoms

Common symptoms include cough, fatigue, fever, headache, hoarse voice, sneezing and sore throat.

Symptoms depend on a number of factors including age, vaccination status, comorbidities and immune competence, and range from asymptomatic to severe illness.

While severe illness and death have been reported at all ages, death is more likely in those:

- Age 65 years and older
- Age 12-64 years with medical conditions outlined in Table 5a.3
- From Black, Asian and minority ethnic backgrounds.

The majority recover from infection without clinical intervention. Persisting symptoms may result (see Section 5a.3.4).

5a.3.2 Pregnancy

Pregnant women are at similar risk of COVID-19 infection to non-pregnant women of the same age. However, pregnant women with COVID-19 infection are more likely to be admitted to ICU or to die than similar aged non- pregnant women with COVID-19. Pregnant women from Black, Asian and minority ethnic backgrounds may be more likely to be admitted to hospital with COVID-19 disease than other pregnant women.

COVID-19 in pregnancy may increase the risk of adverse pregnancy outcomes, such as miscarriage, stillbirth and preterm birth.

The following factors may increase the risks of severe illness in pregnancy:

- Medical conditions listed in Table 5a.3
- Age over 35 years
- Infection in the third trimester (28 weeks' or more)
- BMI of 30 kg/m^2 or more.

5a.3.3 Children and adolescents

The overwhelming majority of children and adolescents who get SARS-CoV-2 infection experience a mild self-limited illness. However, severe disease, ICU admission and extremely rarely death can occur.

The presence of a medical condition as listed in Table 5a.3 significantly increased the risk of COVID-19 hospitalisation, severe disease and death.

Multisystem Inflammatory Syndrome in Children (MIS-C)

MIS-C is a rare but serious hyperinflammatory syndrome related to prior SARS-CoV-2 infection, in which different organs can become inflamed. In the pre-Omicron era, the incidence of MIS-C was about 100/100,000 in those under 21 years of age, with a median age of nine years, and 75% of cases with no underlying medical condition.

Most children recover with appropriate treatment. MIS-C is more rarely seen following Omicron infection. Rarely, adults develop signs and symptoms similar to MIS-C.

5a.3.4 Long COVID

Long COVID is defined by the WHO as the continuation or development of new symptoms three months after the initial SARS-CoV-2 infection, with these symptoms lasting for at least two months with no other explanation. People who have been hospitalised appear to be at greater risk of experiencing longer-term effects, but it may occur in those who had asymptomatic or only mild infection.

Symptoms include fatigue, memory problems, sleep disturbances, shortness of breath, anxiety and depression, general pain and discomfort and difficulty thinking or concentrating. Symptoms may fluctuate and may last for months. Long-term symptoms following COVID-19 are more likely with increasing age, higher BMI and female sex.

5a.3.5 Other effects of COVID-19

A study in the US showed that people aged 60 years and older who previously had COVID-19 were about 40% more likely to develop diabetes up to a year later. There is evidence that COVID-19 infection in children may increase their likelihood of developing Type 1 diabetes.

Other US studies reported an increased risk of cardiovascular and renal disorders after COVID-19 infection.

5a.4 COVID-19 vaccines

5a.4.1 Types of COVID-19 vaccines

Below listed are the COVID-19 vaccines authorised by the EMA and include vaccines previously used in Ireland. For vaccines currently available for use in Ireland please see Table 5a.1 and Table 5a.2.

mRNA vaccines

Recipient's antigen-presenting cells to make a spike protein antigen, thus stimulating an immune response. Rapid degradation of mRNA within cells contributes to the safety profile of these vaccines.

The World Health Organization (WHO) and European Medicines Agency (EMA) continuously monitor available data on circulating variants and vaccine effectiveness. COVID-19 vaccine recommendations are updated based on this information to best target circulating variants.

COVID-19 vaccines licenced by European Medicines Agency (SmPCs)

Comirnaty
Age 12 years and older
Comirnaty 30 micrograms
Comirnaty Original/Omicron BA.1 30 micrograms
Comirnaty Original/Omicron BA.4-5 30 micrograms
Comirnaty Omicron XBB.1.5 30 micrograms
Comirnaty JN.1 30 micrograms
Comirnaty KP.2 30 micrograms
Age 5-11 years
Comirnaty 10 micrograms
Comirnaty Original/Omicron BA.4-5 10 micrograms
Comirnaty Omicron XBB.1.5 10 micrograms
Comirnaty JN.1 10 micrograms
Comirnaty KP.2 10 micrograms
Age 6 months-4 years
Comirnaty 3 micrograms
Comirnaty Omicron XBB.1.5 3 micrograms
Comirnaty JN.1 3 micrograms
Comirnaty KP.2 3 micrograms
Spikevax
Age 12 years and older
Spikevax 100 micrograms
Spikevax bivalent Original/Omicron BA.1 50 micrograms
Spikevax bivalent Original/Omicron BA.4-5 50 micrograms
Spikevax XBB.1.5 50 micrograms
Spikevax JN.1 50 micrograms
Age 6-11 years
Spikevax 50 micrograms
Spikevax XBB.1.5 25 micrograms
Spikevax JN.1 25 micrograms

Age 6 months-5 years
Spikevax 25 micrograms
Spikevax bivalent Original/Omicron BA.4-5 25 micrograms
Spikevax XBB.1.5 25 micrograms
Spikevax JN.1 25 micrograms

Adenoviral vector vaccines

A non-pathogenic virus is genetically modified to encode an antigen which, when expressed by the host cell, provokes an immune response.

- **Vaxzevria*** (AstraZeneca)
- **JCOVDEN** (Janssen)

Protein subunit vaccines

These vaccines are based on injection of key viral antigens stimulating the immune response.

- **Novavax vaccines**
  - Nuvaxovid 5 micrograms
  - Nuvaxovid XBB.1.5 5 micrograms
  - Nuvaxovid JN.1 5 micrograms
- **VidPrevtyn Beta*** (Sanofi GSK) 5 micrograms. Authorised only as a booster vaccine.
- **Bimervax** (HIPRA) 40 micrograms. Authorised only as a booster vaccine.

Other

- **Valneva** (Valneva)

*Withdrawn by manufacturer.

5a.4.2 Vaccine effectiveness

COVID-19 vaccines are effective in preventing hospitalisations, severe disease, and death secondary to SARS-CoV-2 infection. The protection they afford against infection and mild disease is limited. Protection against severe disease is more durable, however, it also wanes gradually over time increasing the risk for those susceptible to severe disease as time from their last vaccine lapses.

Initial clinical trials of COVID-19 vaccines reported efficacy of the primary schedule against hospitalisation ranging from 85-100%. A large mRNA vaccine trial in Israel showed two dose vaccine effectiveness (VE) of 87% against hospitalisation and 92% against severe disease from seven days after the second dose. However, the emergence of new variants coupled with timelapse from vaccination resulted in gradual waning of protection and the need for booster vaccination to enhance protection was recognised.

VE studies of monovalent mRNA vaccines as a first booster showed 77-94% protection that also waned gradually over time. Further booster doses may be used to restore protection. While mRNA, adenoviral vector and protein subunit vaccines can all be used effectively as boosters irrespective of the vaccine type used in the primary schedule, mRNA vaccines are preferred for use as boosters in Ireland.

Adapted mRNA vaccines

Adapted mRNA vaccines have been demonstrated to enhance the immune response against sublineages in recipients.

Duration of immunity

Protection, whether from vaccination, infection, or both, ultimately wanes. Following vaccination, protection peaks at 4-8 weeks and wanes gradually thereafter. It can subsequently be boosted by either vaccination or infection. Hybrid immunity, the combination of protection from infection and vaccination, offers more durable and robust protection than either infection or vaccination alone. The duration of protection of hybrid immunity against severe disease has been shown to persist for at least 12 months.

5a.4.3 COVID-19 vaccine safety

To date more than 5.5 billion people have received at least one dose of a COVID-19 vaccine. Following close post-marketing monitoring, the risk benefit profile of all EMA authorised vaccines remains positive.

Terms used for frequency of adverse events

Very common	≥ 1/10
Common	1/100 and < 1/10
Uncommon	≥ 1/1,000 and < 1/100
Rare	≥ 1/10,000 and < 1/1,000
Very rare	< 1/10,000

For a list of adverse reactions see individual vaccines.

Anaphylaxis

Anaphylaxis is a known rare side effect of all vaccines including COVID-19 vaccines. Information on managing this risk is described in the product information. Healthcare professionals are reminded to refer to the approved product information for COVID-19 vaccines for details on known side effects and frequency of same.

Myocarditis and pericarditis

Myocarditis and pericarditis are very rare side effects of mRNA vaccines and Nuvaxovid, occurring predominantly after the second dose and in males under 30 years of age. Higher rates are reported following Spikevax compared with Comirnaty. The risk is lower following booster vaccination. The risk of vaccine associated myocarditis can be reduced by extending the interval between the first and second mRNA COVID-19 vaccine dose in the primary schedule for immunocompromised.

These conditions can develop within a few days after vaccination and have primarily occurred within 14 days. Available data suggest that the course of myocarditis or pericarditis following vaccination is not different from myocarditis or pericarditis in general.

The EMA concluded that the overall risk benefit profile for all authorised COVID-19 vaccines remains favourable

5a.4.4 Vaccine availability and storage

An up-to-date list of licensed vaccines is available on the Health Products Regulatory Authority (HPRA) website www.hpra.ie

The list of the vaccines currently available from the National Cold Chain Service

(NCCS) can be found at: https://www.hse.ie/eng/health/immunisation/hcpinfo/frequentlyaskedquestions/pilandspc/pilandspc.html. COVID-19 vaccines are delivered by the NCCS at a temperature between +2°C and +8°C and should be stored thereafter at that temperature.

COVID-19 vaccines that have been stored at freezing temperatures will have been thawed prior to delivery and labelled by NCCS with a 'USE BEFORE' label. The 'USE BEFORE' date and time specified on the label indicates the time by which the vial must be administered irrespective of the expiry date on the box or vial.

COVID-19 vaccines that are stored only at a temperature between +2°C and +8°C, are governed by the printed expiry date on the original box and on the vial.

All Comirnaty vaccines are provided in multidose vials. Once the vial has been punctured or diluted, the vaccine must be administered before the 'discard time', the duration of which is vaccine specific and as per individual vaccine SmPC.

Appropriate infection control precautions should always be taken. Specific guidelines are available on the National Immunisation Office (NIO) website at: www.immunisation.ie.

5a.4.5 Interchangeability

The antigenically updated vaccine available for primary and booster vaccination is Comirnaty as an age-appropriate dose, see Table 5a.1 and Table 5a.2.

Where primary vaccination schedule commenced with Comirnaty Omicron XBB.1.5 or Comirnaty JN.1 and Comirnaty KP.2 becomes available, this should be used to complete the primary schedule in those who are immunocompromised and those aged 6 months to 4 years where indicated.

Nuvaxovid and EMA authorised antigenically updated versions can be offered for primary schedule in adults and children aged 12 years and older with a contraindication to an mRNA vaccine, or in those who choose not to receive an mRNA vaccine. A single dose is required for primary vaccination in those who are immunocompetent.

Nuvaxovid and EMA authorised antigenically updated versions may be used for homologous and heterologous boosters in adults and children aged 12 years and older with a contraindication to an mRNA vaccine, or in those who choose not to receive an mRNA vaccine.

5a.4.6 Co-administration with other vaccines

COVID-19 and adult seasonal influenza vaccines should be co-administered where practicable, to maximise uptake. Vaccinees should be informed there may be a slight increase in short term mild adverse events after co- administration with a seasonal influenza vaccine. These include pain at the site of injection, fatigue, headache, and myalgia.

There should be an interval of at least four weeks between mpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis. No interval is required between a COVID-19 vaccine and a subsequent mpox vaccine.

COVID-19 vaccines and other adult vaccines may be administered at the same time or at any interval. Co-administered vaccines should be given in different limbs if possible. If administration in separate limbs is not feasible or desired, administration in the same limb, separated by at least 2.5 cm, is appropriate.

No interaction studies in young children have been performed on co-administration of COVID-19 vaccines with childhood vaccines. Priority should be given to other routine childhood immunisations. Until there is more evidence it is prudent to separate COVID-19 vaccination in children aged 6 months-4 years from other vaccines for a period of 14 days.

5a.4.7 Post vaccination observation period

- Vaccine recipients: 15 minutes
- Those with a history of mastocytosis: 30 minutes
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated.

5a.4.8 Vaccination after COVID-19

Unvaccinated

Those who are unvaccinated and develop SARS-CoV-2 infection should complete a primary vaccination schedule, with the single dose (or first dose for immunocompromised) at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic.

Those with persisting symptoms following COVID-19 may be vaccinated, unless there is evidence of recent clinical deterioration.

Partially vaccinated

Those who are immunocompromised who have had SARS-CoV-2 infection after their first dose of COVID-19 vaccine should be given the subsequent dose at least four to eight weeks after diagnosis or onset of symptoms.

If those who are immunocompromised have SARS-CoV-2 infection more than seven days after the second vaccine dose, a third dose of the primary schedule is not required. They should proceed to a booster dose of vaccine if recommended in Table 5a.2. For those with infection within seven days of their second dose they should have a third dose after an interval of four to eight weeks if a third dose is recommended by a relevant specialist physician.

After completion of primary schedule

Those who have had SARS-CoV-2 infection after completing their primary schedule (i.e., a breakthrough infection), should proceed to a booster dose of COVID-19 vaccine as recommended in Table 5a.2.

Serological testing prior to giving an additional dose (immunocompromised in primary schedule) or for any booster dose of COVID-19 vaccine is not recommended.

5a.4.9 Pregnancy

Continuing evidence regarding mRNA COVID-19 vaccination during pregnancy has demonstrated it to be safe and effective. The primary schedule may be given at any stage in pregnancy (Table 5a.1).

For pregnant adolescents and adults, a dose of COVID-19 vaccine is recommended once in each pregnancy. This recommendation is not seasonal. This dose of COVID-19 vaccine should be given at least six months after their last COVID-19 vaccine dose (primary schedule or booster) or SARS-CoV-2 infection. A dose of vaccine can be given at any stage in pregnancy but ideally should be given between 20-34 weeks' gestation. If it is more than 12 months since their previous COVID-19 vaccine or infection administration earlier in pregnancy should be considered.

For those who are pregnant and are immunocompromised, a second dose of COVID-19 vaccine within the same pregnancy may be considered if six months has elapsed since their last COVID-19 vaccine or SARS-CoV-2 infection.

There is more limited experience of protein subunit COVID-19 vaccines in those who are pregnant, and this should only be considered when the potential benefits outweigh the potential risks.

For more information see FAQs about COVID-19 vaccines in pregnancy.

5a.4.10 Breastfeeding

COVID-19 vaccines can be used during breastfeeding. There is no evidence that breastfeeding after COVID-19 vaccination causes harm to the breastfed infants or interferes with ability to breastfeed.

5a.4.11 Immunocompromised

Those with immunocompromise due to disease or treatment at the time of their primary COVID-19 vaccination may have suboptimal response to their vaccines (see Chapter 3). A two dose primary schedule (with an option for an additional dose as part of the primary schedule, following specialist recommendation) (see Table 5a.1).

For those who have completed their primary schedule, a COVID-19 booster vaccine is recommended in Spring 2025 (see Table 5a.2). Serological testing prior to giving any dose of COVID-19 vaccine is not recommended.

Patients with planned immunosuppressing therapy should ideally complete primary vaccination two weeks before beginning treatment. If a patient with planned immunosuppressant therapy has not received a booster COVID-19 vaccine in the six months prior to starting therapy, they should be offered the vaccine regardless of the time of year.

5a.4.12 Vaccination of those with bleeding disorders or on anticoagulants

See Chapter 2, sections 2.4.6 and 2.4.7 for information, including technique for IM injection, in this patient group.

5a.5 Recommendations

The objective of the COVID-19 vaccination programme is to ensure equitable access to a safe and effective vaccine with the goals of limiting death and illness from COVID-19, protecting healthcare capacity and enabling social and economic activity.

5a.5.1 Primary vaccination schedule

A primary schedule of a COVID-19 vaccine is recommended for:

- Those aged 60 years and older.
- Those aged 18-59 years living in long term care facilities for older adults.
- Those aged 6 months-59 years with:

  - immunocompromise associated with a suboptimal response to vaccination
  - with medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death.
- Health and care workers.
- Pregnant adolescents and adults.

For those aged 6 months-59 years who are healthy, a primary schedule of a COVID-19 vaccine is not routinely recommended. However, access to a primary schedule of a COVID-19 vaccine should be available for those in this age group who, following discussion of their reasons with a healthcare provider (e.g., GP, pharmacist or HSE vaccinator), request vaccination.

A primary schedule of a COVID-19 vaccine is recommended for pregnant adolescents and adults. A COVID-19 vaccine can be given at any stage in pregnancy.

A single dose of a COVID-19 vaccine is recommended for the primary schedule for all age groups except for those with immunocompromise and those aged 6 months-4 years with no prior history of SARS-CoV-2 infection See Table 5a.1 for details about available age-appropriate vaccines and number of recommended vaccine doses.

Antigenically updated COVID-19 mRNA vaccines are the preferred vaccine for use.

Protein subunit vaccines may be used as alternative vaccines in those for whom an mRNA vaccine is contraindicated or declined. Nuvaxovid (antigenically updated) is the preferred alternate and can be used for primary vaccination, when available.

Table 5a.1 Recommendations for primary schedule of COVID-19 vaccines

	Primary schedule	Number of doses	Available vaccines
60 years and older	Recommended	Single dose of Comirnaty mRNA COVID-19 vaccine	Comirnaty KP.2 30 micrograms Nuvaxovid JN.1 5 micrograms
6 months-59 years[1]	Recommended for: ▪ Those aged 18-59 years living in long term care facilities for older adults. ▪ Those with immuno-compromise associated with a sub-optimal response to vaccination.[2] ▪ Those with medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death.[3]	**12-59 years** Single dose of Comirnaty mRNA COVID-19 vaccine	**12-59 years** Comirnaty KP.2 30 micrograms Nuvaxovid JN.1 5 micrograms
		5-11 years Single dose of Comirnaty mRNA COVID-19 vaccine.	**5-11 years** Comirnaty KP.2 10 micrograms
		6 months-4 years Single dose of Comirnaty mRNA COVID-19 vaccine for those with a prior history of SARS-CoV-2 infection.[4] Two doses of Comirnaty mRNA COVID-19 vaccine for those with no prior history of SARS-CoV-2 infection	**6 months-4 years** Comirnaty KP.2 3 micrograms
Health and care workers	Recommended	Single dose of Comirnaty mRNA COVID-19 vaccine.[2]	See above for age-appropriate vaccine
Pregnancy	Recommended	Single dose of Comirnaty mRNA COVID-19 vaccine.[2]	See above for age-appropriate vaccine

1. Access to the primary schedule should be available for those aged 6 months-59 years who, following discussion with a healthcare provider (e.g., GP, pharmacist or HSE vaccinator), request vaccination
2. For immunocompromised, two doses are recommended with a four week interval between dose one and dose two. A third dose may be administered, eight weeks after the second dose, following instruction from a relevant specialist physician. A minimum interval of four weeks between the second and third dose may be used if there is urgency to achieve protection.
3. Medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death are outlined in Table 5a.3.
4. Prior history of COVID-19 can be confirmed by either a positive PCR test, a positive antigen test or by clinical diagnosis. For example, a single dose primary schedule could be considered in a child aged 6 months-4 years who had symptoms consistent with COVID-19 at a time when household contacts tested positive.

5a.5.2 Booster vaccination

A dose of a COVID-19 vaccine is recommended in Spring 2025, six months following the last COVID-19 vaccine or SARS-CoV-2 infection for:

- Those aged 80 years and older.
- Those aged 70-79 years who did not receive a COVID-19 vaccine in the preceding 12 months.
- Those aged 18-79 years living in long term care facilities for older adults.
- Those aged 6 months-79 years with:
  - immunocompromise associated with a suboptimal response to vaccination
- Pregnant adolescents and adults (recommended all year and not seasonal).

For those aged 6 months-79 years who are immunocompetent, a dose of a COVID-19 vaccine in Spring 2025 is not routinely recommended. For those aged 70-79 years who did not receive a COVID-19 vaccine in the preceding 12 months, a dose of COVID-19 vaccine is recommended in Spring 2025. For pregnant adolescents and adults, a COVID-19 vaccine once in pregnancy is recommended, if it is more than six months since their previous COVID-19 vaccine or infection. This recommendation is not seasonal and applies all year. COVID-19 vaccine can be given at any stage in pregnancy, ideally given between 20-34 weeks' gestation.

For those eligible for a COVID-19 vaccine in Spring 2025, a single dose is recommended.

A COVID-19 vaccine may be given in Spring 2025 irrespective of the number of previous doses or types of COVID-19 vaccines received. The recommended minimum interval following infection or vaccination is six months, however shorter intervals down to three months are permissible in exceptional circumstances e.g., planned immunosuppressive therapy or operational reasons.

See Table 5a.2 for details about age-appropriate available COVID-19 vaccines.

Antigenically updated COVID-19 mRNA vaccines are the preferred vaccine for use.

Protein subunit vaccines may be used as alternative vaccines in those for whom an mRNA vaccine is contraindicated or declined. Nuvaxovid (antigenically updated) is the preferred alternate and can be used in Spring 2025, when available.

Table 5a.2 Recommendations for COVID-19 booster vaccination in Spring 2025

Age	Irrespective of the number of previous doses or types of COVID-19 vaccine received, a COVID-19 vaccine is:	Available vaccines
80 years and older	Recommended	Comirnaty KP.2 30 micrograms Nuvaxovid JN.1 5 micrograms
70-79 years	Recommended if have not received a COVID-19 vaccine in the preceding 12 months.	Comirnaty KP.2 30 micrograms Nuvaxovid JN.1 5 micrograms
6 months-79 years	Recommended for: ▪ Those aged 18-79 years living in long term care facilities for older adults. ▪ Those with immunocompromise associated with a suboptimal response to vaccination.	**12-79 years** Comirnaty KP.2 30 micrograms Nuvaxovid JN.1 5 micrograms
		5-11 years Comirnaty KP.2 10 micrograms
		6 months-4 years Comirnaty KP.2 3 micrograms
Pregnancy	Recommended - all year and not seasonal. For pregnant adolescents and adults, a COVID-19 vaccine once[1] in pregnancy is recommended if it is more than six months since their previous COVID-19 vaccine or infection. COVID-19 vaccine can be given at any stage in pregnancy, ideally between 20-34 weeks' gestation.	**See above for age-appropriate vaccine**

[1] For those who are pregnant and are immunocompromised, a second vaccine dose within the same pregnancy may be considered if six months has elapsed since their last vaccine dose or SARS-CoV-2 infection.

Table 5a.3 Medical conditions* associated with a higher risk of COVID-19 hospitalisation, severe disease or death.

Medical conditions*
Cancer
Chronic heart disease
Chronic kidney disease
Chronic liver disease
Chronic neurological disease
Chronic respiratory disease
Diabetes and other metabolic disorders
Haemoglobinopathies
Immunocompromise due to disease or treatment[1]
Body mass index ≥40kg/m^2
Serious mental health conditions
Children and adults with Down syndrome
Children with moderate to severe neurodevelopmental disorders

[1] See Chapter 3
*This list is not exhaustive, and the medical practitioner should apply clinical judgment to consider the risk of COVID-19 infection exacerbating any medical condition that a patient may have as well as the risk of serious illness from COVID-19 infection.

5a.5.3 mRNA vaccines

5a.5.3.1 Comirnaty vaccines

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions to the HPRA.

5a.5.3.1.1 *Comirnaty vaccines for those aged 12 years and older*

Dose, route and schedule

The dose of Comirnaty KP.2 30 micrograms vaccine is 0.3 ml intramuscularly (IM) into the deltoid muscle.

Primary vaccination schedule

The preferred COVID-19 vaccine for primary vaccination of those aged 12 years and older is the antigenically updated vaccine where available. The vaccine should be given as a single dose to those who are immunocompetent. See Table 5a.1.

For those who are immunocompromised a second dose is recommended four weeks after the first dose and a third dose may be given on advice from a relevant specialist physician and this should be eight weeks after the second dose.

If the second dose is given more than four days before the minimum interval to an immunocompromised person this is not considered a valid dose. A further dose should be given at least eight weeks after the invalid dose. If a recommended third dose, for an immunocompromised person, is given before the minimum interval then this is not considered a valid dose, and a further dose should be given eight weeks after the invalid dose. For immunocompromised a relevant specialist physician may recommend a minimum interval of three weeks between dose one and dose two or four weeks between dose two and dose three, if there is urgency to achieve protection.

Booster vaccination

The preferred COVID-19 booster vaccine in those aged 12 years and over is the antigenically updated vaccine where available and should be given as a single dose.

A booster dose of COVID-19 vaccine if indicated should be given six months following the last COVID-19 vaccine or SARS-CoV-2 infection, see Table 5a.2. In exceptional circumstances an interval of three months may be used (e.g., planned immunosuppressive therapy or operational reasons).

See Table 5a.2 for Spring 2025 booster vaccine recommendations in those aged 12 years and older.

Contraindications and Precautions

For full list of contraindications and precautions see Table 5a.4. For those with a contraindication or precaution to mRNA vaccines, consideration may be given to a protein subunit vaccine (primary or booster vaccine) for anyone aged 12 years and older following an individual benefit risk assessment, including pregnant women. Nuvaxovid (antigenically updated) is the preferred alternate when available.

> Appropriate support should be available in case of anaphylaxis or fainting after vaccine administration.
>
> Precautions should be in place to minimise injury from fainting.

For more information see FAQs about COVID-19 vaccines for people with pre-existing allergic conditions.

5a.5.3.1.1.1 Comirnaty KP.2 30 micrograms (0.3 ml)

On receipt from the National Cold Chain Service (NCCS) vaccine vials must be stored in the original package to protect from light, in a refrigerator at +2°C to +8°C and used by the date as per 'USE BEFORE' label. The formulation available is a multi-dose vial with a grey cap.

The vaccine does not require dilution. Once the multidose vial is punctured the vaccine should be kept at +2°C to +30°C and used as soon as possible and within 12 hours. Gently mix by inverting vials 10 times prior to use. Do not shake.

Each dose must contain 0.3 ml of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

Licensed indications

Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older.

Vaccine efficacy

The efficacy of Comirnaty KP.2 30 micrograms is inferred from efficacy data on the prior Comirnaty vaccines.

Adverse reactions

The safety of Comirnaty KP.2 30 micrograms is inferred from safety data on the prior Comirnaty vaccines. Common adverse events are listed below, a full list of adverse reactions may be found in the SmPC.

Local:	Very common: injection site pain and swelling. Common: injection site redness.
General:	Very common: arthralgia, diarrhoea, fatigue, fever, chills, headache, myalgia, pyrexia. Common: nausea, vomiting.

5a.5.3.1.2 *Comirnaty vaccines for those aged 5-11 years*

Dose, route and schedule

The dose of the Comirnaty KP.2 10 micrograms vaccine is 0.3 ml intramuscularly (IM) into the deltoid muscle.

Primary vaccination schedule

The preferred COVID-19 vaccine for primary vaccination of those aged 5-11 years is the antigenically updated vaccine where available. The vaccine should be given as a single dose to those who are immunocompetent. See Table 5a.1.

For those who are immunocompromised a second dose is recommended four weeks after the first dose and a third dose may be given on advice from a relevant specialist physician and this should be eight weeks after the second dose.

If the second dose is given more than four days before the minimum interval to an immunocompromised person this is not considered a valid dose. A further dose should be given at least eight weeks after the invalid dose. If a recommended third dose, for an immunocompromised person, is given before the minimum interval then this is not considered a valid dose, and a further dose should be given eight weeks after the invalid dose. For immunocompromised a relevant specialist physician may recommend a minimum interval of three weeks between dose one and dose two or four weeks between dose two and dose three, if there is urgency to achieve protection.

If an immunocompromised child becomes 12 years of age before completion of the recommended schedule for 5-11 year olds, the schedule should be completed with the age-appropriate dose of Comirnaty KP.2 30 micrograms. If the interval between doses is longer than the recommended interval, the next dose should be given as soon as possible. The schedule does not need to be restarted.

If a child becomes 12 years of age before completion of the recommended schedule for 5-11 year olds in Table 5a.1, the schedule should be completed with the age-appropriate dose of Comirnaty KP.2 30 micrograms. If the interval between doses is longer than the recommended interval, the next dose should be given as soon as possible. The schedule does not need to be restarted.

Booster vaccination

The preferred COVID-19 booster vaccine in those aged 5-11 years is the antigenically updated vaccine where available and should be given as a single dose.

A booster dose of COVID-19 vaccine if indicated should be given six months following the last COVID-19 vaccine or SARS-CoV-2 infection, see Table 5a.2.

In exceptional circumstances an interval of three months may be used (e.g., in a person scheduled to commence chemotherapy).

See Table 5a.2 for Spring booster vaccine recommendations in those aged 5-11 years.

Contraindications and Precautions

For full list of contraindications and precautions to COVID-19 vaccines see Table 5a.4. For more information see Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions.

5a.5.3.1.2.1 Comirnaty KP.2 10 micrograms (0.3ml)

One formulation of Comirnaty KP.2 10 micrograms is available for those aged 5-11 years in Spring 2025 (a multi-dose vial with a blue cap).

On receipt from the National Cold Chain Service (NCCS) vaccine vials must be stored in the original package to protect from light, in a refrigerator at +2°C to +8°C and used by the date as per 'USE BEFORE' label.

The vaccine does not require dilution. Once the multidose vial is punctured the vaccine should be kept at +2°C to +30°C and used as soon as possible and within 12 hours. Gently mix by inverting vials 10 times prior to use. Do not shake.

Each dose must contain 0.3 ml of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

Licensed indications

Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in children aged 5-11 years.

Vaccine efficacy

The efficacy of Comirnaty KP.2 10 micrograms is inferred from the efficacy data on the prior Comirnaty vaccines.

Adverse reactions

The safety of Comirnaty KP.2 10 micrograms is inferred from safety data of the prior Comirnaty vaccines.

Common adverse events are listed below, a full list of adverse reactions may be found in the SmPC.

Local:	Very common: injection site pain, swelling. Common: injection site redness.
General:	Very common: arthralgia, chills, diarrhoea, fatigue, headache, myalgia, pyrexia. Common: nausea, vomiting.

5a.5.3.1.3 *Comirnaty vaccines for those aged 6 months-4 years*

Dose, route and schedule

The dose of the Comirnaty KP.2 3 micrograms vaccine is 0.3 ml intramuscularly (IM) into the deltoid muscle or anterolateral thigh.

In infants from 6-11 months of age, the recommended injection site is the anterolateral aspect of the thigh. In those aged 1-3 years of age, the recommended injection site is the anterolateral aspect of the thigh or the deltoid muscle. In children aged 3 years and older the recommended injection site is the deltoid muscle

Primary vaccination schedule

The preferred COVID-19 vaccine for primary vaccination of those aged 6 months-4 years is the antigenically updated vaccine where available. See Table 5a.1 for details about doses of COVID-19 vaccines.

For those who are immunocompromised a second dose is recommended four weeks after the first dose and a third dose may be given on advice from a relevant specialist physician and this should be eight weeks after the second dose.

If the second dose is given more than four days before the minimum interval to an immunocompromised child, this is not considered a valid dose. A further dose should be given at least eight weeks after the invalid dose. If a recommended third dose, for an immunocompromised child is given before the minimum interval then this is not considered a valid dose and a further dose should be given eight weeks after the invalid dose. For immunocompromised a relevant specialist physician may recommend a minimum interval of three weeks between dose one and dose two or four weeks between dose two and dose three, if there is urgency to achieve protection.

If the second dose is given more than four days before the minimum interval to a child with no prior history of COVID-19 infection, this is not considered a valid dose. A further dose should be given at least eight weeks after the invalid dose. If a child

becomes 5 years of age before completion of the recommended schedule for 6 months-4 year olds in Table 5a.1, the schedule should be completed with the age-appropriate dose of Comirnaty KP.2 10 micrograms.

If the interval between doses is longer than the recommended interval, the next dose should be given as soon as possible. The schedule does not need to be restarted.

Booster vaccination

The preferred COVID-19 booster vaccine in those aged 6 months-4 years is the antigenically updated vaccine where available and should be given as a single dose.

A booster dose of COVID-19 vaccine if indicated should be given six months following the last COVID-19 vaccine or SARS-CoV-2 infection, see Table 5a.2. In exceptional circumstances an interval of three months may be used (e.g., in a person scheduled to commence chemotherapy).

See Table 5a.2 for Spring 2025 booster vaccine recommendations in those aged 6 months-4 years.

Contraindications and Precautions

For full list of contraindications and precautions to COVID-19 vaccines see Table 5a.4. For more information see Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions.

5a.5.3.1.3.1 Comirnaty KP.2 3 micrograms (0.3 ml)

On receipt from the National Cold Chain Service (NCCS) vaccine vials must be stored in the original package to protect from light, in a refrigerator at +2°C to +8°C and used by the date as per 'USE BEFORE' label.

The vaccine requires dilution. Once the multidose vial, with a yellow cap, is punctured the vaccine should be kept at +2°C to +30°C and used as soon as possible and within 12 hours. Gently mix by inverting vials 10 times prior to use. Do not shake.

Each dose must contain 0.3 ml of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

Licensed indications

Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals aged 6 months to 4 years.

Vaccine efficacy

The efficacy of Comirnaty KP.2 3 micrograms is inferred from efficacy data on the prior Comirnaty vaccines.

Adverse reactions

The safety of Comirnaty KP.2 3 micrograms is inferred from safety data on the prior Comirnaty vaccines. Common adverse events are listed below, a full list of adverse reactions may be found in the SmPC.

Local:	Very common: injection site pain, swelling. Common: injection site redness.
General:	Very common: irritability, headache, drowsiness arthralgia, diarrhoea, fatigue, fever, chills, myalgia. Common: nausea, vomiting.

Table 5a.4 Contraindications and precautions to mRNA COVID-19 vaccines

	History	Action
Contraindication	Anaphylaxis after an mRNA vaccine Anaphylaxis after polyethylene glycol (PEG, e.g., some bowel preparations for endoscopy, certain laxatives such as Movicol)	Consider vaccination with non mRNA COVID-19 vaccine in a suitable facility Observe for 30 minutes or Discuss with allergist/immunologist
	Anaphylaxis after trometamol, contained in: • all presentations of Comirnaty EXCEPT Comirnaty 30 micro- grams to be diluted • all presentations of Spikevax	Vaccinate with alternative vaccine
Precautions	Acute severe illness	Defer until recovery
	Recent mpox vaccine	Allow at least a 4 week interval between mpox vaccine and subsequent COVID-19 vaccine. No interval is required between COVID-19 vaccine and subsequent mpox vaccine
	Anaphylaxis after multiple different drug classes, with no identified allergen (may indicate PEG allergy) Anaphylaxis after a vaccine or a medicine known to contain PEG Unexplained anaphylaxis (may indicate PEG allergy)	Clarify if PEG is tolerated (see FAQs) Discuss with allergist/immunologist Consider vaccination with non mRNA COVID-19 vaccine Observe for 30 minutes
	Previous history of myocarditis or pericarditis after any COVID-19 vaccine	Consult with cardiologist
	Children with a previous history of MIS-C	Defer vaccination until clinical recovery or at least 3 months since diagnosis, whichever is the longer
	Mastocytosis	Vaccinate as scheduled Observe for 30 minutes
	Idiopathic anaphylaxis Anaphylaxis after food, venom or medication	Vaccinate as scheduled Observe for 15 minutes

	History	Action
Not a contraindication or a precaution	Non-anaphylactic food allergy Family history of allergy, including anaphylaxis Previous local reaction to any vaccine Hereditary angioedema Contact dermatitis to PEG containing cosmetic product Underlying asthma Hay fever NSAID allergy Chronic spontaneous urticaria	Vaccinate as scheduled Observe for 15 minutes

5a.5.4 Protein subunit vaccines

5a.5.4.1 Novavax vaccines

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions to the HPRA.

5a.5.4.1.1 *Nuvaxovid vaccine for those aged 12 years and older*

Dose, route and schedule

The dose of Nuvaxovid JN.1 5 micrograms is a single dose of 0.5 ml IM in the deltoid muscle.

Primary vaccination schedule

Nuvaxovid JN.1 can be offered for primary vaccination in adults and children aged 12 years and older with a contraindication to a mRNA vaccine, or in those who choose not to receive a mRNA vaccine. For immunocompetent adults and children aged 12 years and above, a single dose is recommended.

For those with immunocompromising conditions, two doses should be administered with a four week interval between dose one and dose two. If a third dose is recommended by a relevant specialist physician, there should be an interval of eight weeks between dose two and three.

Booster vaccination

Nuvaxovid JN.1 can be offered for booster vaccination in adults and children aged 12 years and older with a contraindication to a mRNA vaccine, or in those who choose not to receive a mRNA vaccine.

A booster dose of COVID-19 vaccine, if indicated, should be given six months

following the last COVID-19 vaccine or SARS-CoV-2 infection, see Table 5a.2. In exceptional circumstances an interval of three months may be used (e.g. planned immunosuppressive therapy or operational reasons).

See Table 5a.2 for Spring 2025 booster vaccine recommendations in those aged 12 years and older.

Nuvaxovid JN.1 vaccine may be used as homologous and heterologous boosters.

Immunocompromised

The efficacy, safety, and immunogenicity of Nuvaxovid vaccine has been assessed in a limited number of immunocompromised individuals. The efficacy of Nuvaxovid JN.1 may be lower in immunosuppressed individuals.

Pregnancy

There is limited experience with use of Nuvaxovid in pregnancy. Administration of Nuvaxovid JN.1 in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.

Contraindications

Anaphylaxis following a previous dose of the vaccine or any of its constituents including polysorbate 80 (SmPC).

Precautions

- Acute severe illness; defer until recovery.
- Previous history of myocarditis or pericarditis after any COVID-19 vaccine; seek specialist advice (see Section 5a.4.2).
- Allow a four week interval between mpox vaccine and subsequent Nuvaxovid JN.1. No interval is required between Nuvaxovid JN.1 and subsequent mpox vaccines.

Advice from a relevant specialist should be sought for a person with a history of an immediate severe allergic reaction:

- to multiple drug classes with no identified allergen,
- any other vaccine, injected antibody preparation, or medicine likely to contain polysorbate 80,
- or idiopathic anaphylaxis,

and the risks should be weighed against the benefits of vaccination. See Allergy FAQ.

5a.5.4.1.1.1 Nuvaxovid JN.1 5 micrograms

On receipt from the National Cold Chain Service (NCCS) these single dose vaccine vials must be stored in the original package to protect from light, in a refrigerator at +2°C to +8°C and used by the date as per 'USE BEFORE' label.

The vaccine does not require dilution. Once the single dose vial is punctured, the vaccine should be used immediately.

Licensed indications

Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus in individuals 12 years of age and older.

Vaccine efficacy

The efficacy of Nuvaxovid JN.1 is inferred from the efficacy data of the Nuvaxovid (Original, Wuhan strain) vaccine and immunogenicity data from the adapted vaccine of the Omicron BA.5 strain.

Adverse reactions

Common adverse events are listed below, a full list of adverse reactions may be found in the Summary of Product Characteristics. (SmPC)

Local:	Very common: injection site pain, tenderness
General:	Very common: arthralgia, fatigue, headache, malaise, myalgia, nausea, vomiting, pyrexia*.

*In adolescents.

Myocarditis and pericarditis (section 5a.4.3) are very rare adverse reactions associated with Nuvaxovid vaccines.

5a.6 COVID-19 vaccination outside Ireland

Those who have documentary evidence of a complete COVID-19 vaccination schedule with a COVID-19 vaccine authorised by the EMA, FDA, MHRA or recommended by WHO should be considered fully vaccinated.

Those in whom more than one dose is indicated for the primary schedule and who have partially completed this schedule with a vaccine authorised by the EMA, FDA, MHRA or recommended by WHO should be offered an EMA authorised COVID-19 vaccine to complete the primary schedule as per Table 5a.1. The minimum interval between the last vaccine dose and an EMA authorised COVID-19 vaccine is four weeks.

Those who have received a partial or complete primary schedule of COVID-19 vaccine not authorised by the EMA, FDA, MHRA or recommended by WHO should be offered the primary schedule of an EMA authorised COVID-19 vaccine. The minimum interval between the last dose and an EMA authorised COVID-19 vaccine is four weeks.

5a.7 Post-marketing surveillance (Pharmacovigilance)

The HPRA is responsible for managing the national pharmacovigilance system. The HPRA reports nationally occurring adverse reactions to the EMA. Adverse reaction reporting is an important part of the EMA intensive monitoring plan for COVID-19 vaccines, so that any changes in risk benefit profile can be promptly detected and acted upon. This enables the EMA to continue to safeguard public health safety.

Healthcare professionals and members of the public are encouraged to report suspected adverse reactions to the HPRA following the instructions available on the HPRA website www.hpra.ie

Vaccinated persons should continue to follow current public health guidance to protect themselves and others.

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