5a COVID-19

NOTIFIABLE

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

Acronyms used in this chapter

AEFI	Adverse event following immunisation
BMI	Body mass index
BTS/SIGN	British Thoracic Society/Scottish Intercollegiate Guidelines Network
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
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
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 thrombocytopenia Syndrome
VOC	Variants of concern
WHO	World Health Organization

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Key changes

Chapter 5a was updated to clarify minimum intervals for COVID-19 vaccines. Information on additional formulations of Comirnaty Omicron XBB.1.5.

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Recommendations may be updated when more information becomes available.

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 **Co**rona**vi**rus **d**isease 20**19** (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 December 2023, approximately 1.8 million PCR confirmed COVID-19 cases and 9,466 deaths have been reported in Ireland.

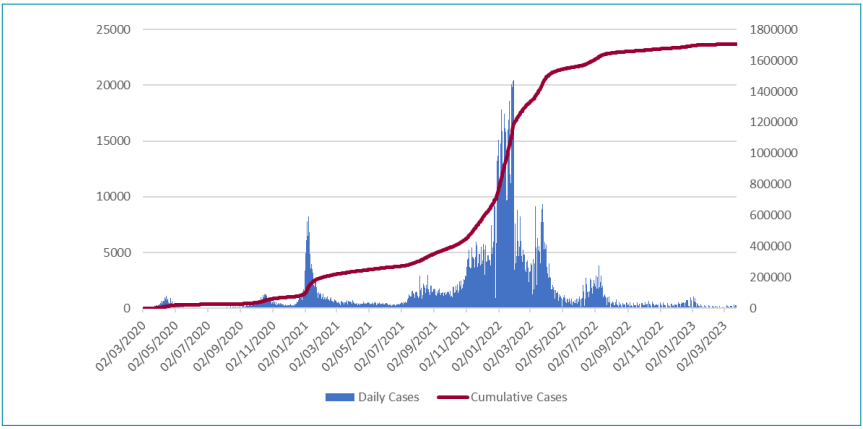

Figure 5a.1 Number and cumulative number of confirmed COVID-19 cases notified in Ireland by notification date to midnight 25 March 2023 Source: HPSC

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 underlying conditions associated with increased risk of hospitalisation are listed in Table 5a.2.

Transmission

Estimates for the basic reproductive number (R_0) 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 R_0 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 underlying conditions outlined in Table 5a.2.
- 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:

- Underlying conditions listed in Table 5a.2
- Age over 35 years
- Infection in the third trimester (28 weeks' or more)
- BMI of 30 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 an underlying condition as listed in Table 5a.2 significantly increased the risk of hospitalisation and severe disease.

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 9 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.

mRNA vaccines

Messenger RNA vaccines include genetic material (mRNA) that instructs the 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. Bivalent mRNA vaccines are adapted versions of the original Comirnaty and Spikevax vaccines which have been modified to target Omicron subvariants in addition to the original strain of SARS-CoV-2. The Comirnaty Omicron XBB.1.5 vaccine has been adapted to target the XBB.1.5 Omicron subvariant which was widely circulating in Autumn 2023.

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

Age 5-11 years

- Comirnaty 10 micrograms
- Comirnaty Original/Omicron BA.4-5 10 micrograms
- Comirnaty Omicron XBB.1.5 10 micrograms

Age 6 months-4 years

- Comirnaty 3 micrograms
- Comirnarty Omicron XBB1.5 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

Age 6-11 years

- Spikevax 50 micrograms

Age 6 months-5 years

- Spikevax 25 micrograms
- Spikevax bivalent Original/Omicron BA.4-5 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 (AstraZenca)

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

VidPrevtyn Beta (Sanofi GSK) 5 micrograms. Authorised only as a booster vaccine.

Bimervax (HIPRA) 40 micrograms. Authorised only as a booster vaccine.

Valneva (Valneva)*

*Valneva was withdrawn by manufacturer in October 2023.

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 time lapse 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.

Bivalent mRNA booster vaccination

Since their introduction in September 2022, bivalent mRNA booster vaccines have been shown to boost protection against COVID-19 related severe disease in adults aged 50 years and over.

Adapted mRNA vaccines

Early data suggest that newly adapted XBB containing vaccines are expected to enhance the immune response against XBB 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.

In Ireland, up to 30th April 2023, the Health Products Regulatory Authority has reported 14 cases of anaphylaxis after mRNA vaccines and less than five cases of anaphylaxis after adenoviral vector vaccines, out of 8.06 million vaccines administered, a rate of 2.2 cases per million doses.

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 COVID-19 vaccines are provided in multi-dose 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 preferred vaccine for primary and booster vaccination is Comirnaty Omicron XBB.1.5 where available as an age appropriate dose, see Table 5a.1. If Comirnaty Omicron XBB.1.5 is not available then Comirnaty Original/Omicron BA.4-5 may be used for primary vaccination.

Where primary vaccination schedule commenced with Comirnaty Original/Omicron BA.4-5 and Comirnaty Omicron XBB.1.5 becomes available, this

should be used to complete the primary schedule in those who are immunocompromised.

Nuvaxovid XBB.1.5 can be offered for primary schedule 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 single dose is required for primary vaccination in those who are immunocompetent.

Nuvaxovid XBB.1.5 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 a 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 arms.

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 their booster dose if recommended in Table 5a.1. 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.

Booster vaccination

Those who have had SARS-CoV-2 infection after completing their primary schedule (i.e., a breakthrough infection), should proceed to booster vaccination as recommended in Table 5a.1.

Serological testing prior to giving an additional dose (either for immunocompromised in primary schedule or for any booster dose) 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 COVID-19 booster vaccine is recommended once in pregnancy. The booster dose should be given at least six months after their last COVID-19 vaccine dose (primary schedule or booster

dose) or SARS-CoV-2 infection. Booster doses can be given at any stage in pregnancy but ideally should be given between 20-34 weeks. 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 booster dose within the same pregnancy may be considered if six months has elapsed since their last booster dose or SARS-CoV-2 infection.

There is more limited experience of Nuvaxovid XBB.1.5 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 *(see Chapter 3)*

Those with severe immunocompromise (Table 5a.2) due to disease or treatment at the time of their primary COVID-19 vaccination may have suboptimal response to their vaccines. A two dose primary course (with an option for an additional dose following specialist recommendation) and subsequent booster vaccination are recommended, see Table 5a.1. Serological testing prior to giving an additional dose is not recommended.

Patients with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval of three weeks between dose one and dose two or four weeks between dose two and dose three, may be used. Specialists should consider the individual's risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of the patient's immune status and likely immune response to vaccination.

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

Aged 12 years and older

A primary schedule of a single dose of Comirnaty mRNA COVID-19 vaccination is recommended for those aged 12 years and older.

Aged 5-11 years

A primary schedule of a single dose of Comirnaty mRNA COVID-19 vaccination is recommended for those aged 5-11 years:

- with underlying conditions
- living with a younger child with complex medical needs
- living with a person who is immunocompromised.

COVID-19 vaccination should be offered to all other children aged 5-11 years because of the favourable risk benefit profile of the vaccine, to protect them from severe disease and the consequences that can follow infection e.g., MIS-C, long COVID, psychosocial and developmental impacts.

Aged 6 months-4 years

A primary schedule of Comirnaty mRNA COVID-19 vaccination is recommended for those aged 6 months-4 years with underlying conditions that place them at higher risk of severe COVID-19:

a. two doses of age-appropriate Comirnaty mRNA COVID-19 vaccine for those with no prior history of SARS-CoV-2 infection (four weeks interval).

b. a single dose of age-appropriate Comirnaty mRNA COVID-19 vaccine for those with a prior history* of SARS-CoV-2 infection.

* Prior history of COVID-19 can be confirmed by any of: positive PCR test, antigen test or clinical diagnosis. For example, a single dose primary series could be considered in a child who had symptoms consistent with COVID-19 at a time when household contacts tested positive.

COVID-19 vaccination should be offered to all others aged 6 months-4 years because of:

- the protection provided against severe COVID-19 and MIS-C and their late consequences
- the enhanced protection vaccination gives to those who have had COVID-19 infection
- the additional protection for immunocompromised household contacts
- the safety profile of the vaccines
- similar vaccine immunogenicity to that in older children and adolescents.

5a.5.2 Booster vaccination

Booster doses should be given as per the recommendations in Table 5a.1.

Table 5a.1 Recommendations for COVID-19 vaccines by age and immune status Spring 2024

Age	Primary schedule	Spring 2024 Recommendations		Available COVID-19 vaccines
		Interdose interval[1]	Further booster doses	
Comirnaty XBB.1.5 is the preferred COVID-19 vaccine				
80 years and older	Recommended: Single dose of Comirnaty mRNA COVID-19 vaccine.	Six months	Irrespective of number of prior booster doses: A spring booster vaccine is recommended.	**For those aged 12 years and older** As primary and booster: Comirnaty Omicron XBB.1.5 30 micrograms Comirnaty Original/ Omicron BA.4-5 30 micrograms Nuvaxovid XBB.1.5 5 micrograms
70-79 years	Recommended: Single dose of Comirnaty mRNA COVID-19 vaccine.	Six months	Access to a spring vaccine should be available for those aged 70 to 79 years who, following discussion with a health care provider (e.g., GP, pharmacist or vaccination centre), request vaccination.	
12-69 years	Recommended: Single dose of Comirnaty mRNA COVID-19 vaccine.	Six months	A spring booster vaccine is recommended for: • those with immunocompromise associated with a suboptimal response to vaccination.	
5-11 years	Recommended: Single dose of Comirnaty mRNA COVID-19 vaccine for those with underlying conditions.[2] Available to others at appropriate dose.	Six months	A spring booster vaccine is recommended for: • those with immunocompromise associated with a suboptimal response to vaccination.	**For those age 5-11 years** As primary and booster: Comirnaty Omicron XBB.1.5 10 micrograms Comirnaty Original/ Omicron BA.4-5 10 micrograms
6 months-4 years	Recommended: For those with underlying conditions.[2] Available to others Two doses for those with no prior history of SARS-CoV-2 infection. Four weeks interval between dose one and dose two. Single dose for those with a prior history of SARS-CoV-2 infection.	N/A	A spring booster vaccine **is not recommended.**	**For those aged 6 months-4 years** As primary: Comirnaty Omicron XBB.1.5 3 micrograms Comirnaty 3 micrograms

Table 5a.1 Recommendations for COVID-19 vaccines by age and immune status Spring 2024 (Continued)

Age	Primary schedule	Spring 2024 Recommendations		Available COVID-19 vaccines
		Interdose interval[1]	Further booster doses	
Comirnaty XBB.1.5 is the preferred COVID-19 vaccine				
Immunocompromised aged 5 years and older	Recommended: Two doses of Comirnaty mRNA COVID-19 vaccine. A third dose may be administered following instruction from a relevant specialist physician. Four weeks interval between doses one and two; and eight weeks interval between doses two and three, if three doses are required.[3]	Six months	A spring booster vaccine is recommended for: • those with immunocompromise associated with a suboptimal response to vaccination.	**Age related as listed above**
Health Care Workers	Recommended: Single dose of Comirnaty mRNA COVID-19 vaccine.	Six months	A spring booster **is not recommended** unless immunocompromised.	**Age related as listed above**
Pregnancy	Recommended: Single dose of Comirnaty mRNA COVID-19 vaccine.	Six months	Recommendation is all year and is not seasonal. For pregnant adolescents and adults, a COVID-19 booster vaccine once[4] 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 • the booster is ideally 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.	**Age related as listed above**

[1] *Interval since last vaccine dose or SARS-CoV-2 infection, in exceptional circumstances a minimum interval of three months may be used*

[2] *Medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death are outlined in Table 5a.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.*

[3] *A minimum interval of four weeks between the second and third dose may be used if there is urgency to achieve protection*

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

Table 5a.2 Conditions or treatments associated with very high or high risk of severe COVID-19 disease.

May also include others, based on clinical judgement and a needs assessment.

Conditions in the shaded areas may be associated with a suboptimal response to vaccines and patients with these conditions should be given an mRNA vaccine if practicable and timely.

Underlying condition or treatment	Very high risk	High risk
Cancer	Receiving or within 6 weeks of receiving systemic cytotoxic chemotherapy, targeted therapy, monoclonal antibodies or immunotherapies Receiving treatment or pending treatment for a haematological cancer Undergoing or within 6 weeks of surgery or radical radiotherapy for lung or head and neck cancer Advanced/metastatic cancer	Haematological[1] - within 5 years of treatment Non haematological cancer within 1 year following immunomodulating treatment All other cancers being treated (excluding hormonal treatment)
Chronic heart and vascular disease		e.g., heart failure, hypertensive cardiac disease
Chronic kidney disease	On dialysis, or eGFR less than 15 ml/min	eGFR less than 30ml/min
Chronic liver disease		e.g., cirrhosis or fibrosis
Chronic neurological disease or condition	With evolving respiratory failure requiring non-invasive ventilation e.g., motor neurone disease, spinal muscular atrophy	Significantly compromised respiratory function and/or the ability to clear secretions e.g., Parkinson's disease, cerebral palsy
Chronic respiratory disease	Severe e.g., severe cystic fibrosis, severe COPD, severe pulmonary fibrosis	Other conditions e.g., stable cystic fibrosis, severe asthma (continuous or repeated use of systemic corticosteroids), moderate COPD
Diabetes	HbA1c 58mmol/mol or greater	All other diabetes (Type 1 and 2)

Immunocompromise due to disease or treatment	Severe e.g., **Transplantation:** - Listed for solid organ or haematopoietic stem cell transplant (HSCT) - Post solid organ transplant at any time - Post HSCT within 12 months **Genetic diseases:**[2] - APECED[2] - Inborn errors in the interferon pathway - Some B and T cell deficiencies **Treatment e.g.,** - Cyclophosphamide, Rituximab, Alemtuzumab, Cladribine or Ocrelizumab in the previous 6 months	Other e.g., High dose systemic steroids[3] HIV, not on treatment or CD4 count less than 200/10^6L for adults
Inherited metabolic diseases	Disorders of intermediary metabolism at risk of acute decompensation e.g., Maple Syrup Urine Disease	Disorders of intermediary metabolism not fulfilling criteria for very high risk
Intellectual disability	Down Syndrome	Intellectual disability excluding Down Syndrome
Obesity	BMI >40 kg/m^2	BMI >35 kg/m^2
Severe mental illness		e.g., schizophrenia, bipolar disorder, severe depression
Sickle cell disease	Sickle cell disease	

[1] Including e.g., leukaemia, lymphomas, blood dyscrasias or other malignant neoplasms affecting the bone marrow or lymphatic systems

[2] APECED - autoimmune polyendocrinopathy candidiasis ectodermal dystrophy

[3] The following doses of prednisolone (or equivalent dose of another glucocorticoid) are likely to be immunosuppressive:

- Adults and children ≥10kg: ≥40mg/day for more than 1 week, or ≥20mg/day for 2 weeks or longer
- Children less than 10kg: 2mg/kg/day for 2 weeks or longer

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 Omicron XBB.1.5 30 micrograms and Comirnaty Original/Omicron BA.4-5 30 micrograms vaccines is 0.3ml intramuscularly (IM) into the deltoid muscle.

Primary vaccination schedule

For schedule see Table 5a.1.

The preferred COVID-19 vaccine for primary vaccination is Comirnaty Omicron XBB.1.5 30 micrograms where available, for all those eligible for primary vaccination schedule, and should be given as a single dose to those who are immunocompetent.

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 Comirnaty Omicron XBB.1.5 30 micrograms is not available, then a single dose of Comirnaty Original/Omicron BA.4-5 30 micrograms may be used and two doses for immunocompromised as above with a third dose on advice of a relevant specialist physician.

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 Comirnaty Omicron XBB.1.5 vaccine is recommended as a spring booster six months following the last COVID-19 vaccine or SARS-CoV-2 infection for those aged 80 years and older as per Table 5a.1. A spring booster is also recommended for those living in long term care facilities for older adults and those with immunocompromise associated with a suboptimal response to vaccination. See Table 5a.1 for booster recommendations.

Contraindications and Precautions

For full list of contraindications and precautions see Table 5a.3.
For those with a contraindication or precaution to mRNA vaccines, consideration may be given to Nuvaxovid XBB.1.5 vaccination (primary or booster) for anyone aged 12 years and older following an individual benefit risk assessment, including pregnant women. This should be given at the interval recommended in Table 5a.1.

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 Omicron XBB.1.5 30 microgram (0.3mls)

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 invert the vial 10 times prior to use. Do not shake the vial.

If more than six 0.3ml doses can be safely and accurately withdrawn from a multidose vial, they can be used as valid doses. There should be no pooling of the contents of different vials.

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

Adverse Reactions
The safety of Comirnaty Omicron XBB.1.5 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 Summary of Product Characteristics.

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.5.3.1.1.2 Comirnaty Original/Omicron BA.4-5 30 micrograms (0.3mls)
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 invert the vial 10 times prior to use. Do not shake the vial.

If more than six 0.3ml doses can be safely and accurately withdrawn from a multidose vial, they can be used as valid doses. There should be no pooling of the contents of different vials.

Licensed indications
Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older who have previously received at least a primary vaccination course against COVID-19.

In December 2022, the EMA's Emergency Task Force concluded that Comirnaty Original/Omicron BA.4-5 vaccines may be used in primary vaccination of previously unvaccinated children and adults.

Adverse reactions
The safety of a booster dose of Comirnaty Original/Omicron BA.4-5 is inferred from safety data for a booster dose of an Omicron BA.1 adapted vaccine, as well as for a booster dose of Comirnaty Original, and supported by post authorisation surveillance.

In the UK over 11.5 million booster doses of Comirnaty bivalent vaccines have been administered including 52,500 doses to those aged under 18 years. No additional safety concerns have been noted. The safety profile in those under 18 years is similar to that of the general population with a lower rate of adverse event reports.

Common adverse reactions 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, swelling
	Common: injection site redness
General:	Very common: arthralgia, chills, diarrhoea, fatigue, headache, myalgia, pyrexia
	Common: nausea, vomiting

Myocarditis and pericarditis (section 5a.4.3) are very rare adverse reactions.

5a.5.3.1.2 Comirnaty vaccines for those aged 5-11 years
For primary and booster schedule, see Table 5a.1

Dose, route and schedule
The dose of Comirnaty Omicron XBB.1.5 10 micrograms and Comirnaty Original/Omicron BA.4-5 10 micrograms vaccines is 0.2ml intramuscularly (IM) into the deltoid muscle.

Primary vaccination schedule
The preferred COVID-19 vaccine for primary vaccination of those aged 5-11 years is Comirnaty Omicron XBB.1.5 10 micrograms where available. If Comirnaty Omicron XBB.1.5 10 micrograms is not available, then Comirnaty Original/Omicron BA.4-5 10 micrograms may be used. The vaccine should be given as a single dose to those who are immunocompetent. 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 a 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, Comirnaty Omicron XBB.1.5 30 micrograms, or Comirnaty Original/Omicron BA.4-5 30 micrograms. If the interval between doses is longer than the recommended interval, the next dose should be given as soon as possible. The course does not need to be restarted.

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.

Booster vaccination

A spring booster vaccine if indicated should be given six months following the last COVID-19 vaccine or SARS-CoV-2 infection, see Table 5a.1. In exceptional circumstances an interval of three months may be used (e.g., in a person scheduled to commence chemotherapy).

Contraindications and Precautions

For full list of contraindications and precautions see Table 5a.3.
For more information see Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions.

See Table 5a.2 for conditions that may be associated with a suboptimal response to vaccines.

5a.5.3.1.2.1 Comirnaty Omicron XBB.1.5 10 micrograms

Two formulations of Comirnaty Omicron XBB.1.5 10 micrograms are available for those aged 5-11 years in the Spring 2024 campaign:

1. Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection. Given that this is a concentrate, it needs to be diluted. After dilution the dose is 0.2ml. This is 10 doses per vial after dilution. SmPC

2. Comirnaty Omicron XBB.1.5 10 micrograms/dose dispersion for injection. This is a ready to use formulation (which does not require dilution). The dose is 0.3ml. This is 6 doses per vial. SmPC

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.

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

Vaccine efficacy
The efficacy of a booster dose of Comirnaty XBB.1.5 is inferred from the efficacy data of the prior Comirnaty vaccines as outlined below.

Adverse reactions
The safety of Comirnaty Omicron XBB.1.5 is inferred from safety data of the prior Comirnaty vaccine.

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

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.5.3.1.2.2 Comirnaty Original/Omicron BA.4-5 10 micrograms (0.2ml)
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 with 1.3ml of 0.9% sodium chloride. After dilution, the vaccine should be kept at +2°C to +30°C and used within 12 hours. Gently invert the vial 10 times prior to use. Do not shake the vial.

If more than ten 0.2ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses. There should be no pooling of the contents of different vials.

Licensed indications
Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5-11 years who have previously received at least a primary vaccination course against COVID-19.

In December 2022, the EMA's Emergency Task Force concluded that Comirnaty Original/Omicron BA.4-5 vaccines may be used in primary vaccination of previously unvaccinated children and adults.

Vaccine efficacy
The efficacy of a booster dose of Comirnaty Original/Omicron BA.4-5 is inferred from the immunogenicity of an Omicron BA.1 adapted vaccine.

Adverse reactions
The safety of a booster dose of Comirnaty Original/Omicron BA.4-5 is inferred from safety data for a booster dose of an Omicron BA.1 adapted vaccine, as well as for a booster dose of Comirnaty Original.

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, 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

5a.5.3.1.3.1 Comirnaty Omicron XBB.1.5 3 micrograms (0.2ml)
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 with 2.2ml of 0.9% sodium chloride. After dilution, the vaccine should be kept at +2°C to +30°C and used within 12 hours.

Gently invert the vial 10 times prior to use. Do not shake the vial.

If more than ten 0.2ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses. There should be no pooling of the contents of different vials.

Licensed indications
Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus in children aged 6 months-4 years.

Dose, route and schedule
The dose of Comirnaty Omicron XBB.1.5 3 micrograms vaccine is 0.2 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 number of recommended doses of Comirnaty Omicron XBB.1.5 3 micrograms depends on a prior history of SARS-CoV-2 infection at the time of the vaccination:

a. two doses of Comirnaty Omicron XBB.1.5 3 micrograms for those with no prior history of SARS-CoV-2 infection (four weeks interval).

b. a single dose of Comirnaty Omicron XBB.1.5 3 micrograms for those with a prior history* of SARS-CoV-2 infection.

* Prior history of COVID-19 can be confirmed by any of: positive PCR test, antigen test or clinical diagnosis. For example, a single dose primary series could be considered in a child who had symptoms consistent with COVID-19 at a time when household contacts tested positive.

If a child becomes five years of age before completion of the recommended schedule for those aged 6 months-4 years, the schedule should be completed with the age appropriate dose, Comirnaty Omicron XBB.1.5 10 micrograms preferably, or as an alternative Comirnaty Original/Omicron BA.4-5 10 micrograms may be given as follows:

- If they have received one dose of Comirnaty 3 micrograms give a single dose of Comirnaty Omicron XBB.1.5 10 micrograms or Comirnaty Original/Omicron BA.4-5 10 micrograms: with an interval of four weeks between dose one and dose two. see section above (Primary vaccination schedule)
- If they have received two doses of Comirnaty 3 micrograms and a third dose is recommended by a relevant specialist physician: leave an interval of eight weeks, then give one dose of Comirnaty Omicron XBB.1.5 10 micrograms.

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

If the second dose is given more than four days before the minimum interval 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.

Booster vaccination
Booster vaccination is not recommended in those aged 6 months-4 years.

Contraindications and Precautions
For full list of contraindications and precautions see Table 5a.3.

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

See Table 5a.2 for conditions that may be associated with a suboptimal response to vaccines.

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: tenderness injection site, injection site redness (6-23 months); injection site pain and redness (age 2-4 years), Common: injection site redness
General: Very common: irritability, drowsiness, decreased appetite, fever, (6-23 months), fatigue, headache, irritability myalgia, fever (2 -4 years), Common: nausea, vomiting

A higher rate of pyrexia was seen after the second dose.

5a.5.3.1.3.2 Comirnaty 3 micrograms (0.2ml)
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 with 2.2ml of 0.9% sodium chloride. After dilution, the vaccine should be kept at +2°C to +30°C and used within 12 hours. Gently invert the vial 10 times prior to use. Do not shake the vial.

If more than ten 0.2ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses. There should be no pooling of the contents of different vials.

Licensed indications

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

Vaccine efficacy

In a study 1,254 children aged 6 months-4 years who were SARS-CoV-2 negative at baseline received three doses of either Comirnaty (n=873) or placebo (n=381). The median follow-up period following dose three was 1.3 months. An estimated vaccine efficacy (VE) against SARS-CoV-2 infection of 73% was observed. A total of 21 cases of SARS-CoV-2 were reported in the placebo group and 13 cases in the vaccinated group.

Dose, route and schedule

The dose of Comirnaty 3 micrograms vaccine is 0.2 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 number of recommended doses of Comirnaty 3 micrograms depends on a prior history of SARS-CoV-2 infection at the time of the vaccination:

a. two doses of Comirnaty 3 micrograms for those with no prior history of SARS-CoV-2 infection (four weeks interval).

b. a single dose of Comirnaty 3 micrograms for those with a prior history* of SARS-CoV-2 infection.

* Prior history of COVID-19 can be confirmed by any of: positive PCR test, antigen test or clinical diagnosis. For example, a single dose primary series could be considered in a child who had symptoms consistent with COVID-19 at a time when household contacts tested positive.

If a child becomes five years of age before completion of the recommended schedule for those aged 6 months-4 years, the schedule should be completed with the age appropriate dose, Comirnaty Omicron XBB.1.5 10 micrograms preferably, or as an alternative Comirnaty Original/Omicron BA.4-5 10 micrograms may be given as follows:

- If they have received one dose of Comirnaty 3 micrograms give a single dose of Comirnaty Omicron XBB.1.5 10 micrograms or Comirnaty Original/Omicron BA.4-5 10 micrograms: with an interval of four weeks between dose one and dose two.
- If they have received two doses of Comirnaty 3 micrograms and a third dose is recommended by a relevant specialist physician: leave an interval of eight weeks, then give one dose of Comirnaty Omicron XBB.1.5 10 micrograms.

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

If the second dose is given more than four days before the minimum interval this is not considered a valid dose. A further dose should be given at least 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.

Contraindications and Precautions

Booster vaccination is not recommended in those aged 6 months-4 years.

For full list of contraindications and precautions see Table 5a.3.

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

See Table 5a.2 for conditions that may be associated with a suboptimal response to vaccines.

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 and swelling. injection site tenderness (6-23 months)
	Common: injection site redness
General:	Very common: arthralgia, chills, decreased appetite (6-23 months), diarrhoea, drowsiness (6-23 months), fatigue, headache, irritability (6-23 months), myalgia, pyrexia
	Common: nausea, rash (6-23 months), vomiting

A higher rate of pyrexia was seen after the second dose.

The most frequent adverse reactions in those that received any dose included:

- in infants 6-23 months of age, irritability (>60%), drowsiness (>40%), decreased appetite (>30%), tenderness at the injection site (>20%), injection site redness and fever (>10%)
- in children 2-4 years of age, pain at injection site and fatigue (>40%), injection site redness and fever (>10%).

In the US, approximately two million children aged 6 months-5 years have received at least one dose of either Comirnaty or Spikevax. The CDC reviewed adverse events and the most commonly reported symptoms were irritability or crying, sleepiness, loss of appetite and fever. Almost all (98%) reports were for non-serious events. Of the serious events reported, two were likely attributable to the vaccination, one febrile convulsion and one anaphylaxis associated with a dosing error. No cases of myocarditis were reported.

Table 5a.3: 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 micrograms 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

5a.5.4.1.1 Nuvaxovid XBB.1.5

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.

The vaccine should be stored at +2°C to +8°C and protected from light. Do not freeze.

The vaccine does not require dilution. Once the multidose vial is punctured, the vaccine should be used immediately. If not used, it may be kept for a single period between +2°C to +25°C and used within six hours.

If more than five 0.5ml doses can be safely and accurately withdrawn from a vial, they can be used as valid vaccines.

Licensed indications

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

Dose, route and schedule

The dose of Nuvaxovid XBB.1.5 5 micrograms is a single dose of 0.5 ml IM in the deltoid muscle.

Primary vaccination schedule

Nuvaxovid XBB.1.5. 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

Booster doses are recommended as per Table 5a.1. Nuvaxovid XBB.1.5 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 XBB.1.5 may be lower in immunosuppressed individuals.

Pregnancy

There is limited experience with use of Nuvaxovid in pregnancy. Administration of Nuvaxovid XBB.1.5 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.

Appropriate support should be available in case of anaphylaxis or fainting after vaccine administration.

Precautions should be in place to minimise injury from fainting.

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 XBB.1.5. No interval is required between Nuvaxovid XBB.1.5 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.

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
Common: injection site erythema, swelling
General: Very common: arthralgia, fatigue, headache, malaise, myalgia, nausea, vomiting
Common: pain in extremity, pyrexia

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

5a.6 COVID-19 vaccination outside Ireland

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

Those who have partially completed a COVID-19 vaccine primary 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 if a second or third vaccine dose is required as per Table 5a.1, and then should be considered fully vaccinated. 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 course 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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