Clinical Guidance for COVID-19 Vaccination

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Update	**NIAC new recommendations for COVID-19 vaccination added to page 7**

Contents

This guidance is intended for vaccinators who are administering COVID-19 vaccines.

Vaccinators should be trained and competent in immunisation practice.

Vaccinators should have undergone training in the administration of COVID-19 vaccine(s), recognition and management of anaphylaxis, and basic life support and intramuscular injection technique. They should also be familiar with the NIAC algorithm on Anaphylaxis: Immediate management in the community available at **https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-02-general-immunisation-**procedures

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 the National Immunisation Advisory Committee should be followed.

1. Introduction

The objective of the vaccination programme for SARS-CoV-2 is to ensure equitable access to a safe and effective vaccine with the goals of limiting mortality and morbidity from COVID-19, protecting healthcare capacity and enabling social and economic activity.

Purpose of the document

This document has been prepared as a means of providing clinical guidance to all clinicians administering COVID-19 vaccines as part of the COVID-19 vaccination programme.

Indemnity for vaccinators

Claims management in relation to claims and litigation initiated in connection with COVID-19 vaccination is to be delegated to the State Claims Agency by means of Government Order. Registered medical practitioners (including GPs), nurses, pharmacists, physiotherapists, dentists, dental hygienists, optometrists, radiographers and radiation therapists, paramedics, advanced paramedics, emergency medical technicians and relevant healthcare students (as per the Statutory Instruments for the administration of COVID-19 vaccines), in receipt of relevant training with regard to administration of the vaccines, who are administering vaccines on the direction of, or on behalf of, the Health Service Executive (HSE) will be indemnified with regard to any adverse product liability-related events arising from their administration of the vaccine. Vaccinators working in GP surgeries and retail pharmacies however, will not be indemnified in respect of malpractice events occurring during the administration of the vaccine. Such malpractice events will be indemnified by their professional insurers.

2. Vaccine recommendations

The National Immunisation Advisory Committee (NIAC) advise the aim of the COVID-19 vaccine programme is to offer year-round protection against severe disease in those populations that are at increased risk of hospitalisation, ICU admissions and death from SARS-CoV-2 infection. To achieve this aim, vaccination once per year is recommended for most at-risk individuals. For those in whom immunity wanes more quickly, twice-yearly vaccination is required.

The following NIAC recommendations for COVID-19 vaccination were published in August. 2025

A COVID-19 vaccine is recommended twice each year for:

o those aged 80 years and older

o those aged 18 to 79 years living in long term care facilities for older adults

o those aged 6 months and older with immunocompromise associated with a suboptimal response to vaccination

A COVID-19 vaccine is recommended once each year for:

o those aged 60 to 79 years

o those aged 6 months to 59 years with medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death.

A COVID-19 vaccine is recommended in each pregnancy for:

o pregnant adolescents and adults with immunocompromise

o pregnant adolescents and adults with medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death.

Access to a COVID-19 vaccine once each year should be available for:

o health and care workers* who chose to receive a vaccine

o pregnant adolescents* and adults* who following discussion with a healthcare provider chose to receive a vaccine

o adults aged 18 to 59 years* who following discussion with a healthcare provider choose to receive a vaccine.

*Health and care workers, pregnant adolescents and adults and adults aged 18 to 59 years with immunocompromise or medical conditions with a higher risk from or SARS-CoV-2 infection (see Table 2) should follow the recommendations in Table 1 below.
A COVID-19 vaccine if indicated, should be given six months following the last COVID19 vaccine or SARS-CoV-2 infection. In exceptional circumstances, an interval of three months may be used (such as planned immunosuppressive therapy or operational reasons).

Table 1: NIAC COVID-19 vaccine recommendations and notes for the recommendations

August 2025

Groups	Recommendations
≥80 years	One dose twice a year (six months apart[1])
60-79 years	One dose once a year
≥18 years living in long term care facilities for older adults	One dose twice a year (six months apart[1])
≥6 months with immunocompromise associated with a suboptimal response to vaccination	One dose[2,3] twice a year (six months apart[1])
6 months-79 years with medical conditions[4] associated with severe COVID-19 infection	One dose[3] once a year
Pregnant adolescents and adults	One dose[5] is recommended in each pregnancy for those with immunocompromise or with medical conditions[4] associated with severe COVID-19 infection. One dose should be available in each pregnancy for pregnant adolescents and adults who chose to receive a vaccine following discussion with a healthcare provider.
Health and care workers (HCWs)	One or two doses a year are recommended if in one of the above risk groups. One dose should be available each year for all HCWs who chose to receive a vaccine.
Adults aged 18-59 years without additional risk factors for COVID-19	One dose should be available each year for those who chose to receive a vaccine following discussion with a healthcare provider.

1. The recommended minimum interval following infection or vaccination is 6 months. However, shorter intervals down to three months are permissible in exceptional circumstances such as planned immunosuppressive therapy or for operational reasons.
2. Two doses are recommended for those with immunocompromise who have never been vaccinated against SARS-CoV-2 infection. There should be a 4 week interval between dose one and dose two. A third dose may be administered, 8 weeks after the second dose, following instruction from a relevant specialist physician.
3. Two doses are recommended for those aged 6 months to 4 years who have no prior history of a SARS-2 infection if they have never been vaccinated against SARS-CoV-2 infection. Prior history of SARS-CoV-2 infection can be confirmed by either a positive PCR test, a positive antigen test or clinical diagnosis.
4. Medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death are outlined in Table 2 below.
5. For those who are pregnant and are immunocompromised, a second dose of COVID-19 vaccine within the same pregnancy may be considered if 6 months has elapsed since their last COVID-19 vaccine or SARS-CoV-2 infection

For further information on the NIAC recommendations for COVID-19 vaccination, please see chapter 5a of the NIAC HIQA Immunisation Guidelines.
https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

Table 2

Medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death (From NIAC Chapter 5a).

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

* 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.

For further information on the NIAC recommendations for COVID-19 vaccination, please see chapter 5a of the NIAC HIQA Immunisation Guidelines:
https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

NIAC recommendations for those who have never been vaccinated against SARS-CoV-2 infection

- For those who have never been vaccinated against SARS-CoV-2 infection, and in whom COVID-19 vaccination is indicated, a single dose of an mRNA COVID-19 vaccine is recommended for all age groups except for those with immunocompromise associated with a suboptimal response to vaccination and those aged six months to four years with no prior history of SARS-CoV-2 infection (Table 1 above see also Table 5a.3 Chapter 5a).

- Those who have never been vaccinated against SARS-CoV-2 infection, who develop SARS-CoV-2 infection should receive a dose of a COVID-19 vaccine if indicated at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who were asymptomatic.

- For adults and children aged 12 years and older who have never been vaccinated against SARS-CoV-2 infection and who have a contraindication to an mRNA vaccine or who choose not to receive an mRNA vaccine, a single dose of an antigenically updated Nuvaxovid vaccine should be given except for those with immunocompromise associated with a suboptimal response to vaccination. See Table 1 above and Table 5a.3 Chapter 5a Immunisation Guidelines for COVID-19 vaccination information for those with immunocompromise available at **https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19**

- Access to a COVID-19 vaccine should be available for all those aged six months to 59 years who have never been vaccinated against SARS CoV-2 infection regardless of their risk of COVID-19 who, following discussion of their reasons with a healthcare provider such as, general practitioner (GP), pharmacist or Health Service Executive (HSE) vaccinator, request vaccination

  https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland

3. COVID-19 vaccines

Table 3 shows the vaccines and dosage recommended by the National Immunisation Advisory Committee (NIAC) following approval by the European Medicines Agency (EMA) that are currently available as part of the COVID-19 Immunisation Programme in Ireland.

Table 3: Vaccines currently used in the COVID-19 Immunisation Programme

mRNA VACCINES		
Comirnaty LP.8.1 3 mcg (0.3 ml) *(Yellow Cap - requires Dilution before use)*	**Pfizer/BioNTech**	Vaccination of children aged 6 months-4 years
Comirnaty LP.8.1 10mcg (0.3ml) *(Blue Cap – Ready to Use (RTU))*	**Pfizer/BioNTech**	Vaccination of individuals aged 5-11 years
Comirnaty LP.8.1 30mcg (0.3ml) *(Grey Cap – Ready to Use (RTU))*	**Pfizer/BioNTech**	Vaccination of individuals aged 12 years and older

Further regulatory information on all COVID-19 vaccines can be found in the approved product information (Summary of Product Characteristics (SPC) for health care professionals, and Package Leaflet (PIL) for the public), and is available via the EMA website www.ema.europa.eu.

4. Infection prevention and control for the administration of COVID-19 vaccines

Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the "WHO five moments of hand hygiene" with emphasis on:

- Before vaccine preparation
- Before drawing up and administering the vaccine
- Before and after each recipient contact

Check Health Protection Surveillance Centre (HPSC) website for the latest guidance on infection prevention and control (IPC) for healthcare workers: https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/

All vaccinators should follow the Infection Prevention and Control (IPC) precautions and management in line with the latest National Clinical Guideline No. 30 (2023) Infection Prevention and Control (IPC), available at https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/

It is not necessary to use gloves for vaccine injections, unless contact with potentially infectious body fluids is possible, or unless the health care worker has an infected lesion on the hand. If gloves are worn, they should be changed for each patient.

If the skin at the injection site is visibly dirty it should be cleaned with soap and water. There is no need to use a disinfectant e.g. alcohol swabs.

If an alcohol swab is used, injection should be delayed for ≥30 seconds, to ensure the alcohol will have evaporated.

There is no need to routinely check temperature either at registration or before vaccination.

Further information on General Immunisation Procedures is available in Chapter 2 of the National Immunisation Advisory Committee guidance for Ireland
https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland

5. Vaccine details, storage and instructions for preparation and administration.

Vaccines undergo rigorous checks and quality steps prior to final release from the manufacturer.

SmPCs usually state: "The vaccine should be inspected visually for particulate matter and discolouration prior to administration. Discard the vial if the suspension is discoloured or visible particles are observed."

When a vaccinator is concerned regarding a vial the following steps should be followed:

- The vaccinator should contact another healthcare professional (HCP) who has experience in using this product and ask for a second opinion
- The affected vial should be returned to the **fridge** and kept there in **Quarantine** (between +2˚C and +8˚C)
- The vial in quarantine should be placed in a clearly marked area in the fridge "Quarantine - do not use"
- The vaccinator and senior experienced HCP should check the other vials in this batch in their fridge by removing one vial at a time and ensuring that the duration out of the fridge is kept to a minimum
- If more vials are considered defective, they should calculate the impact of placing vials into quarantine and arrange for additional deliveries if required.
- The Health Products Regulatory Authority (HPRA), manufacturer and HSE National Immunisation Office (NIO) should be emailed with details of the issue and with a photograph of vial identifying the defect (if possible).
- The NIO will follow up and contact other locations where this batch has been delivered if necessary.

Please ensure vaccines are stored between +2ºC and +8ºC.

Should vaccines be exposed to temperatures outside of these parameters please contact the NIO immediately by emailing pharmacynio@hse.ie

Do not use or discard the vaccines until advised by the National Immunisation Office.

6. COVID-19 mRNA vaccines

For those aged 12 years and older, Comirnaty LP.8.1 30 micrograms/dose dispersion for injection is the preferred vaccine.

OF NOTE: For information about COVID 19 vaccination recommendations for those age 12 years and older for Comirnaty LP.8.1 30 micrograms please consult Section 5a.5 in chapter 5a of the NIAC Immunisation Guidelines. https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

For information about vaccines for children aged 5-11 years see **Section 11 Vaccination of Children aged 5-11 years.**

For information about vaccines for children aged 6 months-4 years see **Section 12 Vaccination of Children aged 6 months-4 years.**

6.1 Vaccine storage - Comirnaty LP.8.1 30 micrograms/dose dispersion for injection:

- The vaccine is delivered from the manufacturer to the HSE NCCS at -90°C to -60°C and this storage condition is continued as the vaccine is stored in an ULT freezer at - 90°C to -60°C.
- The vaccine is supplied to sites/clinics by the HSE NCCS at +2 to +8°C with a shelf life of up to 10 weeks. This new “use before” time and date is labelled by NCCS once vials are removed from ULT.
- Vials have a shelf life of up to 10 weeks when stored at +2 to +8°C (labelled “USE BEFORE” time and date) and up to 12 hours at temperatures between +8 °C and +30 °C.
- After removal from the fridge prior to administration, opened vials must be kept at +2°C to +30°C and used within 12 hours, after which the vial must be discarded.
- The vial has a Grey cap and is ready to use (does not require dilution).

Summary of Comirnaty LP.8.1 30 micrograms/dose dispersion for injection

Title	Description
Type of vaccine	mRNA
Name of vaccines	• Comirnaty LP.8.1 30 micrograms/dose dispersion for injection
Excipients	• ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) • 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) • 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) • Cholesterol • Trometamol • Trometamol hydrochloride • Sucrose • Water for injections
Presentation	The vaccines are contained in a multi-dose clear vial (type I glass)
Number of doses in each vial	6 doses. If a seventh dose of 0.3 ml can be safely and accurately withdrawn from a vial, it is a valid dose.
Dilution	**DO NOT DILUTE**
Latex	The vial stopper does not contain latex.
Dosage	0.3 ml (30 mcg) intramuscularly

6.2 Vaccine preparation

Comirnaty LP.8.1 30 micrograms dispersion for injection is a multidose vial, Do NOT dilute prior to use.

- Check “Use Before” date and time on the vaccine box.
- Verify that the vial has a GREY plastic cap and the product name is Comirnaty LP.8.1 30 micrograms/dose dispersion for injection (12 years and older).

Preparation of 0.3 ml doses:

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible.
- Do not use the vaccine if particulates or discolouration are present.
- Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
- Withdraw 0.3 ml of Comirnaty LP.8.1. Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial.
- 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.
- Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between +8 °C and +30 °C. After first puncture, the vial should be stored between +2 °C to +30 °C.
- Record the appropriate discard date/time on the vial.
- Discard any unused vaccine 12 hours after first puncture.

Shelf life and transportation of Comirnaty 30 micrograms formulations

	Description
Expiry date	The date the vaccine expires when continuously stored in an ULT freezer at -90°C to -60°C. The batch number on the side of each vial is recorded in the patient record. This is linked to the expiry date.
“*USE BEFORE*” date and time - Maximum time from removal from ultra-low temperature (ULT) freezer to expiry, when stored at +2°C to +8°C	**USE BEFORE date and time**. This time and date will be labelled on the box by the NCCS. The vials must be used before the USE BEFORE date and time. The USE BEFORE date must be recorded in the person’s record.
“*Discard*” date and time - Maximum time allowed from first puncture of vial to expiry	After first puncture, the vaccine must be used within 12 hours (when stored at +2 °C to +30 °C) e.g. Vial is punctured 17/09/2025 at 10.00. Discard time is 17/09/2025 at 22.00. This is the date and time that should be written on the vial. Any unused or partially unused vials must be discarded when this time has been reached. From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user

Transportation time	**Unpunctured vial.** No limit within the USE BEFORE date and time, when stored at +2 ˚C to +8 ˚C **Punctured vial** Up to 6 hours transportation time within the 12-hour discard date and time when stored at +2 °C to +30 °C.

7. Contraindications and precautions to COVID-19 vaccines

Of Note: For full list of contraindications and precautions to COVID-19 vaccines see Table 5a.4 and Table 5a.5 in chapter 5a of the NIAC Immunisation Guidelines
https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

Of Note: For Contraindications and precautions to Comirnaty vaccines for those age 12 years and older please see section 5a.5.4.1in chapter 5a of the NIAC Immunisation Guidelines
https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19
Of Note: For information on patients planning immunosuppressing therapy, please see section 5a.5.2in chapter 5a of the NIAC Immunisation Guidelines
https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

Of note: For further information see Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions https://www.rcpi.ie/Healthcare-Leadership/NIAC/Hot-topics-and-resources/Hot-topics-and-general-resource.ie

Refer to section 11 Vaccination of Children age 5-11 years for details of vaccination of children aged 5-11 years

Refer to section 12 Vaccination of Children age 6 months to 4 years for details of vaccination of children aged 6 months-4 years

For information on Vaccination after COVID-19, please see section 5a.5.1in chapter 5a of the NIAC Immunisation Guidelines
https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

8. Clinical considerations for COVID-19 vaccines

8.1 COVID-19 vaccines in pregnancy

Of Note: For information on COVID-19 vaccines in Pregnancy, please see section 5a.5.3.in chapter 5a of the NIAC Immunisation Guidelines
https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

While COVID-19 vaccination remains safe in pregnancy, the benefits of COVID-19 vaccination are less pronounced than they were in previous eras. As a result, NIAC no longer routinely recommends a dose of a COVID-19 vaccine once in each pregnancy. However, NIAC still recommends that pregnant adolescents and adults with immunocompromise or other medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death should receive one dose of a COVID-19 vaccine in each pregnancy. See Table 1 and Table 3 (Medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death).

Continuing evidence regarding mRNA COVID-19 vaccination during pregnancy has demonstrated it to be safe and effective. The NIAC has reviewed the evidence regarding safety and timing of COVID-19 vaccines in pregnancy. Current data are very reassuring regarding the safety of COVID-19 mRNA vaccines given at any stage in pregnancy. The EMA, UK Health Security Agency, and CDC have been monitoring the safety of COVID-19 vaccines in pregnancy[1,2,3]. These safety monitoring systems have not reported any safety concerns for people who receive an mRNA COVID-19 vaccine at any stage of pregnancy. Less data are available regarding non-mRNA vaccines.
See Chapter5a at https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

8.2 Breastfeeding

Of Note: For information on COVID-19 vaccines and breastfeeding, please see section 5a.4.8 in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

8.3 Individuals with a bleeding disorder

Of Note: For information regarding individuals with bleeding disorders, please see section 2.4.6 in chapter 2 of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-02-general-immunisation-procedures

8.4 Individuals taking anticoagulants

Of Note: For information regarding individuals taking anticoagulants, please see section 2.4.6 in chapter 2 of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-02-general-immunisation-procedures

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[1] European Medicines Agency. COVID-19: latest safety data provide reassurance about use of mRNA vaccines during pregnancy 2022 [Available from: https://www.ema.europa.eu/en/news/covid-19-latest-safety-data-provide-reassurance-about-use-mrna-vaccines-during-pregnancy accessed 21 Feb 2023.

[2] Agency UHS. COVID-19 vaccine surveillance report. Week 29, 18 July 2024 [Available from: https://assets.publishing.service.gov.uk/media/669923b20808eaf43b50d1fd/Vaccine_surveillance_report_2024_week_29.pdf accessed 17 Oct 2023.

[3] Centres for Disease Control and Prevention. COVID-19 Vaccination for People who are Pregnant or Breastfeeding 2024 [Available from: https://www.cdc.gov/covid/vaccines/pregnant-or-breastfeeding.html accessed 17 October 2024.

People on Warfarin should follow their usual schedule for international normalised ratio (INR) testing and can be vaccinated if the INR is less than 4.0. If the INR is 4.0 or more, follow the advice of the clinic/practice managing the Warfarin treatment and wait until the INR is less than 4.0 to be vaccinated.

8.5 Technique for IM injections in persons with bleeding disorders or on anticoagulants

Of Note: For information regarding technique for IM injections in persons with bleeding disorders or on
Anticoagulants, please see chapter 2 section 2.4.6 of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-02-general-immunisation-procedures

8.6 Co-administration of COVID-19 vaccines with other inactivated or live vaccines

Of Note: For information on co-administration of COVID-19 vaccines with other vaccines please see section 5a.4.5 in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

8.7 Immunosuppression due to disease or treatment

Individuals with immunosuppression due to disease or treatment should be vaccinated if they have no contraindications.

For further information on Immunocompromised patients, please see section 5a.5.2 in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

8.8 COVID-19 vaccine for those with immunosuppression due to disease or treatment

Comirnaty KPLP.8.1 30micrograms COVID-19 vaccine is the preferable vaccine and should be given as per the optimal or minimum intervals recommended by NIAC.

Please see section 5a.5.2, and section 5a.5.4.1 Comirnaty vaccines in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

8.9 People being treated with chemotherapy for cancer

Chemotherapy is not a contraindication to COVID-19 vaccination. People taking chemotherapy should be vaccinated according to their recommended group (provided there are no contraindications).

Vaccination for children aged 5-11 years is discussed in a separate section within this guidance document (see Section 11 Vaccination of Children age 5-11 years).

Vaccination for children aged 6 months-4 years is discussed in a separate section within this guidance document (see Section 12 Vaccination of children age 6 months to 4 years)

9. Post vaccination

9.1 Recording vaccination

The individual should be given a record of vaccination and HSE post vaccination advice leaflet.

Vaccine administration should be recorded in the IT system.

Record the “USE BEFORE date and the batch number in the vaccination record (written on the vaccine box by the NCCS).

9.2 Observation period

Cases of anaphylaxis have been reported following administration of COVID-19 vaccines.

Please note that NIAC recommends a **15 minute observation** period following administration of a COVID-19 vaccine.

Recommended observation period following COVID-19 vaccination:

- All vaccine recipients (see exceptions below):15 minutes of observation
- 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

Vaccine recipients should be advised to seek urgent medical attention if they have symptoms suggestive of an allergic reaction such as difficulty breathing, feeling faint, rapid heartbeat or a skin rash.

10. Adverse reactions

10.1 Adverse reactions after COVID-19 vaccination

Please refer to the relevant Summary of Product Characteristics for further details.

The adverse events are listed in **Table 8 and Table 9** according to the following frequency:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to <1/1,000)
- Very rare (< 1/10,000)

The safety of Comirnaty LP.8.1 and ComirnatyKP.2 vaccines are inferred from safety data of the prior Comirnaty vaccines.

Table 8: Adverse reactions from COVID-19 vaccine Comirnaty from clinical trials and post authorisation experience

Type of Reaction	Comirnaty® (Pfizer BioNTech)
Very Common (≥ 1/10)	**Local:** injection site pain, injection site swelling
	General: arthralgia, fatigue, fever*****, chills, headache, myalgia, diarrhoea
Common (≥ 1/100 to < 1/10)	**Local:** injection site erythema
	General: nausea, vomiting, lymphadenopathy***
Uncommon (≥1/1,000 to <1/100)	Local: injection site pruritus
	General: insomnia, extremity pain (refers to the vaccinated arm), hyperhidrosis, night sweats, decreased appetite, asthenia, malaise, lethargy, hypersensitivity reactions (e.g. rash, pruritus, urticaria****, angioedema****), dizziness
Rare (≥ 1/10,000 to < 1/1,000)	General: acute peripheral facial paralysis
Very rare (< 1/10,000)	Myocarditis and pericarditis
Not known (cannot be estimated from the available data)	Anaphylaxis, Facial swelling in those who have had dermatological fillers, Extensive swelling of the vaccinated limb, Erythema Multiforme, Paraesthesia, Hypoaesthesia, Heavy menstrual bleeding**

**Most cases appeared to be non-serious and temporary in nature
*** In participants 5 years of age and older, a higher frequency of lymphadenopathy was reported after a booster (≤ 2.8%) dose than after primary (≤ 0.9%) doses of the vaccine.
**** The frequency category for urticaria and angioedema was rare.
*****A higher frequency of pyrexia (after Comirnaty®) was observed after the second dose compared to the first dose.

Events of **anaphylaxis have been reported after COVID-19 vaccination**. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine

Very rare events of **neuroinflammatory disorders** have been reported following COVID-19 vaccination. A causal relationship has not been established

If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g.

paracetamol containing products or ibuprofen) may be used. Note: Ibuprofen is not recommended for pregnant women.

Events of **anaphylaxis have been reported after COVID-19 vaccines**. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine

If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g. paracetamol containing products or ibuprofen) may be used. Note: Ibuprofen is not recommended for pregnant women.

10.2 Myocarditis and pericarditis

Myocarditis and pericarditis are very rare side effects of mRNA vaccines. Healthcare professionals should consult applicable guidance and/or consult a Cardiologist for advice on management.
Myocarditis or pericarditis usually present with symptoms of chest pain, tachycardia or breathlessness. Vaccinees should always be made aware of these symptoms and told to seek medical advice if such symptoms occur after vaccination.

Of Note: For information on myocarditis and pericarditis please see section 5a.4.2 (COVID-19 vaccine safety) and section 5a.5.4.1 in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19Please see Summary of Product Characteristics (SmPC) for further information on www.hpra.ie

10.3 Reporting adverse reactions

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 benefit risk balance can be promptly detected and acted upon. This enables the EMA to continue to safeguard public health safety.

COVID-19 vaccines are subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals and members of the public are encouraged to report any suspected adverse reactions to the HPRA following the instructions available on the HPRA website www.hpra.ie. As much information as is known should be provided, and where possible, the vaccine batch number should be included.

10.4 Reporting of incidents during the vaccination session to HSE

In the case of medication errors that directly involve the vaccine recipient, i.e. wrong medication/dose/route being administered or another medication error, the vaccinator must remain with the person and closely monitor them for any adverse reactions.

The incident must be reported to the relevant line manager/person in charge as soon as possible. The

incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day. (National Incident Report Form (NIRF 01 – V12)) (2021) available at: https://www.hse.ie/eng/about/qavd/incident-management/

The **vaccine recipient and/or significant others should be informed of the incident**. An incident report form must be completed by the vaccinator and forwarded to local or regional Risk Manager as per local policy.

Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.

11. Vaccination of children aged 5-11 years

The National Immunisation Advisory Committee (NIAC) advise that **Comirnaty LP.8.1. 10 micrograms is the preferred vaccine for Covid -19 vaccination for those aged 5-11 years.**

Comirnaty LP.8.1 10 micrograms/dose dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years.

11.1 NIAC recommendations

Recommendations for COVID-19 vaccination of those aged 5-11 years

OF NOTE: For information on those who have never been vaccinated against SARS-CoV-2 infection, please see Section 5a.5.1 and table 5a.3 in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19
OF NOTE: For the COVID-19 vaccination and scheduling for those age 5-11 years for Comirnaty LP.8.1. 10 micrograms please see Section 5a.5.1, in chapter 5a of the NIAC Immunisation Guidelines. Those who have never been vaccinated against SARS-CoV-2 infection https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

Recommendations for booster vaccination of those aged 5-11 years

OF NOTE: For booster vaccination recommendations, please see section 5a.5.2, table 5a.2 and section 5a.5.3.1.2 in chapter 5a NIAC Immunisation Guidelines https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

11.2 Vaccine storage

Comirnaty 10 micrograms/dose dispersion for injection:

- The vaccine is delivered from the manufacturer to the HSE NCCS at -90°C to -60°C and this storage condition is continued as the vaccine is stored in an ULT freezer at - 90°C to -60°C.
- The vaccine is supplied to sites/clinics by the HSE NCCS at +2 to +8°C with a shelf life of up to 10 weeks. This new “use before” time and date is labelled by NCCS once vials are removed from ULT.
- Vials have a shelf life of up to 10 weeks when stored at +2 to +8°C (labelled “USE BEFORE” time and date) and up to 12 hours at temperatures between +8 °C and +30 °C.
- After removal from the fridge prior to administration, opened vials must be kept at +2°C to +30°C and used within 12 hours, after which the vial must be discarded
- The vial has a Blue cap and is ready to use (does not require dilution).

Summary of Comirnaty 10 micrograms/dose dispersion for injection

Title	Description
Type of vaccine	mRNA
Name of vaccines	Comirnaty LP.8.1 10 micrograms/dose dispersion for injection
Excipients	((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol Trometamol Trometamol hydrochloride Sucrose Water for injections
Presentation	The vaccines are contained in a multi-dose clear vial (type I glass)
Number of doses in each vial	6 doses If a seventh dose of 0.3 ml can be safely and accurately withdrawn from a vial, it is a valid dose
Dilution	**DO NOT DILUTE**
Dosage	0.3 ml (10 mcg) intramuscularly
Latex	The vial stopper does not contain latex.
Preservatives	None

Prior to vaccination

- Check valid consent has been obtained
- Check for contraindications or precautions
    - See later in this chapter and the NIAC Immunisation guidelines for COVID-19 available at https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland
- Vaccinators who are vaccinating using a medicines protocol should check vaccine recipient's eligibility under the protocol
- Check the interval when administering a second or third dose of the schedule for those who are immunocompromised
- Explain the procedure
- Answer questions
- Maintain privacy & dignity

11.3 Infection prevention and control

- Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the "WHO five moments of hand hygiene" with emphasis on:
    - Before vaccine preparation
    - Before drawing up and administering the vaccine
    - Before and after each recipient contact
- It is not necessary to use gloves for vaccine injections, unless contact with potentially infectious body fluids is possible, or unless the health care worker has an infected lesion on the hand. If gloves are worn, they should be changed for each patient.
- If the skin at the injection site is visibly dirty it should be cleaned with soap and water. There is no

need to use a disinfectant e.g. alcohol swabs.

- If an alcohol swab is used, injection should be delayed for ≥30 seconds, to ensure the alcohol will have evaporated.
- There is no need to routinely check temperature either at registration or before vaccination.
- All vaccinators should follow the Infection Prevention and Control (IPC) precautions and management in line with the latest National Clinical Guideline No. 30 (2023) Infection Prevention and Control (IPC), available at https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/
- Check Health Protection Surveillance Centre (HPSC) website for the latest guidance on infection prevention and control (IPC) for healthcare workers: https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/

11.4 Vaccine preparation

Comirnaty LP.8.1 10 micrograms/dose dispersion for injection is a multidose vial. Do NOT dilute prior to use.

- Check the use before date and time on the box containing the vials.
- Verify that the vial has a BLUE plastic cap, and the product name is Comirnaty LP.8.1 10 micrograms/dose dispersion for injection (children 5 to 11 years). If the vial has another product name on the label, please refer to the Summary of Product Characteristics for that formulation.

Preparation of 0.3 ml doses:

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible.
- Do not use the vaccine if particulates or discolouration are present.
- Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
- Withdraw 0.3 ml of Comirnaty LP.8.1. Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial.
- 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.
- Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between +8 °C and +30 °C. After first puncture, the vial should be stored between +2 °C to +30 °C.
- Record the appropriate discard date/time on the vial.
- Discard any unused vaccine 12 hours after first puncture.

Shelf life and transportation of Comirnaty 10 micrograms formulations

	Description
Expiry date	The date the vaccine expires when continuously stored in an ULT freezer at -90°C to -60°C. The batch number on the side of each vial is recorded in the patient record. This is linked to the expiry date.

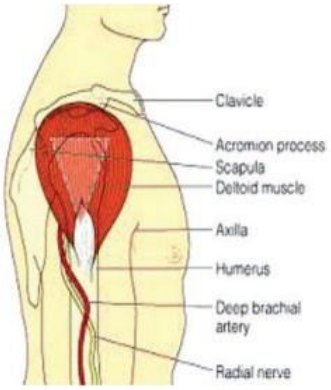
"*USE BEFORE*" date and time - Maximum time from removal from ultra-low temperature (ULT) freezer to expiry, when stored at +2°C to +8°C	**USE BEFORE date and time**. This time and date will be labelled on the box by the NCCS. The vials must be used before the USE BEFORE date and time. The USE BEFORE date must be recorded in the person's record.
"*Discard*" date and time - Maximum time allowed from first puncture of vial to expiry	After first puncture, the vaccine must be used within 12 hours (when stored at +2 °C to +30 °C) e.g. Vial is punctured 17/09/2025 at 10.00. Discard time is 17/09/2025 at 22.00. This is the date and time that should be written on the vial. Any unused or partially unused vials must be discarded when this time has been reached. From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user
Transportation time	**Unpunctured vial.** No limit within the USE BEFORE date and time, when stored at +2 ˚C to +8 ˚C **Punctured vial** Up to 6 hours transportation time within the 12-hour discard date and time when stored at +2 °C to +30 °C.

11.5 Vaccine administration

- Administer vaccine to patient intramuscularly, into the deltoid muscle
- Dispose the syringe and the needle into the sharps bin
- Do not leave the empty vials unattended
- Dispose the empty vials safely into a sharps bin
- Low dead space syringes should be used if available in order to maximise the number of doses that can be drawn from the vial
- **There should be no pooling of vaccine** solution from different vials.

11.6 Method of IM vaccine administration

- Intramuscular injection technique for children aged 5-11 is the same as for older children and adults
- Vaccine to be given Intramuscularly into the deltoid muscle
- The light triangle in figure indicates site for IM injection into the deltoid muscle

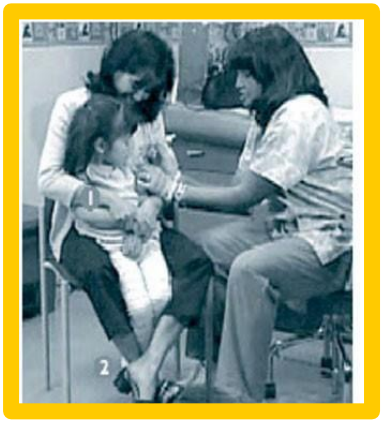


- The upper border of the triangle is approximately two finger-breadths below the acromion process and the apex is at the midpoint of the humerus
- The needle size for IM injection is the same as that for adults (23 gauge / 25 gauge in size and 25mm

in length needle)
- At the injection site spread the skin taut between the thumb and forefinger with the non- dominant hand
- Do not bunch up the skin as this leads to administering the vaccine into subcutaneous tissue inadvertently
- Further information is available at www.immunisation.ie

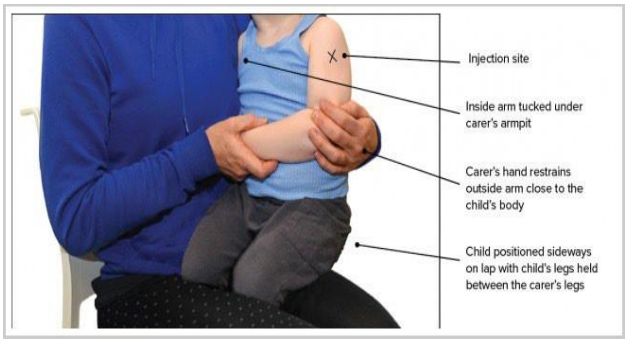
11.7 Positioning for vaccination

For younger/smaller children:
- The child sits on the parent/carer's lap or stands in front of them as they sit
- The parent/carer embraces the child during the process, holding both the child's arms as they do so both of the child's legs are anchored between the parent/carer's thighs



Source: Immunisation guidelines of the NIAC

Alternative positioning
- Sit child facing to the side. One arm is tucked under the parent/carer's armpit (A cuddle position)



Source: Australian Immunisation handbook

For older/bigger children
- It may be appropriate to ask the parent/carer and the child the preferred sitting position for vaccine administration
- They may prefer to sit on the parent/carer's lap or to sit independently

11.8 Techniques for vaccinating children
- Be honest and calm. Take time to explain in simple terms what to expect. Explain that the child may feel a little pinch and it will go away very quickly.
- Use words like "pressure" or "pinch" rather than "pain" or "shot"
- Distraction techniques can help in reducing pain and anxiety during vaccination. Keep the distraction going after the vaccine is given

- Looking at toys, books, etc.
- Pointing out interesting things in the room
- Telling or reading stories
- Taking deep breaths to help “blow out” the pain
- Counting to five backwards

What to do if the child does not want to be vaccinated

- Only one person should hold the child for vaccination at any time (to avoid risk of needle stick injury)
- If the child cannot be held/positioned by the parent/carer so that vaccination is possible, then the child should not be vaccinated
- Repeated attempts to vaccinate the child are unlikely to help
- Check with your clinical lead for advice
- It may be better to bring the child back another time
- With the parent if parent was not present.
- They may benefit from vaccination during quiet times

Prevention and Management of Syncope in Vaccination Clinics

- Syncope is rare in younger children, it is more common in adolescents
- Syncope episodes mostly occur within 15 minutes of vaccine administration
- Reassurance about the procedure may help to prevent fainting
- Recipients should be seated (or lying down - if past history of fainting) when being administered their vaccines in case of an immediate faint
- There should be facilities in place in case of fainting
- So that the person can be placed in a recumbent position/lie down or sit with head between knees for several minutes if lying down is not possible
- It may be helpful to loosen any tight clothing and apply cool, damp cloths to the person’s face and neck
- Further information is available on the www.immunisation.ie and at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/

11.9 Contraindications and precautions to COVID-19 vaccination

Of Note: For full list of contraindications and precautions to COVID-19 vaccines in children age 5-11 years see Table 5a.4 in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19
Of Note: For information on patients planning immunosuppressing therapy, please see section 5a.5.2 in chapter 5aof the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19
For further information see Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions www.rcpi.ie

11.10 Post-vaccination procedures

Documentation post vaccination

- Record vaccine batch number in the record/IT system
- It will automatically link to the expiry date, so there is no need to record the expiry date
- Boxes delivered by NCCS will be labelled with a Use before date and time
- **This use before date and time should be recorded in the patient record**
- Give record card to vaccinee or parent/guardian
- Give the post vaccination information leaflet to vaccinee and parent/guardian

Observation post-vaccination

- Vaccine recipients: 15 minutes of observation
- Those with a history of mastocytosis: 30 minutes of observation

- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

Advice following vaccination

- Give the parent/carer the after-care leaflet information
- Parent/carer should be advised that COVID-19 vaccines may cause a fever which usually resolves within 48 hours. This is a common, expected reaction and isolation and further investigation is not required unless COVID-19 is suspected
- If fever lasts for > 48 hours, or if other symptoms of COVID-19 are present, the person should self-isolate and seek medical advice
- Paracetamol or ibuprofen can be taken after vaccination if the child develops pain, fever or myalgia
- Advise the child's parent/carer that vaccinated children may still get infected and transmit the virus so they should continue to follow all current public health guidance to protect themselves and others
- Please refer to the NIAC immunisation guidelines available at https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

11.11 Adverse events

Of Note: For Adverse Events – Comirnaty LP.8.1 10 micrograms for those aged 5-11 years, please see section 5a.5.4.1 in chapter 5a of the NIAC Immunisation Guidelines

Of Note: Common adverse events are listed in section 5a.5.4.1and section 5a.5.4.2 (protein sub unit vaccines) in chapter 5a of the NIAC Immunisation guidelines. https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

A full list of adverse reactions may be found in the Summary of Product Characteristics (SmPC) on www.hpra.ie.

Myocarditis and pericarditis

Of Note: For further information on myocarditis and pericarditis, please see section 5a.4.2 (COVID-19 vaccine safety) in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19 Please see Summary of Product Characteristics (SmPC) for further information on www.hpra.ie

Reporting of adverse events following immunisation

Adverse Events Following Immunisation should be reported to the HPRA:
https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form

For further information, please see **section 11.3** of this document: Reporting adverse reactions

11.12 Clinical considerations

Vaccination after COVID-19

Of Note: For information on Vaccination after COVID-19, please see section 5a.5.1in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19
Co-administration with other vaccines

Of Note: For information on co-administration of COVID-19 vaccines with other vaccines please see section 5a.4.5 in chapter 5a NIAC Immunisation Guidelines https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

Children who are immunocompromised

Children with immunosuppression due to disease or treatment should be vaccinated if they have no contraindications.
Of Note: For further information on Immunocompromised children, please see section 5a.4.11 in chapter 5a of the NIAC Immunisation Guidelines https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

Of Note: For vaccination schedule recommendations, please see section 5a.5.2, and section 5a.5.4.1. (Comirnaty vaccines for those age 5-11 years) in chapter 5a of the NIAC Immunisation Guidelines https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

Vaccination of those with bleeding disorders or on anticoagulants

Of Note: For information regarding individuals taking anticoagulants, please see section 2.4.6 in chapter 2 of the NIAC Immunisation Guidelines https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

Of Note: Technique for IM injections in persons with bleeding disorders or on anticoagulants
For information regarding technique for IM injections in persons with bleeding disorders or on Anticoagulants, please see chapter 2 of the NIAC Immunisation Guidelines https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

12. Vaccination of children aged 6 months to 4 years:

The National Immunisation Advisory Committee advice that Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection is the preferred Covid-19 vaccine for those aged 6 months to 4 years

The vial has a YELLOW cap and the dose is 0.3 ml (3 microgram) **after dilution**.

12.1 NIAC recommendations

For information on those who have never been vaccinated against SARS-CoV-2 infection, please see Section 5a.5.1 in chapter 5a of the NIAC Immunisation Guidelines
OF NOTE: For the COVID-19 vaccination dosage and scheduling for those age 6 months to 4 years for Comirnaty LP.8.1 3 micrograms please see Table 3 above and Section 5a.5.1,
In chapter 5a NIAC Immunisation Guidelines. https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

12.2 Vaccine storage

- From delivery by the manufacturer to the NCCS the vaccine is stored at -90°C to -60°C.
- The vaccine is supplied to sites/clinics by the NCCS at +2°C to +8°C with a shelf life of up to 10 weeks. Vials should be stored in pharmaceutical fridge between +2°C to +8°C. The new “USE BEFORE “date and time is on the “HSE Scan me label” which has been affixed by the NCCS once vials are removed from ULT freezer. Do not refreeze vials. The vaccine in each multi-dose vial requires dilution with 1.1 ml of sodium chloride 0.9% solution for injection.
- Sodium chloride 0.9% solution for injection is supplied separately to the vaccine and should be stored at room temperature.
- Undiluted vials of Comirnaty LP.8.1 3 micrograms for 6 months to 4 years (Yellow Cap) have a shelf life of up to 10 weeks when between +2°C to +8°C. Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between +8 °C and +30 °C.
- After dilution, the vaccine must be kept at +2°C to +30°C and used within 12 hours, after which the vial must be discarded.

Summary of Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection

Title	Description
Type of vaccine	mRNA
Name of vaccines	Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection.
Constituents	((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol Trometamol Trometamol hydrochloride Sucrose Water for injections
Number of doses in each vial	After dilution 3 doses If more than 3 doses can be accurately withdrawn from a diluted vial, it is a valid dose.
Dilution	**Yes, dilute with sodium chloride 0.9% solution for injection (supplied separately).**
Latex	The vial stopper does not contain latex.
Preservatives	No
Dosage	0.3 ml
Number of doses required and interval between doses	Please see chapter 5a for further information. **https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19**

12.3 Vaccine dose

Comirnaty LP.8.1 vaccine for infants and children aged 6 months to 4 years contains a lower dose of antigen (3 micrograms per dose) than for other age groups. The dose of the diluted vaccine is 0.3 ml.

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 LP.8.1 10 micrograms.

Please see chapter 5a NIAC Immunisation Guidelines for further information.
https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

12.4 Prior to vaccination

- Check valid consent has been obtained from a parent of legal guardian.
- Check for contraindications or precautions

See later in this chapter and the NIAC Immunisation guidelines for COVID-19 available
https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

  -
- Vaccinators who are vaccinating using a medicines protocol should check vaccine recipient's eligibility under the protocol
- Check the interval when administering a second or third dose in the schedule for immunocompromised patients
- Explain the procedure
- Answer questions

- Maintain privacy and dignity

12.5 Consumables needed

Low dead-volume syringes and/or needles are recommended. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.

- For dilution- 3ml syringes should be used and needle (length and size) 25 mm ,23-25 gauge (21 gauge or narrower needle)
- For administration- 1ml syringes should be used and needle (length and size) 25 mm ,23-25 gauge

Ampoules of Sodium Chloride 0.9% Solution for Injection will also be required. You will need 1.1 ml of Sodium Chloride (0.9%) to dilute every vial

12.6 Infection prevention and control

- Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the "WHO five moments of hand hygiene" with emphasis on:
    - Before vaccine preparation
    - Before drawing up and administering the vaccine
    - Before and after each recipient contact
- It is not necessary to use gloves for vaccine injections, unless contact with potentially infectious body fluids is possible, or unless the health care worker has an infected lesion on the hand. If gloves are worn, they should be changed for each patient.
- If the skin at the injection site is visibly dirty it should be cleaned with soap and water. There is no need to use a disinfectant e.g. alcohol swabs.
- If an alcohol swab is used, injection should be delayed for ≥30 seconds, to ensure the alcohol will have evaporated.
- There is no need to routinely check temperature either at registration or before vaccination.
- All vaccinators should follow the Infection Prevention and Control (IPC) precautions and management in line with the latest National Clinical Guideline No. 30 (2023) Infection Prevention and Control (IPC), available at https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/
- Check Health Protection Surveillance Centre (HPSC) website for the latest guidance on infection prevention and control (IPC) for healthcare workers: https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/

12.7 Vaccine Dilution and Preparation for Administration

- Check "Use before" date and time on the vaccine box.
- Verify that the vial has a yellow plastic cap and the product name is Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection (infants and children 6 months to 4 years).
- If the vial has another product name on the label, or a different cap colour, please make reference to the Summary of Product Characteristics for that formulation.

Dilution

- Allow the vial to come to room temperature and gently invert it 10 times prior to dilution Do not shake.
- Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.
- Vaccine must be diluted in its original vial with **1.1 ml sodium chloride 9 mg/ml (0.9%) solution for injection**, using a 21 gauge or narrower needle and aseptic techniques.
- Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.1 ml air into the empty diluent syringe.
- Gently invert the diluted dispersion 10 times. Do not shake.

- The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
- The diluted vials should be marked with the appropriate **discard date and time**.
- After dilution, store at +2 ºC to +30 ºC and use within **12 hours**.
- Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

Preparation of 0.3 ml doses

- After dilution, the vial contains 1.58 ml from which **3 doses of 0.3 ml** can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw **0.3 ml** of Comirnaty LP.8.1 for infants and children aged 6 months to 4 years. Standard syringes and/or needles can be used in order to extract 3 doses from a single vial.
- 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.
- Discard any unused vaccine within 12 hours after dilution.

12.8 Vaccine administration

Method of IM Vaccine Administration

- Intramuscular injection technique is to be used
    - For infants aged 6 months to 11 months, the recommended injection site is the vastus lateralis muscle (anterolateral aspect of the thigh).
    - For children aged 1 year to 3 years of age, either the deltoid muscle or the vastus lateralis muscle (anterolateral aspect of the thigh) can be used as the injection site.
    - For children aged 3 years and older, the recommended injection site is the deltoid muscle.
- Dispose the syringe and the needle into the sharps bin
- Do not leave the empty vials unattended
- Dispose of the empty vials safely into a sharps bin
- Low dead space syringes and needles should be used if available in order to maximise the number of doses that can be drawn from the vial
- There should be no pooling of vaccine solution from different vials

<u>IM injection into the deltoid muscle</u>

- The light triangle in the below figure indicates the site for IM injection into the deltoid muscle. The upper border of the triangle is approximately two finger-breadths / 2.5cms below the acromion process and the apex is at the midpoint of the humerus.

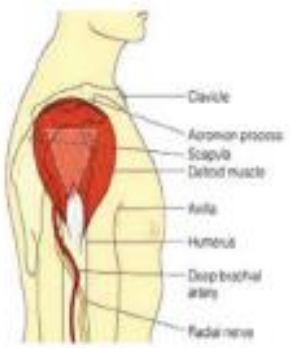


Figure 8: IM injection site into the deltoid muscle

IM injection site is the Vastus lateralis muscle

- The vastus lateralis muscle is located on the anterolateral aspect of the thigh, from one of the patient's hand breadths below the greater trochanter to one hand's breath above the knee. The middle third of the muscle is the site for injections. The width of the injection site extends from the mid-line of the thigh anteriorly to the mid-line of the outer thigh.
- The injection site is the middle third of the Vastus lateralis, in the anterolateral thigh (shaded area)

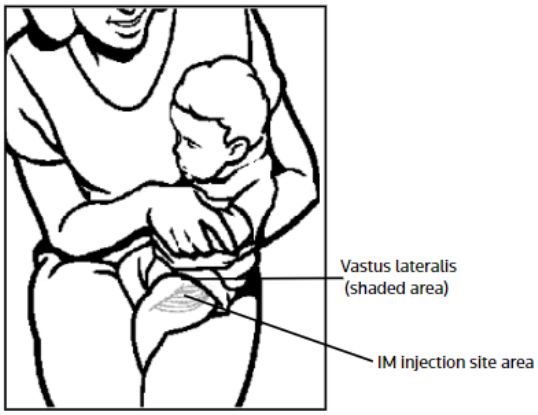


Figure 9: IM injection site into the middle third of the vastus lateralis

- At the injection site (whether using deltoid or vastus lateralis), spread the skin taut between the thumb and forefinger with the non-dominant hand. Do not bunch up the skin as this leads to administering the vaccine into subcutaneous tissue inadvertently.
- Further information is available at NIAC Immunisation Guidelines. Chapter 02. General immunisation procedures | Royal College of Physicians of Ireland (preservica.com)

Positioning for vaccination

For infants:

- Sit the infant on parent/guardian's lap, facing to the side.
- One arm is tucked under the parent/guardian's armpit (cuddle position). The infant's other arm is held in the parent/guardian's arms.
- Both of the infant's legs are anchored between the parent/guardian's thighs

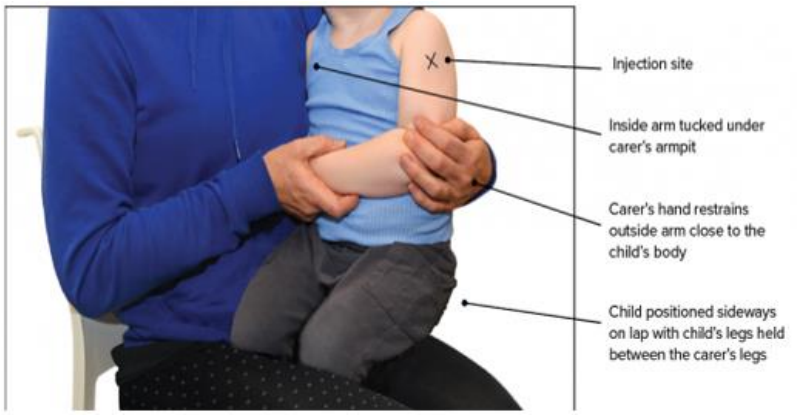


Figure 10: Postioning of infants (*Source: Australian Immunisation handbook)*

For older children:

- The child sits on the parent/guardian's lap or stands in front of them while the parent/guardian is sitting
- The parent/guardian embraces the child during the process, holding both the child's arms as they do so both of the child's legs are anchored between the parent/guardian's thighs
- Some children may prefer to sit on the guardian/parent's lap or sit independently
- Alternatively, the positioning for infants may also be used

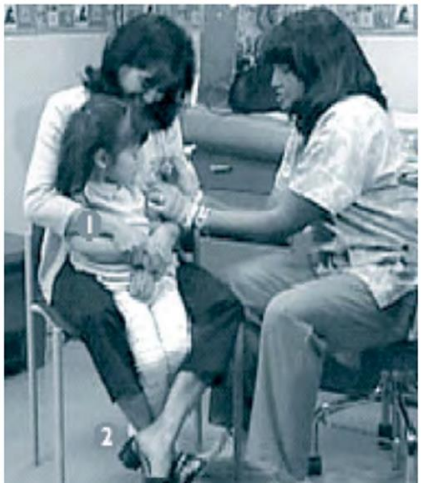


Figure 11: Positioning for older children (*Source: Immunisation Guidelines of the National Immunisation Advisory Committee)*

Techniques for vaccinating children

- Be honest and calm. Take time to explain in simple terms what to expect. Explain that the child may feel a little pinch and it will go away very quickly.
- Use words like "pressure" or "pinch" rather than "pain" or "shot"
- Distraction techniques can help in reducing pain and anxiety during vaccination. If possible, keep the distraction going after the vaccine is given.
    - Looking at toys, books, etc.
    - Pointing out interesting things in the room
    - Telling or reading stories
    - Taking deep breaths to help "blow out" the pain
    - Counting from 5 backwards

What to do if the child does not want to be vaccinated

- Only one person should hold the child for vaccination at any time (to minimise risk of needle stick injury)
- If the child cannot be held/positioned by the parent/carer so that vaccination is possible, then the child should not be vaccinated
- Repeated attempts to vaccinate the child are unlikely to help
- Check with your clinical lead for advice
- It may be better to bring the child back another time with a parent/guardian if they were not present
- They may benefit from vaccination during quiet times

Prevention and Management of Syncope in Vaccination Clinics

- Syncope is rare in babies and young children; it is more common in adolescents
- Syncope episodes mostly occur within 15 minutes of vaccine administration
- Reassurance about the procedure may help to prevent fainting
- Recipients should be seated (or lying down, if past history of fainting) when being administered their vaccines in case of an immediate faint
- There should be facilities in place in case of fainting
    - So that the patient can be placed in a recumbent position/lie down or sit with head between knees for several minutes if lying down is not possible
- It may be helpful to loosen any tight clothing and apply cool, damp cloths to the person's face and neck
- Further information is available at www.immunisation.ie and at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/

12.9 Contraindications and precautions to COVID-19 vaccination

Of Note: For full list of contraindications and precautions to COVID-19 vaccines in children age 6 months to 4 years see Table 5a.4 in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

12.9 Post-vaccination procedures

Documentation post-vaccination

- Record vaccine batch number in the record/IT system
    - It will automatically link to the expiry date, so there is no need to record the expiry date
- Boxes delivered by NCCS will be labelled with a "use before" date and time
- This "use before" date and time should be recorded in the patient record
- Give the record card to the parent/guardian

Observation post-vaccination

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

Advice following vaccination

- Parent/guardian should be advised that COVID-19 vaccines may cause a fever which usually resolves within 48 hours. This is a common, expected reaction and isolation and further investigation is not required unless COVID-19 is suspected.
- If fever lasts for >48 hours, or if other symptoms of COVID-19 are present, the person should self-isolate and seek medical advice
- Paracetamol or ibuprofen can be taken after vaccination if the child develops pain, fever, or myalgia

- Advise the child's parent/guardian that vaccinated children may still get infected and transmit the virus so they should continue to follow all current public health guidance to protect themselves and others
- Please refer to the NIAC immunisation guidelines available at **https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19**

12.10 Adverse events

Of Note: For information on adverse events for Comirnaty LP.8.1 3 micrograms vaccines for those aged 6 months to 4 years, please see section 5a.5.4.1 in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

A full list of adverse reactions may be found in the Summary of Product Characteristics (SmPC) on www.hpra.ie.

Myocarditis and pericarditis

Of Note: For further information on myocarditis and pericarditis, please see section 5a.4.2**and section 5a.5.4.1 (COVID-19 vaccine safety) in chapter 5a NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19**

Please see Summary of Product Characteristics (SmPC) for further information on www.hpra.ie

Reporting of adverse events following immunisation

Healthcare professionals are asked to report any suspected adverse reactions to the HPRA.
https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form

For further information, please see **section 12.3** of this document: Reporting adverse reactions

12.11 Clinical considerations

Vaccination after COVID-19

Of Note: For information on Vaccination after COVID-19, please see section 5a.5.1 in chapter 5a NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

Co-administration with other vaccines

Of Note: For information on co-administration of COVID-19 vaccines with other vaccines please see section 5a.4.5 in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

Children who are immunocompromised

Children with immunosuppression due to disease or treatment should be vaccinated if they have no contraindications. **Of Note: For further information on Immunocompromised children, please see section 5a.4.11 in chapter 5a of the NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19**

For vaccination schedule recommendations, including optimal and minimal intervals, please see section 5a.5.2 and table 5a.3 a in chapter 5a of the NIAC Immunisation Guidelines
https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19

Vaccination of those with bleeding disorders or on anticoagulants

Of Note: For information regarding individuals with bleeding disorders, please see section 2.4.6 in chapter 2 NIAC Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-02-general-immunisation-procedures

Useful links

- Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions https://www.rcpi.ie/Healthcare-Leadership/NIAC/Hot-topics-and-resources/Hot-topics-and-general-resources

- Immunisation Guidelines for Ireland: Chapter 5a COVID-19. **https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-05a-covid-19**procedures

- HSE Management of cold chain guidance (2-8°C) https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01fridge.pdf

- HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes. https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02box.pdf

- Licensed documentation for vaccines: Summary of Product Characteristics (SmPC) for health care professionals, and Package Leaflet (PL) for the public, available via the European Medicines Agency websites https://www.ema.europa.eu/en.

- Health Products Regulatory Authority. Human Medicines Adverse Reaction Report https://www.hpra.ie/homepage/about-us/report-an-issue/covid-19-vaccine-adverse-reaction

- National Clinical Guideline No. 30 (2023) Infection Prevention and Control (IPC), available at https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/

- The latest Health Protection Surveillance Centre (HPSC) guidance on infection prevention and control (IPC) for healthcare workers: https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/