



Master medicine protocol for the administration of Comirnaty LP.8.1 30 micrograms/dose dispersion for injection COVID-19 mRNA vaccine (to vaccine recipients aged 12 years and older)

This medicine protocol is a specific written instruction for the administration of Comirnaty LP.8.1 30 micrograms/dose dispersion for injection, COVID-19 mRNA vaccine to vaccine recipients aged 12 years and older included in Statutory Instruments S.I. No 418 of 2025 by healthcare professionals in healthcare professions included in Statutory Instruments S.I. No. 245 of 2021 who are registered with their respective regulatory body. This medicine protocol is valid for the 2025/2026 HSE Winter Vaccination Programme. This medicine protocol enables the healthcare professionals described above who are employed in the voluntary and statutory services of the Health Service Executive (HSE) and who have undertaken the required education and training programmes to administer Comirnaty LP.8.1 30 micrograms/dose dispersion for injection, COVID-19 mRNA vaccine to vaccine recipients ages 12 years and older, with reference to guidelines and guidance from the National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SPC) for Comirnaty LP.8.1 30 micrograms/dose dispersion for injection as detailed by the European Medicines Agency (EMA).


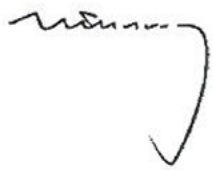
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* Online Update available at www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland
- HSE National Immunisation Office *Clinical Guidance for COVID-19 Vaccinations*, available at www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/cgc19.html
- Summary of Product Characteristics available at www.medicines.ie/medicines/comirnaty-lp-8-1-10-micrograms-dose-dispersion-for-injection-mdv-36532/spc

The Nursing and Midwifery Board of Ireland (NMBI) defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect.” (An Bord Altranais, 2007, page 35).

A medicine protocol is a nationally approved prescription for the supply and administration of a medicine as per above definition. The HSE Chief Clinical Officer and Director of National Health Protection have approved the use of medicine protocols by healthcare professionals listed in S.I. No. 245 of 2021 and S.I. No 418 of 2025. This medicine protocol is developed to facilitate the delivery of HSE winter vaccination programme 2025/2026 in line with NIAC recommendations endorsed by the Department of Health (DoH).



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Document reference number	Version 3-NIO - Comirnaty LP.8.1 30 micrograms/dose - August 2025
1.0 Critical elements	
Name of organisation and settings where medicine protocol applies	<p>Health Service Providers across the voluntary and statutory services of the HSE, non-HSE healthcare facilities, HSE mobile vaccination clinics and central vaccination centers.</p> <p>This Medicine Protocol applies to: Healthcare professionals who are registered with their respective regulatory body in healthcare professions included in S.I. No. 245 of 2021 and S.I. No 418 of 2025 who are registered with their regulatory body and have undertaken the required education and training programmes relevant to their professions...</p>
Date the medicine protocol comes into effect	September 2025
Date for review of medicine protocol	September 2026 (Regularly updated in line with the NIAC recommendations & DoH policy)
Document prepared by	HSE National Immunisation Office (NIO)
Names and Signatures of the employing authority who is authorising the implementation of the medicine protocol <i>"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"</i>	<p>Name: Dr. Éamonn O' Moore, Director of National Health Protection, HSE</p> <p> Signature:</p> <p>Name: Dr Colm Henry, Chief Clinical Officer, HSE</p> <p>Signature: </p>

2.0 Clinical Criteria	
Clinical condition for use of the medicine protocol	The clinical condition for which this medicine protocol has been developed is for the vaccination of vaccine recipients aged 12 years and older against COVID-19 (see Inclusion Criteria).
Circumstances in which the medicine protocol applies	Targeted immunisation programme for vaccine recipients aged 12 years and older against COVID-19 based on the NIAC recommendations endorsed by the Department of Health
Inclusion criteria for vaccine recipient using the medicine protocol	<p>Inclusion Criteria:</p> <p>Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older in line with NIAC Chapter 5a.</p> <p>A COVID-19 vaccine is recommended twice each year for:</p> <ul style="list-style-type: none"> Those aged 80 years and older (Table 5a.3) Those aged 18 to 79 years living in long term care facilities for older adults (Table 5a.3) Those aged 6 months and older with immunocompromise associated with a suboptimal response to vaccination (Table 5a.3). <p>A COVID-19 vaccine is recommended once each year for:</p> <ul style="list-style-type: none"> Those aged 60 to 79 years (Table 5a.3) Those aged 6 months to 59 years with medical conditions (Table 5a.1 and Table 5a.3) associated with a higher risk of COVID-19 hospitalisation, severe disease or death. <p>A COVID-19 vaccine is recommended in each pregnancy for:</p> <ul style="list-style-type: none"> Pregnant adolescents and adults with immunocompromise (Table 5a.3) Pregnant adolescents and adults with medical conditions (Table 5a.1 and Table 5a.3) associated with a higher risk of COVID-19 hospitalisation, severe disease or death. <p>Access to a COVID-19 vaccine once each year should be available for:</p> <ul style="list-style-type: none"> Healthcare workers* who chose to receive a vaccine Pregnant adolescents* and adults* who following discussion with a healthcare provider chose to receive a vaccine Adults aged 18 to 59 years* who following discussion with a healthcare provider choose to receive a vaccine. <p><i>*Healthcare workers, pregnant adolescents and adults and adults aged 18 to 59 years with immunocompromise or medical conditions should follow the recommendations in Table 5a.3.</i></p> <p>For those who have been vaccinated before, a COVID-19 vaccine if indicated, should be given six months following the last COVID-19 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). Therefore, there should be at least a 3 month interval from last infection or vaccine before getting vaccinated.</p> <p>For those who have never been vaccinated against SARS-CoV-2 infection, and in whom COVID-19 vaccination is indicated (as per groups above), a single dose of an mRNA COVID-19 vaccine is recommended for those aged 12 years and older except for those with immunocompromise associated with a suboptimal response to vaccination. Access to a COVID-19 vaccine should be available for all those aged 12 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 request vaccination.</p>
Precautions for individuals 12 years of age and older using this medicine protocol for administration of Comirnaty® LP.8.1 30 micrograms	<p>Precautions:</p> <ul style="list-style-type: none"> Acute severe illness: <ul style="list-style-type: none"> Defer until recovery. Recent mpox vaccine: <ul style="list-style-type: none"> 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.

	<ul style="list-style-type: none"> 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): <ul style="list-style-type: none"> Clarify if PEG is tolerated (see the Allergies FAQs) Discuss with allergist/immunologist Consider vaccination with non mRNA vaccine Observe for 30 minutes Previous history of myocarditis or pericarditis after any COVID-19 vaccine: <ul style="list-style-type: none"> Consult with Cardiologist Idiopathic Anaphylaxis or Anaphylaxis after food, venom or medication: <ul style="list-style-type: none"> Vaccinate as scheduled and observe for 15 minutes Mastocytosis: <ul style="list-style-type: none"> Vaccinate as scheduled and observe for 30 minutes Vaccination is not contraindicated for those with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM (intramuscular) injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopenia (platelet count $<50 \times 10^9/L$) consult the supervising consultant. See Chapter 2 of the Immunisation Guidelines of Ireland, sections 2.4.6 and 2.4.7 for information, including the technique for IM injection, in this patient group. Those with inherited coagulopathies receiving factor replacement therapy should be given IM vaccination within a few days after treatment See Chapter 2 of the Immunisation Guidelines of Ireland, sections 2.4.6 and 2.4.7 for information, including the technique for IM injection, in this patient group. <p>Co administration</p> <ul style="list-style-type: none"> COVID-19 vaccines and other adult vaccines may be administered at the same time or at any interval. Co-administered vaccines should be given in different limbs if possible. If administration in separate limbs is not feasible or desired, administration in the same limb, separated by at least 2.5cm, is appropriate COVID-19 and adult seasonal influenza vaccines should be co-administered where practicable, to maximise uptake. Vaccine recipients 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.
Exclusion criteria for vaccine recipient using the medicine protocol	<p>Comirnaty® LP.8.1 30 micrograms/dose COVID-19 mRNA vaccine should not be given under this medicine protocol if the vaccine recipient has:</p> <ul style="list-style-type: none"> Anaphylaxis after an mRNA vaccine Anaphylaxis after polyethylene glycol (PEG, e.g., some bowel preparations for endoscopy, certain laxatives such as Movicol) Anaphylaxis after trometamol Those with a contraindication to one mRNA COVID-19 vaccine should not receive another mRNA vaccine.
Actions to be taken for those who are excluded from the medicine protocol or who have a precaution	<ul style="list-style-type: none"> All individuals with precautions should be assessed by the vaccinator for suitability and if required referred to a specialist medical team for advice. All individuals meeting exclusion criteria must be referred to the relevant medical professional for an individual medical assessment. Document assessment in clinical notes/on NIIS system.

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	<ul style="list-style-type: none"> Where Comirnaty® LP.8.1 30 micrograms/dose concentrate for dispersion is prescribed following medical assessment, the vaccinator may administer the vaccine within his/her scope of practice <p>Note: In determining their scope of practice, vaccinators must make judgements about their competency to carry out a role or activity in accordance with the guidance from their regulator</p>
Action to be followed for vaccine recipients who do not wish to receive the vaccine	Advise of the risks of not having the vaccine, including risk of possible severe COVID-19 in those for whom the vaccine is recommended by NIAC.
Description of circumstances and referral arrangements when further advice or consultation is required	Refer to/discuss with relevant medical practitioner/clinical lead/lead vaccinator if the vaccine recipient had previous adverse reaction or other clinical concerns as outlined in exclusion criteria or precautions
Documentation required to support implementation of the medicine protocol	<ul style="list-style-type: none"> Check for and ensure consent has been obtained for all who receive the vaccine as per the HSE national consent policy Vaccine Information Leaflets NIIS record/ Patient held record cards <p>It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of Comirnaty LP.8.1 30 micrograms which includes the following:</p> <ul style="list-style-type: none"> <i>Medicine Protocol for the Administration of Comirnaty® LP.8.1 30 micrograms/dose concentrate COVID-19 mRNA vaccine to vaccine recipients aged 12 years and older</i> Please refer to Section B for registered nurses / midwives and <i>Self- Assessment of Competency Form</i> Anaphylaxis: Immediate Management in the Community. NIAC (2023), Immunisation Guidelines for Ireland. Chapter 5a COVID-19 from NIAC Immunisation Guidelines for Ireland HSE NIO Clinical Guidance for COVID-19 Vaccination
3.0 Name of Medicine and recommendations in line with the Immunisation Guidelines of Ireland	
Name of Medicine	<p>Comirnaty LP.8.1 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine</p> <p>Note: This vaccine <u>NOT</u> to be diluted (DO NOT DILUTE).</p> <p>Please check the SmPC for this vaccine preparation and administration available at https://www.medicines.ie/medicines/comirnaty-lp-8-1-30-micrograms-dose-dispersion-for-injection-mdv-36533/spc</p>
Dose & Route of administration	<ul style="list-style-type: none"> Dose: The dose is 0.3ml Route of administration: Intramuscular (IM) Site: The preferred site is the deltoid muscle Do not inject the vaccine intravascularly, subcutaneously or intradermally
Those who have never been vaccinated against SARS-CoV-2 infection, and in whom COVID-19 vaccination is indicated	<p>For those aged 12 years and older 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 except for those with immunocompromise associated with a suboptimal response to vaccination.</p> <p>Access to a COVID-19 vaccine should be available for all those aged 12 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 request vaccination.</p>

<p>Recommendations for individuals aged 12 years and older with immunocompromise</p>	<ul style="list-style-type: none"> • Individuals with immunocompromise due to disease or treatment may be vaccinated if they have no contraindications • Those with immunocompromise due to disease or treatment at the time of their COVID-19 vaccination may have suboptimal response to their vaccines • Two doses of an mRNA COVID-19 vaccine are recommended for those with immunocompromise if previously unvaccinated. There should be a four week interval between dose one and dose two. A third dose may be administered, eight weeks after the second dose, following instruction from a relevant specialist physician. A minimum interval of four weeks between the second and third dose may be used if there is urgency to achieve protection. • If the second dose is given more than four days before the minimum interval to a person with immunocompromise, this is not considered a valid dose. A further dose should be given at least eight weeks after the invalid dose. If a third dose (recommended for a person with immunocompromise), 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. • If a child with immunocompromise who has received an mRNA vaccine becomes 12 years of age before completion of the recommended schedule for five to 11 year olds, the schedule should be completed with the age appropriate dose of the currently available mRNA vaccine. If the interval between doses is longer than the recommended interval, the next dose should be given as soon as possible. The schedule does not need to be restarted. • If a previously vaccinated patient with planned immunosuppressant therapy has not received a COVID-19 vaccine in the six months prior to starting therapy, they should be offered a vaccine dose regardless of the time of year. • Those who have never been vaccinated against SARS-CoV-2 infection, with planned immunosuppressing therapy should ideally complete COVID-19 vaccination (one to three doses as indicated by their underlying condition), two weeks before beginning treatment, adhering to minimum intervals. • Those with immunocompromise, who have never been vaccinated against SARS-CoV-2 infection, who develop SARS-CoV-2 infection, should receive a first dose of a COVID-19 vaccine at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who were asymptomatic. Those with persisting symptoms following COVID-19 infection may be vaccinated, unless there is evidence of recent clinical deterioration. • Those with immunocompromise who develop 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, followed by a third dose if recommended by a relevant specialist physician. • Those with immunocompromise who develop SARS-CoV-2 infection more than seven days after the second vaccine dose, do not require a third dose. Those who have SARS-CoV-2 infection within seven days of their second dose should have a third dose after an interval of four to eight weeks, if a third dose is recommended by a relevant specialist physician.
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<p>Recommendations for pregnant adolescents and adults</p>	<p>One COVID-19 vaccine is recommended in each pregnancy for:</p> <ul style="list-style-type: none"> • Pregnant adolescents and adults with immunocompromise • Pregnant adolescents and adults with medical conditions and associated with a higher risk of COVID-19 hospitalisation, severe disease or death. <p>If a COVID-19 vaccine is given during pregnancy, it should be given at least six months after the previous dose of COVID-19 vaccine or SARS CoV-2 infection. A COVID-19 can be given at any stage of pregnancy but ideally should be given between 20 and 34 weeks' gestation.</p> <p>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 SARSCoV-2 infection.</p> <p>There will be some women and infants with additional risk factors such as those with certain high-risk pregnancies including those whose infant have an antenatal diagnosis of congenital heart or lung disease, who would benefit from vaccination more than others. COVID-19 vaccines should therefore be available year round for those who choose to receive it following a discussion with their healthcare provider.</p> <p>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.</p>
<p>Recommendations for Healthcare workers</p>	<p>Access to a COVID-19 vaccine once each year should be available for:</p> <ul style="list-style-type: none"> • Healthcare workers* who chose to receive a vaccine <p><i>Healthcare workers with immunocompromise or medical conditions should follow the recommendations in Table 5a.3</i></p>
<p>Link to medicine details of product information and other data including instructions for supply and administration is available from the European Medicines Agency (EMA)</p>	<p>Link to SmPC https://www.medicines.ie/medicines/comirnaty-lp-8-1-30-micrograms-dose-dispersion-for-injection-mdv-36533/spc and Patient Information Leaflet https://www.medicines.ie/medicines/comirnaty-lp-8-1-30-micrograms-dose-dispersion-for-injection-mdv-36533/patient-info#tabs</p>
<p>Potential adverse reactions and procedures for treatment of same</p>	<p>Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area for at least 15 minutes to allow monitoring of any immediate reaction including suspected anaphylactic reaction.</p> <p>The vaccine recipient /Parent/Legal Guardian should be advised to contact the relevant medical personnel in the event of an adverse reaction occurring following administration of the vaccine (General Practitioner (GP) /out of hours/Emergency Department) after the above period of observation.</p> <p>Reporting side effects The vaccine recipient's parent/legal guardian should be advised that they can report any side effects to the Health Products Regulatory Authority (HPRA) at www.hpra.ie .</p>
<p>Procedure for reporting adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)</p>	<p>The vaccinator should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting can be carried out online at http://www.hpra.ie.</p> <p>The vaccine recipients should be advised that they can also report any side effects to the Health Products Regulatory Authority (HPRA) at https://www.hpra.ie.</p> <p>The vaccine recipient's General Practitioner (GP) should be informed of any clinically significant reported adverse reactions.</p>



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	<p>In the event of anaphylactic reaction, the incident and all actions taken must be promptly recorded in accordance with the National Immunisation Advisory Committee (2023) <i>Anaphylaxis: Immediate Management in the Community</i> available at: https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland</p>
Procedure for the reporting and documentation of errors and near misses involving the medicine	<p>In the case of medication errors that directly involve the vaccine recipient, i.e. wrong medicine/dose/route being administered or another medicine error, the vaccinator must remain with the person and closely monitor them for any adverse reactions.</p> <p>Vital signs should be recorded and the vaccine recipient should be reviewed by the relevant medical practitioner/ clinical lead/lead vaccinator.</p> <p>The incident must be reported to the relevant line manager/person in charge as soon as possible.</p> <p>The incident and all actions taken must be promptly recorded and the relevant National Incident Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day, available online</p> <p>The patient must be informed of the incident. Further information can be found in the HSE Open Disclosure Policy 2025</p> <p>Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below and as per local policy.</p> <p>Any errors and near misses not involving medications (i.e. needle stick injuries etc.) the incident and all actions taken must be promptly recorded on the relevant National Incident Management Report form and forwarded to the relevant line manager.</p> <p>Refer to 'EMI Tool Kit'</p>
Resources and equipment required	<ul style="list-style-type: none">• Vaccine: Comirnaty LP.8.1 30 micrograms dispersion for injection COVID-19 mRNA Vaccine (Ready to use - Do not dilute)• Syringe and 23 gauge/25 gauge needle for IM administration• Fridge/cooler box with data logger with external temperature monitoring display to maintain cold chain temperature between +2° to +8°C• Disposable kidney dishes/trays• 70% alcohol swabs (for sterilizing vials)• Gauze swabs, tape/plasters• Sharps bins, and bins for the disposal of healthcare risk and non-risk waste• Alcohol hand sanitiser• Access to telephone• Resuscitation equipment and drugs in accordance with <i>Anaphylaxis: Immediate Management in the Community</i> (NIAC 2023) online• Safe storage areas for medicines and equipment• Current medicine protocol for the administration of Comirnaty LP.8.1 30 micrograms
Audit process to identify appropriate use of the medicine protocol or unexpected outcomes	<p>All documentation will be held for review and audit purposes as per local/national agreement.</p>

4.0 Information for vaccine recipient	
<p>Advice to be given to the vaccine recipient before and after vaccination</p>	<p>Vaccine Information material must be supplied to the vaccine recipient prior to administration of the vaccine.</p> <p>Before vaccination</p> <ul style="list-style-type: none"> • Check and confirm that informed consent has been obtained. • Discuss the Comirnaty LP.8.1 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine and the importance of protecting their health. • Inform vaccine recipient that patient information leaflet is available online at: https://www.medicines.ie/medicines/comirnaty-lp-8-1-30-micrograms-dose-dispersion-for-injection-mdv-36533/patient-info#tabs <p>Discuss common adverse events as listed below: A full list of and further details about adverse reactions may be found in the SmPC, available at: https://www.medicines.ie/medicines/comirnaty-lp-8-1-30-micrograms-dose-dispersion-for-injection-mdv-36533/patient-info#tabs</p> <p>Local: Very common: injection site pain and swelling Common: injection site redness</p> <p>General: Very common: arthralgia, chills, diarrhea, fatigue, headache, myalgia, pyrexia Common: nausea, vomiting</p> <p>Myocarditis and pericarditis Myocarditis and pericarditis are very rare side effects of mRNA vaccines, occurring predominantly after the second dose and in males under 30 years of age. 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.</p>
<p>Advice to be given to the vaccine recipient after treatment</p>	<p>After vaccination</p> <ul style="list-style-type: none"> • Discuss potential side effects and give advice how to manage common adverse reactions. • Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction. <p>NIAC recommends the following monitoring for the post-vaccination period:</p> <ul style="list-style-type: none"> • 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. <p>The vaccine recipient should not leave the healthcare facility if they are feeling unwell and must report any side effects to a member of the vaccination team.</p> <p>The vaccine recipient should be advised to report any side effects to the relevant medical practitioner.</p>



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	<p>If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g. paracetamol or ibuprofen-containing products) may be used. Ibuprofen is not recommended in pregnancy.</p> <p>If more serious adverse or persistent effects occur, vaccine recipient should be advised to contact their GP/out of hours service.</p> <p>Ensure the post vaccination advice is given</p>
Details of any necessary follow-up, action and referral arrangements	<p>In the event of an adverse reaction, the vaccination team must ensure that all procedures are adhered to as outlined in Section 3.</p>
5.0 Staff authorised to use this medicine protocol	
Professional qualifications, training and competence required prior to using this medicine protocol	<p>1) Be a registered healthcare professional, on the active register maintained by the relevant professional regulatory body in Ireland</p> <p>2) An approved <i>Basic Life Support for Health Care Providers Course</i> within the last two years (For e.g. Irish Heart Foundation (IHF), American Heart Association (AHA))</p> <p>3) Initial <i>National Anaphylaxis Education Programme for Health Care Professionals</i> accessible on www.HSELand.ie followed by a two-hour classroom based skills workshop. Recertification is required every two years by completing the on-line <i>National Anaphylaxis Education Programme for Health Care Professionals</i> accessible on www.HSELand.ie or the relevant anaphylaxis management programme approved by their professional organisation.</p> <p>4) mRNA COVID-19 Vaccine Formulations for people aged 12 years and older (recommendations and clinical considerations video for children aged 12 years+ and pharmacy storage and handling modules for the vaccine formulations) accessible on www.HSELand.ie</p> <p>5) <i>Storing and Managing Vaccines</i> accessible on www.HSELand.ie</p> <p>Note: In addition to the above, the vaccinator must complete the education, training, and self-assessment of competence requirements as recommended by their professional organisation /regulatory authority.</p> <p>Registered Nurses and Registered Midwives, Registered Physiotherapists, Radiographers, Radiation Therapists, Optometrists and Vaccinators registered with Pre-Hospital Emergency Care Council (PHECC) must read their Section B document specific to this medicine protocol and complete the Self-Assessment of Competency Form relevant to their profession.</p>



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References

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais

Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Registered Midwives on Medication Administration*. Dublin: Nursing and Midwifery Board of Ireland available at:
<https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020>

Health Service Executive (2022) Revised National Consent Policy 2022 V1
www.hse.ie/nationalconsentpolicy

Health Service Executive (2025) Open Disclosure Policy <https://www2.healthservice.hse.ie/files/220/>

National Immunisation Advisory Committee (2023) Anaphylaxis: Immediate Management in the Community. Available at
<https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland>

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

Chapter 5a National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*: available at
<https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland>

S.I. No. 245/2021 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020. Available at <https://www.irishstatutebook.ie/eli/2021/si/245/made/en/print>

S.I. No. - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020. Available at <https://www.irishstatutebook.ie>

Comirnaty LP.8.1 10 micrograms/dose concentrate for dispersion for injection
COVID-19 mRNA Vaccine SUMMARY OF PRODUCT CHARACTERISTICS
available at www.medicines.ie/medicines/comirnaty-lp-8-1-30-micrograms-dose-dispersion-for-injection-mdv-36533/spc