

## Medicine Protocol for the Administration of COVID-19 Vaccine Janssen® to Vaccine Recipients

This medicine protocol is a specific written instruction for the administration of COVID-19 Vaccine Janssen to vaccine recipients by healthcare professionals included in Statutory Instruments S.I. No. 698 of 2020, S.I. No. 81 of 2021 and S.I. No. 245 of 2021 who are registered with their respective regulatory body and students in healthcare professions included in S.I. No. 245 of 2021. This medicine protocol is valid for the 2021/2022 HSE COVID-19 Vaccination Programme. This medicine protocol enables the healthcare professionals and students described above employed in the voluntary and statutory services of the Health Service Executive (HSE) who have undertaken the required education and training programmes to administer COVID-19 Vaccine Janssen to vaccine recipients, 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 for COVID-19 Vaccine Janssen as detailed by the European Medicines Agency (EMA).



- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* Dublin: Royal College of Physicians Ireland (*Online Update available at <http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/>*)
- National Immunisation Office (2020) *Clinical Guidance for COVID-19 Vaccinations* <https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf>
- Summary of Product Characteristics <https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-janssen>

A medicine protocol has been defined as follows: written directions that allow for the supply and administration of a named medicinal product by specified healthcare professionals and students in identified clinical situations. A medicine protocol involves the authorisation of the healthcare professional or student 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.

The HSE has developed this medicines protocol to facilitate the delivery of COVID-19 immunisation in line with NIAC recommendations, Department of health (DoH) and HSE policy.

The professional groups and students using this protocol must ensure that the protocol is organisationally authorised by an appropriate authorising person, related to the professional or student cohort of vaccinators by whom the vaccine is to be administered, including requirements of registration, training and assessment of competency.

## Medicine Protocol for the Administration of COVID-19 Vaccine Janssen to vaccine recipients

<b>Document reference number:</b>	NIO 001.4
<b>1.0 Critical Elements</b>	
<b>Name of Organisation where medicine protocol applies</b>	Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE), non-HSE healthcare facilities and mass vaccination clinic venues. This Medicine Protocol applies to: Registered healthcare professionals included in S.I. 698, S.I. 81 and S.I. No. 245 employed in the voluntary and statutory services of the Health Service Executive (HSE) and students in healthcare professions included in S.I. No. 245 of 2021 who have undertaken the required education and training programmes.
<b>Date the medicine protocol comes into effect</b>	April 2021
<b>Date for review of medicine protocol</b>	April 2022
<b>Document prepared by:</b>	The National Immunisation Office (NIO)
<b>Names and Signatures of the employing authority who is authorising the implementation of the medicine protocol</b>  <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: <b>Dr. Lorraine Doherty</b>, National Clinical Director Health Protection, HSE</p> <p>Signature: </p> <p>Name: <b>Dr Colm Henry</b>, Chief Clinical Officer, HSE</p> <p>Signature: </p>

<b>2.0 Clinical Criteria</b>	
<b>Clinical Condition for use of the medicine protocol</b>	The clinical condition for which this medicine protocol has been developed is for the immunisation of vaccine recipients (see Inclusion Criteria) against COVID-19.
<b>Circumstances in which the medicine protocol applies</b>	Targeted immunisation programme for vaccine recipients against COVID-19 as identified in the DoH policy based on the NIAC recommendations. The World Health Organisation declared COVID-19 outbreak as a pandemic on 11th March 2020 which is still ongoing.
<b>Inclusion criteria for vaccine recipient using the medicine protocol</b>	<p><b>Inclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>● Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals aged <math>\geq 50</math> years.</li> <li>● In circumstances where a two-dose mRNA vaccination schedule is not a feasible alternative for those aged 18 – 49 years, the single dose COVID-19 vaccine Janssen® can be given/considered.</li> <li>● People aged 70 years and older should be offered an mRNA vaccine as this is Department of Health policy.</li> </ul> <p><b>Precautions:</b></p> <ul style="list-style-type: none"> <li>● Acute severe febrile illness defer until recovery</li> <li>● Advice from a relevant specialist should be sought for a person with a history of an immediate severe allergic reaction to any other vaccine or injectable therapy and the risks should be weighed against the benefits of vaccination. The patient should be observed for 30 minutes after vaccination.</li> <li>● Vaccination should be deferred until clinical recovery from COVID-19 at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic</li> <li>● Vaccination is not contraindicated for those with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration</li> <li>● 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 <math>&lt;50 \times 10^3/\text{ml}</math>) consult the supervising consultant</li> <li>● Those with inherited coagulopathies who require factor replacement therapy should receive it on the day of vaccination, prior to the IM vaccination. If there is uncertainty about the need for cover, contact the patient’s Comprehensive Care Centre</li> <li>● COVID-19 vaccines and other vaccines may be administered at the same time or at any interval. As it is not known if COVID-19 vaccine reactogenicity is increased with coadministration, vaccines should preferably be given in different limbs.</li> <li>● Patients with planned immunosuppressive therapy should ideally receive the vaccine two weeks before treatment.</li> </ul>

	<p><b>Pregnancy:</b> Pregnant women should be offered an mRNA vaccine (Comirnaty® or COVID-19 vaccine Moderna®)</p> <p><b>Breastfeeding:</b> There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping.</p>
<b>Exclusion criteria for vaccine recipient using the medicine protocol</b>	<p>COVID-19 Vaccine Janssen should not be given under this medicine protocol if the vaccine recipient has:</p> <ul style="list-style-type: none"> <li>● Past anaphylaxis (serious systemic allergic reaction requiring medical intervention) to any of its constituents (including polysorbate 80).</li> </ul>
<b>Actions to be taken for those who are excluded from the medicine protocol</b>	<ul style="list-style-type: none"> <li>● Refer to/discuss with the relevant Medical Practitioner/Clinical lead/Lead vaccinator for an individual medical assessment</li> <li>● Document action in clinical record or IT System</li> <li>● Where COVID-19 Vaccine Janssen is prescribed following medical assessment, the vaccinator may administer the vaccine within his/her scope of practice.</li> </ul> <p><b>Note:</b> 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>
<b>Action to be followed for vaccine recipients who do not wish to receive the vaccine</b>	<p>Advise of the risks of not having the vaccine, including risk of possible severe COVID-19 disease. Advise regarding minimisation of risk</p>
<b>Description of circumstances and referral arrangements when further advice or consultation is required</b>	<p>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.</p>
<b>Documentation required to support implementation of the medicine protocol</b>	<ul style="list-style-type: none"> <li>● Check for and ensure consent has been obtained</li> <li>● Vaccine Information Leaflets</li> <li>● Patient held record cards</li> <li>● Health Products Regulatory Authority Adverse Reaction Reporting forms</li> <li>● National Incident Management System Form NIRF-01-v11 available at: <a href="https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf">https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf</a></li> </ul> <p>It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of COVID-19 Vaccine Janssen which includes the following:</p> <ul style="list-style-type: none"> <li>● Medicine Protocol for the Administration of COVID-19 Vaccine Janssen to vaccine recipients</li> <li>● Treatment of anaphylaxis in the community. National Immunisation Advisory Committee, Immunisation Guidelines for Ireland. <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis">https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis</a></li> <li>● Clinical Guidance for Covid-19 Vaccination, available at <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf</a></li> <li>● COVID-19 chapter from NIAC immunisation Guidelines for Ireland (2020) available at <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf</a></li> </ul>

<b>3.0 Name of Medicine</b>	COVID-19 Vaccine Janssen
<b>Dose &amp; Route of administration</b>	<ul style="list-style-type: none"> <li>● The dose is 0.5ml</li> <li>● Route of administration: Intramuscular (IM)</li> <li>● Site: The preferred site is the deltoid muscle</li> <li>● Number of doses: One dose ONLY</li> <li>● Do not inject the vaccine intravascularly, subcutaneously or intradermally</li> </ul>
<b>Link to Medicine</b> <b>Details of product information and other data including instructions for supply and administration is available from the European Medicines Agency (EMA)</b>	<p><b>Link to Summary of Product Characteristics and Patient Information Leaflet</b></p> <p>Available at: <a href="https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf</a></p>
<b>Potential adverse reactions and procedures for treatment of same</b>	<p>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> <ul style="list-style-type: none"> <li>● Those with no history of anaphylaxis from any cause: 15 minutes</li> <li>● Those with a history of anaphylaxis from any cause: 30 minutes</li> <li>● Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated</li> </ul> <p>The vaccine recipient should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the COVID-19 Vaccine Janssen after the above period of observation.</p>
<b>Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)</b>	<p>The vaccinator should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out on line at <a href="http://www.hpra.ie">http://www.hpra.ie</a> or through use of the yellow card system which is available in a downloadable format from the HPRA website, or on request from the HPRA.</p> <p>The vaccine recipient's General Practitioner should be informed of any clinically significant reported adverse reaction.</p> <p>In the event of anaphylaxis, the incident and all actions taken must be promptly recorded in accordance with the Management of a Patient with Anaphylaxis: Treatment in the Community (National Immunisation Advisory Committee 2019), available online at <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf</a></p>
<b>Procedure for the reporting and documentation of errors and near misses involving the medicine</b>	<p>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 vaccine recipient should be reviewed by the relevant medical practitioner/clinical lead/lead vaccinator and vital signs should be recorded. 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 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 – V11)) (2020) available at: <a href="https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf">https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf</a> The vaccine recipient and/or significant others should be informed of the incident.</p> <p>An incident report form must be completed by the vaccinator and forwarded to local or regional Risk Manager as per local policy.</p> <p>Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.</p>
<p><b>Resources and equipment required</b></p>	<ul style="list-style-type: none"> <li>● A multidose vial of COVID-19 vaccine Janssen</li> <li>● 1 ml/2ml/2.5ml syringe, 23/25 gauge needle for IM administration</li> <li>● Fridge/Cooler box with data logger with external temperature monitoring display to maintain cold chain temperature between +2° to +8°C</li> <li>● Disposable kidney dishes/trays</li> <li>● 70% alcohol swabs (for sterilizing vials)</li> <li>● Gauze swabs, tape/plasters</li> <li>● Sharps bins, and bins for disposal of healthcare risk and non-risk waste</li> <li>● Alcohol hand sanitiser</li> <li>● Access to telephone</li> <li>● Resuscitation equipment and drugs in accordance with <i>Anaphylaxis: Treatment in the Community</i> (National Immunisation Advisory Committee, 2019) available at <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf</a></li> <li>● Safe storage areas for medicines and equipment</li> <li>● Current COVID-19 Vaccine Janssen medicine protocol</li> </ul>
<p><b>Audit process to identify appropriate use of the medicine protocol or unexpected outcomes</b></p>	<p>All documentation will be held for review and audit purposes as per local/national agreement.</p>
<p><b>4.0 Information for vaccine recipient</b></p>	
<p><b>Advice to be given to the vaccine recipient before treatment</b></p>	<p><b>Vaccine information material must be supplied with the consent form to the vaccine recipient prior to administration of the vaccine.</b></p> <p><b>Before Treatment</b></p> <p>Check and confirm that consent has been obtained</p> <p>Discuss the COVID-19 Vaccine Janssen and the importance of protecting their health. Inform vaccine recipient that patient information leaflet is available online at <a href="https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf">https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf</a></p> <p>Discuss potential side effects as below.</p> <p>Side effects may occur with following frequencies:</p> <p>Local:</p> <p>Very common: injection site pain</p> <p>Common: injection site erythema, swelling</p> <p>General:</p>

**Advice to be given to the recipient after treatment**

Very common: fatigue, headache, myalgia, nausea  
Common: arthralgia, chills, cough, pyrexia  
Uncommon: asthenia, back pain, hyperhidrosis, malaise, muscular weakness, oropharyngeal pain, pain in extremity, rash, sneezing, tremor  
Rare: hypersensitivity, urticaria  
Very rare: Thrombosis in combination with thrombocytopenia

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine Janssen®. This includes severe cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of these cases occurred within the first fourteen days following vaccination. Recipients of COVID-19 Vaccine Janssen® should be instructed to seek prompt medical assistance and mention recent vaccination if they have any of the following in the weeks after receiving COVID-19 Vaccine Janssen®

- breathlessness,
- pain in the chest or stomach,
- swelling or coldness in leg,
- severe or worsening headache or blurred vision after vaccination,
- persistent bleeding,
- multiple small bruises, reddish or purplish spots, or blood blisters under the skin

Additionally, anyone with neurological symptoms including severe or persistent headaches (particularly 3 or more days after vaccination) blurred vision, seizures or mental status changes or who develops petechiae or ecchymoses beyond the site of vaccination, should seek prompt medical attention

A full list of adverse reactions may be found in the Summary of Product Characteristics (SmPC), available at [https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf)

**After Treatment**

Discuss potential side effects

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.

Events of anaphylaxis have been reported therefore NIAC recommends the following monitoring for the post-vaccination period:

- Post vaccination observation period
- Those with no history of anaphylaxis from any cause: 15 minutes
- Those with a history of anaphylaxis from any cause: 30 minutes
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

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.

The vaccine recipient should be advised to report any side effects to the relevant medical practitioner.

If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g. paracetamol or ibuprofen-containing products) may be used.

If more serious adverse or persistent effects occur, vaccine recipient should be advised to contact their GP/out of hours service.

**Details of any necessary follow-up, action and referral arrangements**

In the event of an adverse reaction the vaccination team must ensure that all procedures are adhered to as outlined in Section 3.



## References

Health Service Executive (2010) *Healthcare Risk Waste Management Segregation Packaging and Storage Guidelines for healthcare Risk Waste*. Dublin: Health Service Executive.

National Immunisation Advisory Committee (2019) Anaphylaxis: Treatment in the Community. Available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf>

National Immunisation Advisory Committee *Immunisation Guidelines for Ireland (2020)* Dublin: Royal College of Physicians Ireland. Online update available at <http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/>

National Immunisation Office (2020) *Clinical Guidance for COVID-19 Vaccinations* (available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/>)

S.I. No. 81/2021 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No.4) Regulations 2021. Available at <http://www.irishstatutebook.ie/eli/2021/si/81/made/en/pdf>

S.I. No. 698/2020 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020. Available at <http://www.irishstatutebook.ie/eli/2020/si/698/made/en/pdf>