



# Clinical Practice Guidelines





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#### Version 4 – 23/12/2021

#### Introduction

As part of the national response to the COVID-19 pandemic, PHECC and the Medical Advisory Committee have acted to enable Practitioner administration of licensed COVID-19 vaccines in support of the National Vaccination Programme.

The administration of COVID-19 vaccines by PHECC Registered Practitioners is now permitted according to the specially created vaccination edition of the Clinical Practice Guidelines.

These CPGs permit PHECC Registered Practitioners who operate for Licensed CPG Providers to participate in the National Vaccination Programme.

This edition will be maintained separately to the general Clinical Practice Guidelines publication to enable the swift addition of further medications as they are approved for use.

As with all CPGs, PHECC Registered Practitioners are subject to the PHECC triple lock of licensing, credentialing, and privileging and the PHECC care principles.

All PHECC Registered Practitioners who participate in the vaccination process must complete training, as specified by the HSE, prior to conducting any vaccinations.

**Dr David Menzies, Chair Medical Advisory Committee** 

#### **SECTION 1 - Care Principles**

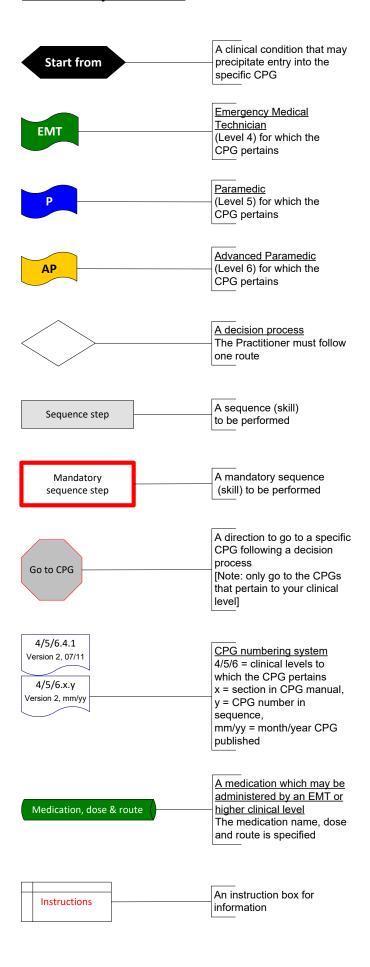
Care principles are goals of care that apply to all patients. Scene safety, standard precautions, patient assessment, primary and secondary surveys and the recording of interventions and medications on the Patient Care Report (PCR) or the Ambulatory Care Report (ACR), are consistent principles throughout the guidelines and reflect the practice of practitioners. Care principles are the foundations for risk management and the avoidance of error.

#### **PHECC Care Principles**

- 1. Ensure the safety of yourself, other emergency service personnel, your patients, and the public.
  - 1.1 Ensure correct PPE is utilised in all situations and is compliant with latest guidance on standard, contact, droplet and airborne PPE. Place facemasks on patients when required. Handwashing and hand hygiene should be performed before and after all patient interactions. Utilise PPE checklists for correct donning and doffing procedures.
- 2. A person has capacity in respect to clinical decisions affecting themselves unless the contrary is shown (Assisted Decision-Making (Capacity) Act 2015).
- 3. Seek consent prior to initiating interventions and/or administering medications.
- 4. Identify and manage life-threatening conditions.
- 5. Ensure adequate ventilation and oxygenation.
- 6. Optimise tissue perfusion.
- 7. Make a working diagnosis, after considering differential diagnoses.
- 8. Provide appropriate pain relief within the scope of practice. Painmanagement:
  - 8.1 should not delay the diagnosis of conditions or injuries,
  - 8.2 should be implemented for all relevant patients,
  - 8.3 should commence within ten minutes on scene,
  - 8.4 goal is to reduce pain to a tolerable level,
  - to take cognisance of immediate and short-term pain management requirements by administering appropriate combinations of analgesia.
- 9. Identify and manage other conditions.
- 10. Place the patient in the appropriate posture according to the presenting condition.
- 11. Ensure maintenance of normal body temperature (unless a CPG indicates otherwise).
- 12. Provide reassurance at all times.
- 13. Monitor and record patient's vital observations.
- 14. Maintain responsibility for patient care until handover to an appropriate practitioner.
- 15. Arrange transport to an appropriate medical facility if clinically required, and in an appropriate time frame.

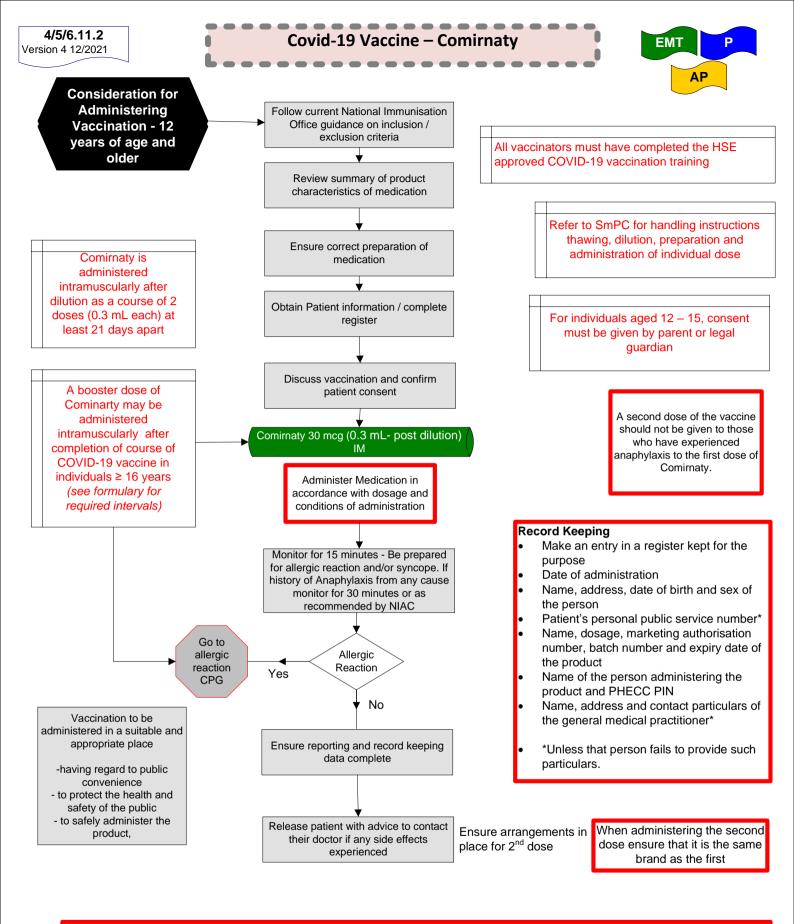
- 16. Complete a patient care record following an interaction with a patient.
- 17. Identify the clinical lead on scene; this shall be the most qualified practitioner on scene. In the absence of a more qualified practitioner, the practitioner providing care during transport shall be designated clinical lead as soon as practical.
- 18. Ambulances, medical rooms and equipment should be decontaminated as appropriate following an interaction with a patient.

#### **Codes Explanation**



# CLINICAL PRACTICE GUIDELINES FOR ADMINISTRATION OF:

- I) COMIRNATY
- II) JANSSEN
- III) SPIKEVAX (formerly MODERNA)
- ${f IV})$  VAXZEVRIA (formerly AstraZeneca)



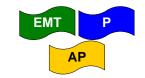
#### Reporting Requirements

Within 7 days of the administration, forward, by electronic means or otherwise, a copy of the particulars, entered in "the register" to the Health Service Executive

\*Unless that person fails to provide such particulars.

**4/5/6.11.3**Version 4 12/2021

# COVID-19 Vaccine Spikevax Dispersion for Injection COVID-19 mRNA Vaccine



Consideration for Administering Vaccination - 30 years of age and older

This vaccine is administered as a course of 2 doses (0.5 mL each) at least 28 days apart

A booster dose of
Spikevax 0.25 mL may be
administered
intramuscularly after
completion of course of
COVID-19 vaccine in
individuals ≥ 30 years (see
formulary for required
intervals)

Follow current National Immunisation Office guidance on inclusion / exclusion criteria

Review summary of product characteristics of medication

Ensure correct preparation of medication

Obtain Patient information / complete register

Discuss vaccination and confirm patient consent

COVID-19 Vaccine Spikevax 100mcg (0.5 mL) - IM

> Administer Medication in accordance with dosage and conditions of administration

Monitor for 15 minutes - Be prepared for allergic reaction and/or syncope. If history of Anaphylaxis from any cause monitor for 30 minutes or as recommended by NIAC

Allergic

Reaction

Vaccination to be administered in a suitable and

-having regard to public convenience

appropriate place

- to protect the health and safety of the public
- to safely administer the product,

Ensure reporting and record keeping data complete

Nο

Release patient with advice to contact their doctor if any side effects experienced All vaccinators must have completed the HSE approved COVID-19 vaccination training

This is a multi-dose vial which is ready for use once thawed. No further dilution is required

Refer to SmPC for handling instructions thawing, preparation and administration of individual dose

A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of COVID-19 Vaccine Spikevax

#### Record Keeping

- Make an entry in a register kept for the purpose
- Date of administration
- Name, address, date of birth and sex of the person
- Patient's personal public service number\*
- Name, dosage, marketing authorisation number, batch number and expiry date of the product
- Name of the person administering the product and PHECC PIN
- Name, address and contact particulars of the general medical practitioner\*
- \*Unless that person fails to provide such particulars.

Ensure arrangements in place for 2<sup>nd</sup> dose

When administering the second dose ensure that it is the same brand as the first

#### Reporting Requirements

Within 7 days of the administration, forward, by electronic means or otherwise, a copy of the particulars, entered in "the register" to the Health Service Executive

\*Unless that person fails to provide such particulars.

Go to

allergic

reaction

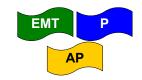
**CPG** 

Yes

Reference: SmPC as approved by the EMA – January 2021

**4/5/6.11.4** Version 2, 04/2021

COVID-19 Vaccine Vaxzevria suspension for Injection (formerly COVID-19 vaccine Astra Zeneca)
COVID-19 Vaccine (ChAdOx1-S [recombinant])



Consideration for Administering Vaccination - 18 years of age and older

This vaccine is administered as a course of 2 doses (0.5 mL each).

2<sup>nd</sup> dose **between 4 and 12 weeks (28 – 84 days)** 

Vaccination to be administered in a suitable and appropriate place

- -having regard to public convenience
- to protect the health and safety of the public
- to safely administer the product,

Follow current National Immunisation
Office guidance on inclusion /
exclusion criteria

Review summary of product characteristics of medication

Ensure correct preparation of medication

Obtain Patient information / complete register

Discuss vaccination and confirm patient consent

COVID-19 Vaccine AstraZeneca 0.5 mL - IM

> Administer Medication in accordance with dosage and conditions of administration

Monitor for 15 minutes - Be prepared for allergic reaction and/or syncope. If history of Anaphylaxis from any cause monitor foη 30 minutes

Go to allergic reaction CPG

Yes

Allergic Reaction

No

Ensure reporting and record keeping data complete

Release patient with advice to contact their doctor if any side effects experienced

All vaccinators must have completed the HSE approved COVID-19 vaccination training

A multi-dose vial which is ready for use. No further dilution required.

#### **Unopened/Unpierced vial**

- stable at 2°-8°C for 6 months

#### Opened vial

- (1) administration for no more than 48 hours at 2°-8°C
- (2) Vaccine may be kept and administered at <30°C for a single period for up to 6 hours. **Discard after time period has passed.**

Refer to SmPC for handling instructions, preparation and administration of individual dose

A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of COVID-19 Vaccine Vaxzevria

#### Record Keeping

- Make an entry in a register kept for the purpose
- Date of administration
- Name, address, date of birth and sex of the person
- Patient's personal public service number\*
- Name, dosage, marketing authorisation number, batch number and expiry date of the product
- Name of the person administering the product and PHECC PIN
- Name, address and contact particulars of the general medical practitioner\*
- \*Unless that person fails to provide such particulars.

Ensure arrangements in place for 2<sup>nd</sup> dose

When administering the second dose ensure that it is the same brand as the first

#### Reporting Requirements

Within 7 days of the administration, forward, by electronic means or otherwise, a copy of the particulars, entered in "the register" to the Health Service Executive

\*Unless that person fails to provide such particulars.

Version 1, 03/2021 **Consideration for** Administering Follow current National Immunisation Vaccination - 18 All vaccinators must have completed the HSE Office guidance on inclusion / exclusion criteria approved COVID-19 vaccination training years of age and older Review summary of product Single dose vaccine. characteristics of medication Unopened/Unpierced vial - stable at -25° to -15°C for 2 years. Once thawed, the vaccine should not be re-frozen. Ensure correct preparation of medication Opened vial (after first puncture of the vial) - preferable to use immediately -can be stored between 2°C - 8°C for a maximum of 6 hours or remain at room temperature (maximally Obtain Patient information / complete 25°C) up to 3 hours after first puncture of the vial. register Discard after time period has passed Discuss vaccination and confirm patient consent **COVID-19 Vaccine Janssen** Vaccination to be 0.5mL - IM administered in a suitable and Refer to SmPC for handling appropriate place instructions, preparation and administration of individual dose -having regard to public Administer Medication in convenience accordance with dosage and - to protect the health and conditions of administration safety of the public Record Keeping - to safely administer the product Make an entry in a register kept for the Monitor for 15 minutes - Be prepared purpose for allergic reaction and/or syncope. If Date of administration history of Anaphylaxis from any cause Name, address, date of birth and sex of monitor for 30 minutes the person Patient's personal public service number\* Go to Name, dosage, marketing authorisation allergic Allergic number, batch number and expiry date of reaction Reaction Yes the product **CPG** Name of the person administering the product and PHECC PIN No Name, address and contact particulars of the general medical practitioner\* Ensure reporting and record keeping data complete \*Unless that person fails to provide such particulars Release patient with advice to contact

**D-19 Vaccine Janssen** 

#### Reporting Requirements

4/5/6.11.5

Within 7 days of the administration, forward, by electronic means or otherwise, a copy of the particulars, entered in "the register" to the Health Service Executive

their doctor if any side effects experienced

\*Unless that person fails to provide such particulars

# APPENDIX:

I) MEDICATION FORMULARY





Medication	Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine		
Classification	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus		
Presentation	A multi-dose vial which must be diluted before use.		
	One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution - If it is not possible to withdraw 0.3mL for a 6th dose, the vial should be discarded. There should be no pooling of vaccine solution from different vials.		
	Concentrate for dispersion for injection (sterile concentrate).		
	Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles		
Administration	IM administration		
	Frozen vials should be transferred to an environment of 2°C to 8°C to thaw, where they remain stable for 5 days.		
	Allow the thawed vial to come to room temperature. Gently invert vial 10 times prior to dilution. <b>Do not shake</b>		
	The thawed vaccine must be diluted in its original vial with 1.8 mL Sodium Chloride 0.9%.		
	Gently invert the diluted dispersion 10 times. <b>Do not shake.</b>		
	Once diluted, the vaccine is stable for 6 hours at 2°C to 30°C.		
Indications	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus		
Contra-Indications	Hypersensitivity to the active substance or to any of the excipients.		
Usual Dosages	Adult Primary Immunisation schedule:		
	Administered intramuscularly after dilution as a course of 2 doses (0.3 mL each).		
	It is recommended to administer the second dose up to 28 days after the first dose.		
	(Timing since Covid-19 infection: 4 weeks)		
	The preferred site is the deltoid muscle of the upper arm.		
	Paediatric: Individuals 12 years of age and older		
	Administered intramuscularly after dilution as a primary course of 2 doses, at least 21 days		
	apart (0.3 mL each). (Timing since Covid-19 infection: 4 weeks)		
	Administration of booster doses Age ≥16 years		
	One single 0.3mL dose IM		
	Interval since finishing primary vaccination course or Timing since COVID-19		
	breakthrough infection		
	Refer to current HSE guidelines:     https://www.bso.io/opg/boolth/immunication/boolinfo/covid10vaccinoinfo/hps/c10bo		
	https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/c19bo oster/faqsbc19.html		
	Headache, Nausea, Arthralgia, Myalgia, Injection site pain, Fatigue, Pyrexia		
Side effects	Very rare cases of myocarditis and pericarditis have been observed following vaccination with Comirnaty		

#### Additional information

The diluted vaccine should present as an off-white dispersion with no particulates visible.

Discard the diluted vaccine if particulates or discolouration are present

Discard any unused vaccine within 6 hours after dilution

Do not inject the vaccine intravascularly, subcutaneously or intradermally.

#### Hypersensitivity and anaphylaxis:

Close observation for at least 15 minutes is recommended following vaccination. If history of Anaphylaxis from any cause monitor for 30 minutes.

For changes to recommended observation periods, refer to current HSE guidelines:

https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/c19booster/faqsbc19.html

All vaccinators must have completed the HSE approved COVID-19 vaccination training



EMT	P	AP

Medication	COVID-19 Vaccine Janssen suspension for Injection COVID-19 Vaccine (Ad26.COV2-S [recombinant])
Classification	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Presentation	Suspension for injection – colourless to slightly yellow, clear to very opalescent suspension.
	Each multi-dose vial contains 5 doses of 0.5 mL per 2.5 mL vial, which is ready for use. No
	further dilution is required. An additional overfill may be included in each vial. Do not pool
	excess from multiple vials.
	Each dose (0.5 mL) contains: Adenovirus type 26 encoding the SARS-CoV-2 spike
	glycoprotein* (Ad26.COV2-S), not less than 8.92 log10 infectious units (Inf.U).
Administration	IM administration
	Each multidose vial is ready for administration, no further dilution required.
	Unopened/Unpierced vial storage:
	-25°C to -15°C at expiry as indicated by manufacturer or 2°-8°C for 3 months (Record
	new expiry on outer packaging)
	Opened vial – Use immediately after first opening. Record date and time of opening vial or
	time vial should be discarded.
	- Chemical and physical in-use stability has been demonstrated for 6 hours at 2°- 8°C.
	Discard after this time period.
	- Product may be kept and administered at maximum 25°C for a single period for up to 3
	hours. Discard after this time period.
	- Prior to administration of a dose of vaccine, gently swirl the vial in an upright position
	for 10 seconds. <b>Do not shake.</b>
Indications	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Contra-Indications	Hypersensitivity to the active substance or to any of the excipients.
Usual Dosages	Adult:
	Covid-19 Vaccine Janssen is administered as a single-dose of 0.5 mL by intramuscular
	injection only. The preferred site is the deltoid muscle of the upper arm.
	Paediatric:
	Not Indicated
Side effects	Headache, Nausea, Cough, Arthralgia, Myalgia, Injection site erythema or swelling,
	Fatigue, Pyrexia, Chills, Tremor, Sneezing, Oropharyngeal pain, Rash, Hyperhidrosis,
	Muscular weakness, Pain in extremity, Back pain, Asthenia, Malaise.
Additional information	Discard the vaccine vial if particulates or discolouration are present prior to administration.
	Do not inject the vaccine intravascularly, intravenously, subcutaneously or intradermally.
	Hypersensitivity and anaphylaxis: Close observation for at least 15 minutes. If history of
	Anaphylaxis from any cause, monitor for 30 minutes.
	All vaccinators must have completed the HSE approved COVID-19 vaccination
	training



EMT	P	AP

Medication	Spikevax dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)
Classification	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Presentation	Dispersion for injection – white to off-white dispersion A multi-dose vial which is ready for use once thawed. No further dilution is required
	One 5 mL vial contains 10 doses of 100 mcg/0.5 mL mRNA each. An additional overfill is included to ensure 10 doses can be delivered.
Administration	IM administration
	Frozen storage: -25° to -15°C until expiry date
	(store in original carton to protect from light) Thaw each vial before use:
	2 hr 30min in refrigerator at 2°- 8°C     OR
	1 hr at room temperature 15°- 25°C
	Once thawed, maximum expiry of <i>unpunctured</i> vials:
	30 days refrigerator 2°- 8°C      40 has a selector and the result of the selector and
	12 hrs cool storage up to room temperature 8°- 25°C
	Swirl vial gently after thawing and before each withdrawal. (Do not shake or dilute) The withdrawn dose in the syringe should be administered immediately.
	After <b>first dose</b> has been withdrawn:
	Vial may be held between 2°- 25°C (refrigerator or room temperature)
	Record date and time on vial
	Discard punctured vial after 6 hours of first dose.
Indications	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Contra-Indications	Hypersensitivity to the active substance or to any of the excipients.
Usual Dosages	Adult ≥ 30 years :  • Administered intramuscularly as a course of 2 doses (100 mcg/0.5 mL mRNA
	each). It is recommended to administer the second dose not less than 28 days
	after the first dose.
	Timing since Covid-19 infection: 4 weeks
	The preferred site is the deltoid muscle of the upper arm.
	Administration of booster doses Age ≥30 years
	<ul> <li>A booster dose (0.25 mL, containing 50 micrograms mRNA, which is half of the primary dose) of Spikevax may be administered intramuscularly.</li> </ul>
	Interval since finishing primary vaccination course or Timing since COVID-19
	breakthrough infection
	Refer to current HSE guidelines: https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/c19booster/faqsbc19.html
Side effects	Headache, Nausea, Arthralgia, Myalgia, Injection site pain, Fatigue, Pyrexia, Chills, Fever, Very rare cases of myocarditis and pericarditis have been observed following vaccination

# Additional information

The dispersion for injection vaccine should present as an off-white dispersion with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present Discard any unused vaccine after 6 hours after withdrawal of first dose/ vial puncture. Do not inject the vaccine intravascularly, subcutaneously or intradermally.

#### Hypersensitivity and anaphylaxis:

Close observation for at least 15 minutes is recommended following vaccination. If history of Anaphylaxis from any cause monitor for 30 minutes.

For changes to recommended observation periods, refer to current HSE guidelines: https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/c19booster/faqsbc19.html

All vaccinators must have completed the HSE approved COVID-19 vaccination training



Medication	Vaxzevria suspension for injection (formerly COVID-19 vaccine Astra Zeneca) COVID-19 Vaccine (ChAdOx1-S [recombinant])
Classification	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Presentation	Suspension for injection – colourless to slightly brown, clear to slightly opaque.
	One dose (0.5 ml) contains: Chimpanzee Adenovirus encoding the SARS-CoV-2 Spike glycoprotein (ChAdOx1-S) * , not less than 2.5 × 108 infectious units (Inf.U)
	A multi-dose vial which is ready for use. No further dilution is required
	Multidose vials which contain 8 doses of 0.5ml per vial. (8 doses in 4ml vial) Multidose vials which contain 10 doses of 0.5ml per vial (10 doses in 5ml vial)
Administration	An additional overfill is included in each vial. Do not pool excess from multiple vials.
Administration	IM administration
	Each multidose vial is ready for administration, no further dilution required.
	Unopened/Unpierced – stable at 2°- 8°C for 6 months
	Opened vial – Use immediately after first opening. Record date and time of opening vial. Chemical and physical in-use stability has been demonstrated from the time of vial opening (first puncture) to administration for no more than 48 hours at 2°-8°C. Product may be kept and administered at <30°C for a single period for up to 6 hours. Discard after this time period.
Indications	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Contra-Indications	Hypersensitivity to the active substance or to any of the excipients.
Usual Dosages	Adult:
	Administered intramuscularly as a course of <b>2 separate doses of 0.5ml</b> each containing Chimpanzee Adenovirus encoding the SARS-CoV-2 Spike glycoprotein (ChAdOx1-S) *, not less than 2.5 × 108 infectious units (Inf.U).
	It is recommended to administer the second dose between 4 and 12 weeks (28 – 84 days) after the first dose. The preferred site is the deltoid muscle of the upper arm.
	Paediatric:
	Not Indicated
Side effects	Very common / common: Headache, Nausea, Arthralgia, Myalgia, Injection site pain, Fatigue, Pyrexia, Chills, Fever
	Very rare: Thrombosis in combination with thrombocytopenia
Additional information	The dispersion for injection vaccine should present as an colourless to slightly brown, clear to slightly opaque. Discard the diluted vaccine if particulates or discolouration are present Discard any unused vaccine after 6 hours at <30° (48 hours if 2°-8°C) after withdrawal of first dose/ vial puncture.  Do not inject the vaccine intravascularly, subcutaneously or intradermally.  Hypersensitivity and anaphylaxis: Close observation for at least 15 minutes. If history of Anaphylaxis from any cause monitor for 30 minutes. A second dose should not be administered to those who experience anaphylaxis from first dose.  All vaccinators must have completed the HSE approved COVID-19 vaccination training

Comirnaty concentrate	te for dispersion for injection		
COVID-19 mRNA Vaccine			
Heading	Add	Delete	
Usual Dosages		A booster dose (third dose) of	
		Comirnaty may be administered	
		intramuscularly at least 6 months	
		after the second dose in	
		individuals 18 years of age and	
		older	
	Adult Primary Immunisation schedule (new heading)		
	(Timing since Covid-19 infection: 4 weeks)		
	Administration of booster doses Age ≥16 years		
	One single 0.3mL dose IM		
	Interval since finishing primary vaccination course or Timing		
	since COVID-19 breakthrough infection		
	Refer to current HSE guidelines:		
	https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccin		
	einfo4hps/c19booster/faqsbc19.html		
Additional Information	For changes to recommended observation periods, refer to current		
	HSE guidelines:		
	https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccin		

einfo4hps/c19booster/faqsbc19.html

Spikevax dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)			
Heading	Add	Delete	
Medication			
Usual dosages		Paediatric: Individuals 12 years of age and older Administered as a course of 2 (two) 100 microgram doses (0.5 mL each). It is recommended to administer the second dose 28 days after the first dose	
	Adult ≥ 30 years		
	Timing since Covid-19 infection: 4 weeks		
	Interval since finishing primary vaccination course or Timing since COVID-19 breakthrough infection Refer to current HSE guidelines: <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/c19booster/faqsbc19.html">https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/c19booster/faqsbc19.html</a>		
Additional Information	Hypersensitivity and anaphylaxis: Close observation for at least 15 minutes is recommended following vaccination. If history of Anaphylaxis from any cause monitor for 30 minutes. For changes to recommended observation periods, refer to current HSE guidelines: <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/c19booster/faqsbc19.html">https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/c19booster/faqsbc19.html</a>		





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