



# Management of COVID-19 Vaccine Janssen®

## Guidance at vaccination Clinics

This document is under regular review and will be updated when relevant new information becomes available. Please check [www.immunisation.ie](http://www.immunisation.ie) for the current version.

### 1. Background

COVID-19 vaccine Janssen® was granted conditional marketing authorisation by the European Commission on 11<sup>th</sup> March 2021. <https://www.ema.europa.eu/en/medicines/human/EPAR/COVID-19-vaccine-janssen>

COVID-19 vaccine Janssen® will be delivered stored at -25°C to -15°C in freezers in the National Cold Chain Service (NCCS). Once removed from the freezers and transferred to fridge conditions of +2°C to +8°C, a label will be applied to the box with a “use before” date and time calculated at 3 months from removal from freezer. The box will be labelled prior to dispatch.

The site will take ownership of the vaccine stored at +2°C to +8°C upon delivery.

### 2. Responsibilities

It is the responsibility of the Responsible Person to ensure that this SOP is followed.

### 3. Scope

The scope of this document is to set a standardised protocol of procedures to be followed in the provision of the COVID-19 Vaccine Janssen®. Separate documents are available for other COVID-19 vaccines.

### 4. Purpose

The purpose of this document is to outline the management of the COVID-19 vaccine Janssen® at the vaccination clinic level, and to provide supporting guidance in relation to:

- Safe and temperature controlled storage
- Vaccines decommissioning
- Safe handling, including management of shelf life reduction processes following thawing and first puncture of the vial
- Stock reconciliation

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The document provided may be used as a template to be adapted for local use, or may be used as reference sources to check that existing local procedures are robust and comprehensive.

### 4.1 Safe and temperature controlled storage

Upon arrival at your vaccination centre:

- Read the temperature of the fridge/s
- Record maximum, minimum and current temperature
- Reset after recording

For additional information the following document may be consulted:

<https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf>

### 4.2 Vaccines decommissioning

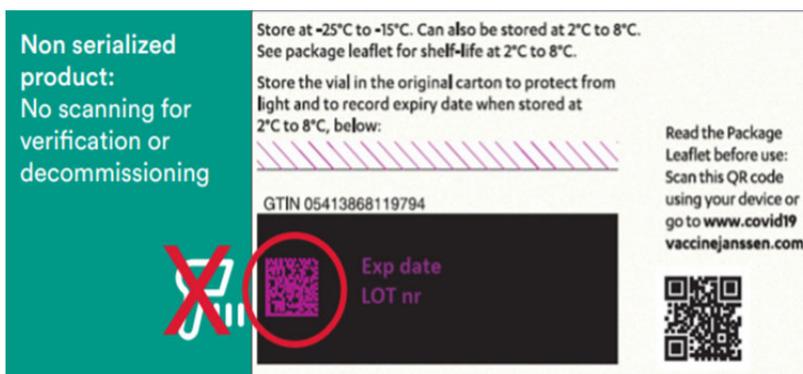
COVID-19 vaccines will be serialised and once the serialised boxes become available these boxes will require to be decommissioned. Decommissioning will be done by Hospitals and by Retail Pharmacies or by NCCS as per Article 23.

COVID-19 vaccines delivered to GPs, HSE locations including Vaccination Clinics will be decommissioned by the NCCS as these locations are exempt.

### 4.3 Safe handling, including management of shelf life reduction processes following thawing and first puncture of the vial

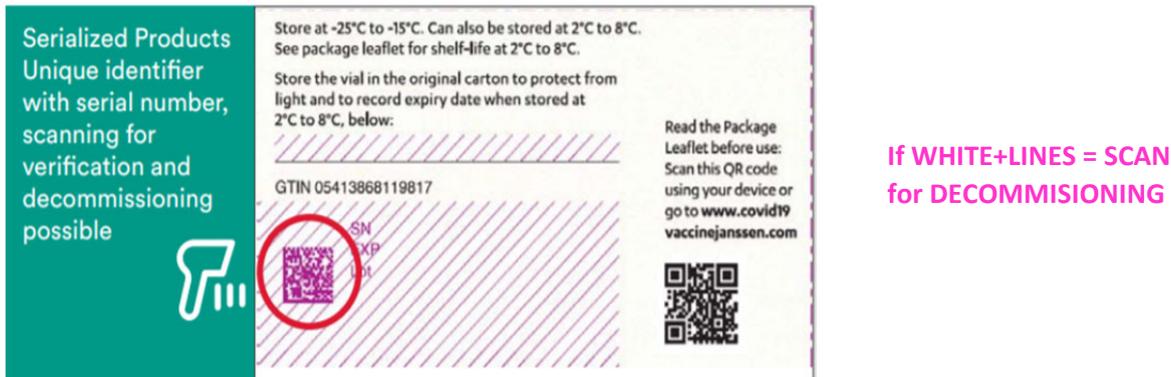
COVID-19 vaccine Janssen® comes as a multi dose vial (MDV) containing at least 5 doses. Boxes may contain 10 vials or 20 vials

Initially some boxes may not be serialised and therefore will not require to be decommissioned:



If BLACK = DO NOT SCAN  
for DECOMMISSIONING

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If boxes are NOT serialised (black rectangle) they will not need to be decommissioned. While if boxes are serialised (white with lines rectangle), they will need to be decommissioned.

The boxes must be checked to determine whether they are serialised and require decommission.

COVID-19 Janssen® will be delivered at temperature of +2°C to +8°C by NCCS.

Prior to delivery to vaccination sites by NCCS the boxes will have been thawed and stored at +2°C to +8°C. The NCCS will label the vaccine box with the new storage condition and **USE BEFORE date and time**: this is 3 months after thaw (and within original expiry date). This should be recorded in the patient record.

This “**USE BEFORE**” label will only be on the BOX.

Receipt delivery of stock and scan stock onto the system as you unpack the delivery.

Place the stock immediately in the fridge at a temperature of +2°C to +8°C. The vials should remain in their original box to be protected from light, for maximum of 3 months (and within original expiry date).

**Unopened** vials may be kept between +9°C and +25°C for up to 12 hours after which the product must be discarded. This is not recommended storage but may guide decisions for use in temporary temperature excursions.

**DISCARD date and time** must be recorded on the vial once the vial is initially **punctured**. This is calculated by adding 3 hours to the time of first puncture. During this 3 hour period the vaccine can be stored at room temperature of up to +25°C.

#### 4.4 Stock Reconciliation

It is a requirement that vaccines delivered are tracked and any vaccine “wastage” i.e. not used for any reason are accounted for.

COVID-19 Vaccine Janssen® Reconciliation Forms can be found at the links below. Please note they are editable PDF:

**GP form:** <https://www.hse.ie/eng/health/immunisation/hcpinfo/COVID19vaccineinfo4hps/janssen/janssen-vaccine-reconciliation-form-gp.pdf>

**Clinic form:** <https://www.hse.ie/eng/health/immunisation/hcpinfo/COVID19vaccineinfo4hps/janssen/janssen-vaccine-reconciliation-form-clinic-form.pdf>

### 5. Consumables, Patient Information Leaflet (PIL), Record Cards & other equipment

These will be delivered in advance by HSE in the required quantities to match the quantity of vaccine ordered/supplied. A national distribution service will purchase and deliver all necessary supplies, to handle, prepare, and administer the vaccine including PPE and critical clinical and non-clinical consumables. These are not included in this SOP.

- **Anaphylaxis Kits**

Refer to National Immunisation Advisory Committee Guidelines:

<https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf>

In the HSE central vaccination clinics settings, the epinephrine will be purchased and decommissioned by a pre-determined community/ hospital pharmacy as agreed by the lead governance organization CHO/HG.

- **Storage Equipment**

A pharmaceutical fridge must be used to store vaccines. The set point for the fridge temperature and alarms should take into account the need to maintain the temperature above +2°C to prevent freezing and remain less than +8°C. The temperature should be set to maintain +5°C +/- 3°C.

Fridges should be validated and monitored in accordance with existing local procedures

### 6. Stock control, Security & Monitoring of Wastage

A physical stock count of COVID-19 vaccine vials should be performed. In the HSE central vaccination clinics settings the physical stock count of the COVID-19 vaccine Janssen® should match the stock count recorded on the IT system.

Sites will need to ensure that vaccines are stored securely at all points between receipt and use and including disposal of vials.

Dispose empty vials after vial reconciliation, into sharps bins safely as per health care management policy. Dispose syringes and needles into sharps bins according to normal local waste management procedures.

Original cartons must have their labels defaced using permanent black marker pens, and placed into appropriate waste sack for incineration, as soon as possible after they become empty.

Records of vaccine dose reconciliation should be maintained at the site.

Any un-opened and unused vaccines vials must also be accounted for. A reconciliation form must be completed and submitted as per standard procedure and vials returned to NCCS following collection arrangements.

**7. Health & Safety**

There are no special handling requirements for routine handling of COVID-19 Vaccine Janssen®. Should a spillage occur this should be disinfected with an appropriate antiviral disinfectant (active on adenovirus).

Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.