Guidance on Moderna Vaccines

1. Available products/batches and their usages
2. Storage, handling, transportation
3. Reporting of adverse events and special situations

November 2022
Updated: January 2023

Note : This guidance may be subject to update and revisions

1. Available products & usages

- Volume received from Moderna in October 2022: **33,600 doses** of **3 different presentations / products**

SPIKEVAX is available in two presentations:

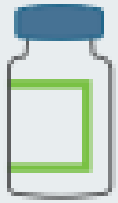
Red cap vial
SPIKEVAX
0.20 mg/mL
Multidose vial 5 mL

6,000 doses

Royal blue cap vial
SPIKEVAX
0.10 mg/mL
Multidose vial 2.5 mL

6,000 doses

SPIKEVAX Bivalent is available in one presentation:



Royal blue cap vial with green label
SPIKEVAX Bivalent Original / Omicron BA.1
0.10 mg/mL | multidose vial (2.5 mL)
Drug Identification Number (DIN): **02530252**

21,600 doses

1. Available products & usages

- Moderna Spikevax® COVID-19 vaccine

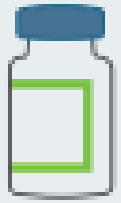
Red cap vial
SPIKEVAX
0.20 mg/mL
Multidose vial 5 mL

Royal blue cap vial
SPIKEVAX
0.10 mg/mL
Multidose vial 2.5 mL

	Age Range	Dose	Vial Presentation	Dose Volume
1 Primary Series SPIKEVAX is administered as a series of **2 doses**	≥12 years	100 mcg		**0.50 mL**
	6 to 11 years	50 mcg	OR	**0.50 mL** (OR **0.25 mL**)
2 Booster Dose	≥12 years	50 mcg	OR	**0.25 mL** OR **0.50 mL**

1. Available products & usages

- Moderna Spikevax® Bivalent (Original & Omicron BA.1)



Royal blue cap vial with green label
SPIKEVAX Bivalent Original / Omicron BA.1
0.10 mg/mL | multidose vial (2.5 mL)
Drug Identification Number (DIN): **02530252**

Booster Dose

A booster dose of 50 mcg may be administered intramuscularly **4 to 6 months after** completion of a primary series and/or a previous booster dose in individuals 12 years of age or older.

Age Range	Dose	Vial Presentation	Dose Volume
 ≥12 years	50 mcg		**0.50 mL**

Product currently approved by several Stringent Regulatory Authorities including Canada, EU, UK.

- For its delivery to the UN, Moderna is leveraging the Canadian marketing application

1. Available products & usages

- Recap and batch details

Product	Usage	Lot no.	Expiration	Doses
 **Red cap vial** SPIKEVAX 0.20 mg/mL Multidose vial 5 mL **Product expired**	Primary 12 yrs+ (2 doses) Booster 12 yrs+ (half-dose)	019D22A	27 Jan 2023	6,000
 **Royal blue cap vial** SPIKEVAX 0.10 mg/mL Multidose vial 2.5 mL	Primary 6-11 yrs (2 doses) Booster 12 yrs+	051F22A	01 May 2023	6,000
 **Royal blue cap vial with green label** SPIKEVAX Bivalent Original / Omicron BA.1 0.10 mg/mL | multidose vial (2.5 mL)	Booster 12 yrs+	AS5051C	21 Jun 2023	21,600

2. Storage, handling, transportation

Packaging, distribution

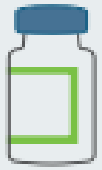
Red cap vial
SPIKEVAX
0.20 mg/mL
Multidose vial 5 mL

Expired
No longer available

- **10 full doses** (0.5mL) per vial
- Up to 20 booster doses (0.25mL) - **maximum 20 punctures**

Royal blue cap vial
SPIKEVAX
0.10 mg/mL
Multidose vial 2.5 mL

- **5 doses / boosters** (0.5mL) per vial



Royal blue cap vial with green label
SPIKEVAX Bivalent Original / Omicron BA.1
0.10 mg/mL | multidose vial (2.5 mL)

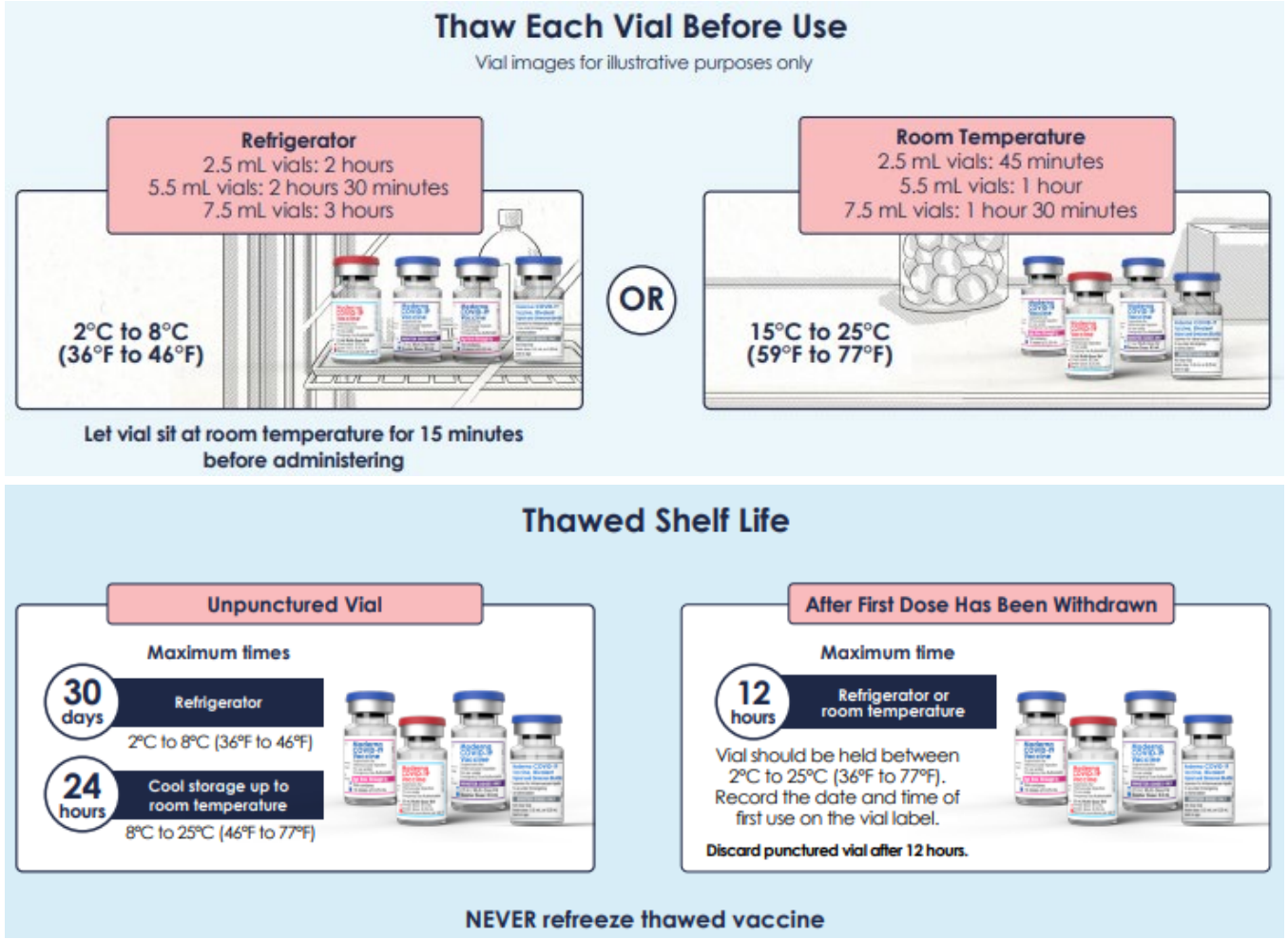
- **5 doses / boosters** (0.5mL) per vial

- Delivered in **cartons of 10 vials**
  - SPIKEVAX Red cap vials: **100 doses per carton**
  - SPIKEVAX Blue cap vials and SPIKEVAX Bivalent: **50 doses per carton**
  - Each country shipment is rounded up to the nearest carton

2. Storage, handling, transportation

Frozen Storage

- All Moderna COVID-19 Vaccine and Bivalent presentations can be stored and handled in a consistent way and can be **stored frozen until expiration date**
  - Store vials frozen **at -50°C to -15°C** until EXP date
  - Once thawed, store vials at 2°C to 8°C for up to 30 days from the day of thawing but not after EXP date



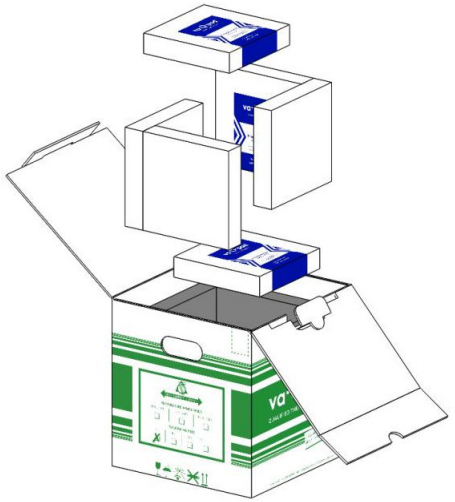
https://eua.modernatx.com/covid19vaccine-eua/providers/EUA_6+_Bivalent_Booster_StorageHandling.pdf

2. Storage, handling, transportation

Transportation

- Vaccine should be transported **in the frozen state at -50°C to -15°C**

- If transport at -50° to -15°C is not feasible, transportation of thawed vials for **up to 12 hours at 2° to 8°C is acceptable**
  - Use shipping containers qualified to maintain 2°C to 8°C
  - Vials cannot be re-frozen
  - Once thawed, **the 30-day count starts**



3. Reporting of Adverse Events & Special Situations

Contract with Moderna includes mandatory reporting of adverse events by UN to allow the manufacturer to comply with regulatory requirements

- **Non-Serious Adverse Event**: Event that typically is mild or moderate, short-lived, and self-limited. Examples of non-serious adverse events are local or general reactions such as pain at the site of injection, axillary swelling, redness, fatigue, headache and myalgia
  - UN will provide statistical listings to Moderna on a monthly basis, based on information **recorded in Everbridge**, including:
    - Date
    - Batch number
    - Patient age & sex
    - Description of the adverse event

3. Reporting of Adverse Events & Special Situations

Contract with Moderna includes mandatory reporting of adverse events by UN to allow the manufacturer to comply with regulatory requirements

- **Serious Adverse Event**[1]: A medically important event that requires medical intervention, may be life-threatening or disabling
  - Reported to Moderna **within 1 business day**
  - In case of an SAE: record in Everbridge & **email** covidvaccines@un.org **immediately** with a narrative description of the adverse event(s), including signs/symptoms, clinical course, and treatments with dates/timelines. Moderna may follow up later for additional information.

[1]**Full definition**: "Any untoward medical occurrence that results in death, is life-threatening (refers to an event in which the patient was at risk of death at the time of the event or reaction; does not refer to an event or reaction which hypothetically might have caused death if it were more severe), requires hospitalization, results in prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, is a medically important event or reaction (refers to an event that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above)."

3. Reporting of Special Situations & Special Situations

Reporting of pregnancy & breastfeeding cases, also a regulatory requirement on Moderna

- Anonymized data will be shared by the Programme on a regular basis, based on information entered in Everbridge

- Individuals who are pregnant or breastfeeding may consent to be contacted by Moderna for follow-up purposes
  - Consent is not a mandatory pre-requisite to receiving vaccination
  - If an individual consents to being contacted by Moderna, their email information should be provided to covidvaccines@un.org (please cc. the concerned individual)

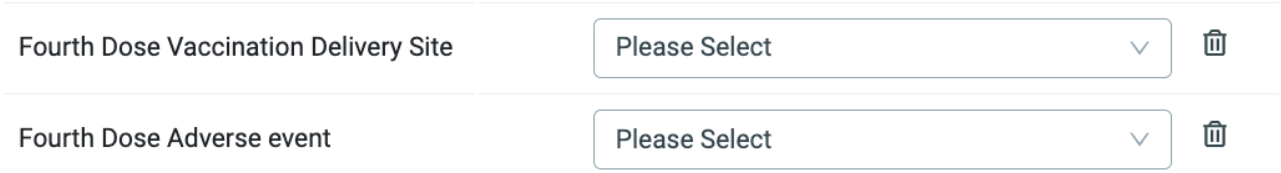
- Any other Special Situations (e.g. abuse or misuse, medication error or overdose, etc.) should be reported immediately via email to covidvaccines@un.org

3. Reporting of Special Situations & Special Situations

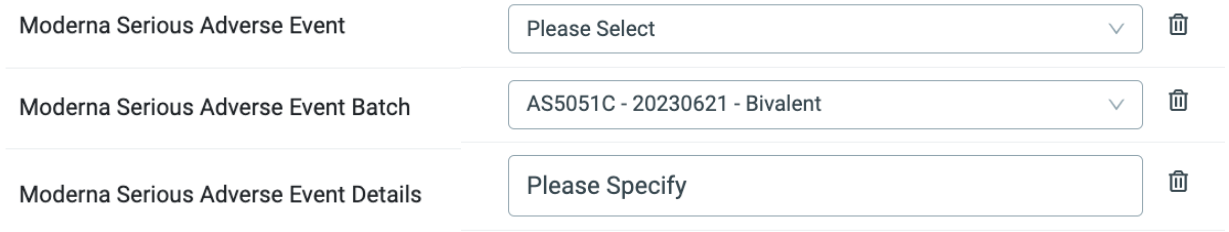
Recording in Everbridge

Adverse events

- All adverse events: use existing fields



- In case of a **serious adverse event**: also fill out newly created fields, specific to Moderna batches



Pregnancy / breastfeeding cases

- Already part of the screening questions