Respiratory Syncytial Virus (RSV) mRNA Vaccine
mRESVIA® Supplier: Moderna

INDICATIONS:[A]

- Individuals 75 years of age and older
- Indigenous (First Nations, Métis, and Inuit) individuals 60 years of age and older [B]

RECOMMENDED BY NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION BUT NOT PROVIDED FREE IN BC:

- Adults 65 to 74 years of age who are at increased risk of severe RSV disease
- Adults 18 years of age and older who:
  - are residents of nursing homes and other chronic care facilities
  - have had a lung transplant
  - have had a hematopoietic stem cell transplant (in the previous two years or who remain on immunosuppression)
  - are on home oxygen or require chronic oxygen therapy regardless of living at home or elsewhere
  - are receiving dialysis

This product is not approved for use in individuals under 18 years of age or in pregnancy.

DOSES AND SCHEDULE:

- 1 dose given as 0.5 mL **IM**.

ADMINISTRATION:

The vaccine is supplied as single dose 0.5 mL prefilled syringes (PFS).

Storage and Handling:

Storage:

- The vaccine (PFS format) can be stored:
  - Frozen between -40°C to -15°C until its labelled expiry date.
  - Refrigerated at +2°C to +8°C for up to 90 days from the date of transfer from frozen storage conditions. Ensure the vaccine carton has been updated to reflect the new expiry date.

Thawing:

- Frozen vaccine can be thawed in the refrigerator (+2°C to +8°C) or at room temperature (+15°C to +25°C). The time required to thaw the vaccine depends upon the thawing environment as indicated in the table below.

Thawing Times Based on Thawing Environment		
Thawing Environment	**Single PFS**	**Carton of 10 PFS**
Refrigerator (+2°C to +8°C)	1 hour 40 minutes	2 hours 40 minutes
Room Temperature (+15°C to +25°C)	40 minutes	1 hour 20 minutes

- **Do not refreeze thawed vaccine.**

[A] Individuals previously vaccinated with an RSV vaccine are not eligible for an additional dose as the boosting effects of subsequent doses are not yet clear.

[B] Indigenous peoples may be disproportionately affected by RSV because of longstanding inequities related to the intersecting structural and social determinants of health due to the impacts of settler colonialism.

Respiratory Syncytial Virus (RSV) mRNA Vaccine
mRESVIA® Supplier: Moderna

ADMINISTRATION (continued):

Use:

- The vaccine is a white to off-white dispersion. It may contain white or translucent product related particulates.
- Syringes should be visually inspected for foreign particulate matter and/or discoloration prior to administration. Do not use if either of these conditions exist.
- Pre-filled syringes may be stored at +8°C to +25°C for a total of 24 hours after removal from refrigerated conditions. Discard the pre-filled syringe if not used within this time.
- Do not shake.

BOOSTER DOSES:

No booster doses are recommended at this time.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

1. History of an anaphylactic reaction to a previous dose of any RSV vaccine or to any component of mRESVIA®.
2. Children less than 2 years of age due to an increased risk of severe and/or life-threatening RSV-enhanced respiratory disease reported in infants during a pediatric study.

PRODUCT COMPONENTS:

Potential allergens: 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG)

Other components: cholesterol; 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC); acetic acid; SM-102; sodium acetate trihydrate; sucrose; tromethamine (trometamol); tromethamine hydrochloride (trometamol hydrochloride).

PRECAUTIONS:

Not applicable.

SPECIAL CONSIDERATIONS:

- mRESVIA® can be administered concomitantly or at any time before or after the administration of other vaccines.
- At this time, no data are available on the safety and efficacy of mRESVIA® for immunocompromised individuals, including those receiving immunosuppressive therapy. These individuals may have a diminished immune response to mRESVIA®.
- The duration of protection of RSV vaccines is expected to be at least three years, however it is unclear if the protection offered by vaccination can be boosted by subsequent doses of vaccine.

ADVERSE EVENTS:

Local: pain, axillary lymphadenopathy, swelling, redness.

Systemic: fatigue, headache, myalgia, arthralgia, chills, nausea and vomiting, and fever.