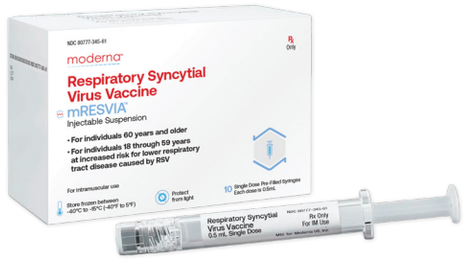
mRESVIA® (Respiratory Syncytial Virus Vaccine)

Product and Reimbursement Information



mRESVIA is the only ready-to-use RSV vaccine in a pre-filled syringe[1–3]

mRESVIA is ready to use once thawed to room temperature.[1]

Shipped Frozen

Frozen Storage (Stock)*

Store frozen at **-40 °C to -15 °C (-40 °F to 5 °F)**

Thawing From Frozen

Refrigeration Thaw Duration:
2 °C to 8 °C (36 °F to 46 °F)

- **Single syringe (removed from carton):** 100 minutes
- **Carton of 2 syringes:** 100 minutes
- **Carton of 10 syringes:** 160 minutes

OR

Room Temperature Thaw Duration:
15 °C to 25 °C (59 °F to 77 °F)

- **Single syringe (removed from carton):** 40 minutes
- **Carton of 2 syringes:** 40 minutes
- **Carton of 10 syringes:** 80 minutes

Storage After Thawing†

Refrigeration:
2 °C to 8 °C (36 °F to 46 °F)
Beyond use date: Must not exceed 90 days

OR

Room Temperature:
8 °C to 25 °C (46 °F to 77 °F)
Beyond use date: Must not exceed 24 hours

Preparing for Use

- Reconstitution is not required
- Remove the tip cap by twisting counterclockwise until the tip cap releases; avoid pulling the tip cap while twisting[4]
- The pre-filled syringe may contain an air bubble; however, priming is not required. Entire volume should be injected[4]
- Immunizer should select a needle of appropriate size and gauge for intramuscular injection
- Discard syringe after use

Transportation of Thawed Syringes at 2 °C to 8 °C (36 °F to 46 °F): Thawed pre-filled syringes can be transported at 2 °C to 8 °C (36 °F to 46 °F) in shipping containers qualified to maintain 2 °C to 8 °C (36 °F to 46 °F). Once thawed and transported at 2 °C to 8 °C (36 °F to 46 °F), pre-filled syringes should not be refrozen and should be stored at 2 °C to 8 °C (36 °F to 46 °F) until use, for up to 90 days.[1]

*During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.[1]
†After thawing, do not refreeze. Do not shake. Syringes should not be returned to the refrigerator after standing at room temperature.[1]

Dosing and Administration[1]

For intramuscular injection only.

Indication	Dose and Schedule
Individuals 60 years of age and older	**0.5 mL, single dose**
Individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV	**0.5 mL, single dose**

Product Identification and Diagnosis Codes

Type	Code	Description
NDC[1]	80777-345-63 (10-digit) | 80777-0345-63 (11-digit)	Paperboard tray carton of 2 pre-filled syringes
	80777-345-89 (10-digit) | 80777-0345-89 (11-digit)	Blister carton of 2 pre-filled syringes
	80777-345-61 (10-digit) | 80777-0345-61 (11-digit)	Paperboard tray carton of 10 pre-filled syringes
	80777-345-96 (10-digit) | 80777-0345-96 (11-digit)	Blister carton of 10 pre-filled syringes
	80777-345-01 (10-digit) | 80777-0345-01 (11-digit)	Pre-filled syringe
ICD-10-CM[5]	Z23	Encounter for immunization

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

References: 1. mRESVIA Prescribing Information. Moderna; 2025. **2.** AREXVY Prescribing Information. GlaxoSmithKline Biologics SA. **3.** ABRYSVO Product Information. Pfizer Inc. **4.** Data on file. Moderna, Inc.; 2024. **5.** ICD10Data.com. 2025 ICD-10-CM diagnosis code Z23. Accessed June 6, 2025. https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z20-Z29/Z23-/Z23

INDICATION

mRESVIA (Respiratory Syncytial Virus Vaccine) is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older and individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer mRESVIA to individuals with a history of severe allergic reaction (e.g., anaphylaxis) to any component of mRESVIA.

Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of mRESVIA.
- **Syncope:** Syncope (fainting) may occur in association with administration of injectable vaccines, including mRESVIA. Procedures should be in place to avoid injury from fainting.
- **Altered Immunocompetence:** Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to mRESVIA.

Adverse Reactions

In a clinical trial conducted in participants 60 years of age and older, the most commonly reported (≥10%) adverse reactions were injection-site pain (55.9%), fatigue (30.8%), headache (26.7%), myalgia (25.6%), arthralgia (21.7%), axillary (underarm) swelling or tenderness (15.2%) and chills (11.6%).

In a clinical trial conducted in participants 18 through 59 years of age at increased risk for LRTD caused by RSV, the most commonly reported (≥10%) adverse reactions were injection site pain (73.9%), fatigue (36.9%), headache (33.3%), myalgia (28.9%), arthralgia (22.7%), chills (19.9%), axillary (underarm) swelling or tenderness (17.1%), and nausea/vomiting (10.8%).

To report suspected adverse reactions, contact ModernaTX, Inc. at 1-866-663-3762 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

For Colorado and Connecticut price disclosure, please visit https://modernadirect.com/wac-disclosure.

Please scan or click the QR code or ask your representative for mRESVIA Full Prescribing Information.

moderna