# Respiratory Syncytial Virus Vaccine (mRNA)

**AHFS Class:** 80:12 — Vaccines (tofc-80)

# Respiratory Syncytial Virus Vaccine (mRNA) *(AHFS DI)*

**Respiratory Syncytial Virus Vaccine**

## Introduction

Respiratory syncytial virus (RSV) vaccine (mRNA) is a nucleoside modified mRNA vaccine that stimulates active immunity to RSV infection.[1,3]

## Uses

### ▪ Prevention of Lower Respiratory Tract Disease Caused by Respiratory Syncytial Virus (RSV)

RSV vaccine (mRNA) is used for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals ≥60 years of age.[1] RSV vaccine (mRNA) also is used for active immunization for the prevention of LRTD caused by RSV in adults 18 through 59 years of age who are at increased risk for LRTD caused by RSV.[1]

#### *Clinical Experience*

Efficacy and safety of RSV vaccine (mRNA) in older adults (≥60 years of age) are based principally on a single, randomized, placebo-controlled, multinational study (NCT05127434) in individuals ≥60 years of age with or without underlying medical conditions.[1,2] Individuals with LRTD risk factors (e.g., chronic obstructive pulmonary disease [COPD], asthma, chronic respiratory disease, diabetes, congestive heart failure [CHF], advanced liver disease, or advanced renal disease) were eligible to participate; patients with a history of myocarditis, pericarditis, or myopericarditis within 2 months prior to screening and those with autoimmune conditions requiring systemic immunosuppressants (except stable HIV-positive participants) were excluded.[1,2] The primary efficacy endpoints were the prevention of a first episode of RSV-LRTD with at least 2 signs or symptoms or with at least 3 signs or symptoms starting 14 days after vaccination.[1,2] The participant must have had RT-PCR-confirmed RSV infection and experienced new or worsening of at least 2 (or at least 3) of the following signs/symptoms for at least 24 hours: shortness of breath, cough and/or fever (≥37.8°C), wheezing and/or rales and/or rhonchi, sputum production, tachypnea (≥20 breaths per minute or increase of ≥2 breaths per minute from baseline measurement in those who had baseline tachypnea), hypoxemia (new oxygen saturation ≤93% or new or increasing use of supplemental oxygen), or pleuritic chest pain.[1] If signs/symptoms could not be captured, radiologic evidence of pneumonia with RT-PCR-confirmed RSV infection was also considered as RSV-LRTD.[1]

Participants were randomized to receive either a single dose of RSV vaccine (mRNA) or placebo.[1,2] The median age of participants was 67 years (range 60–96 years); 49.1% were female, 63.4% were white, 12.2% were Black, 8.7% were Asian, and 5.1% were American Indian or Alaska Native.[1] At baseline, 7% of patients had protocol-defined LRTD risk factors (CHF and/or COPD) and 29.5% had one or more comorbidities of interest (COPD, asthma, chronic respiratory disease, diabetes, CHF, advanced liver disease, or advanced renal disease).[1] The median duration of efficacy follow-up was 3.7 months (range 15 to 379 days) when at least 50% of targeted RSV-LRTD cases had accrued.[1]

A total of 17,561 individuals were included in the vaccine group and 17,503 individuals were included in the placebo group.[1] Both primary efficacy analyses met the predefined success criterion, with vaccine efficacy for prevention of 2 or more signs/symptoms reported as 78.7% and vaccine efficacy for prevention of 3 or more signs/symptoms reported as 80.9%.[1] An additional analysis of efficacy was performed after a median of 8.6 months when 94.2% of participants had reached 6 months of follow-up after vaccination; the same success criterion was met with vaccine efficacy for prevention of 2 or more signs/symptoms reported as 62.5% and vaccine efficacy for prevention of 3 or more signs/symptoms reported as 61.1%.[1]

The effectiveness of RSV vaccine (mRNA) in adults 18–59 years of age at increased risk of LRTD caused by RSV is based on a comparison of RSV neutralizing geometric mean titers (GMTs) and seroresponse rates between the evaluable immunogenicity population and a subset of participants 60 years of age or older in the placebo-controlled, multinational study described above.[1] Among the study population of adults 18–59 years of age, 57.2% had at least one chronic medical condition (COPD, asthma, chronic respiratory disease, diabetes, CHF, advanced liver disease, or advanced renal disease).[1] At day 29 after vaccination, individuals 18–59 years of age who received a single dose of RSV vaccine (mRNA) had similar neutralizing antibody titers and seroresponse rates compared with adults 60 years of age or older without comorbid conditions, meeting the noninferiority criteria.[1]

#### *Clinical Perspective*

RSV causes respiratory tract infections in individuals of all age groups.[3] In older adults, RSV is a common cause of LRTD that can lead to severe disease requiring hospitalization for respiratory support, including supplemental oxygen and/or mechanical ventilation.[2,3] Infection rates, ICU stays, and mortality are similar among older adults hospitalized with respiratory viral infections caused by RSV and influenza.[3] Severity of RSV disease increases with age and comorbidities (e.g., COPD, CHF, asthma).[2,3]

The US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommends that all adults ≥75 years of age receive a single dose of RSV vaccine.[8] ACIP also recommends that adults 50–74 years of age who are at increased risk of severe RSV disease receive a single dose of RSV vaccine.[15,16] Clinical considerations that place these adults at increased risk of severe RSV include chronic lung or respiratory disease, chronic cardiovascular disease,

moderate or severe immune compromise, diabetes mellitus with end-organ damage, severe obesity (BMI ≥40 kg/$m^2$), neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness, advanced chronic kidney disease, chronic liver disease, chronic hematologic disorders, residence in a nursing home, and other chronic medical conditions that a healthcare provider determines increases risk of severe disease due to respiratory infection.[8,] Additional clinical considerations may be published by the CDC as they become available.[15,] At this time, RSV vaccination is recommended as a single dose only; individuals who have already received RSV vaccination are not recommended to receive another dose.[15,]

The Center for Infectious Disease Research and Policy (CIDRAP) has established the Vaccine Integrity Project to provide evidence-based guidance on key immunizations for the upcoming respiratory season focusing on influenza, RSV, and COVID.[77,] The Vaccine Integrity Project is an initiative to safeguard vaccine use in the US and disseminate evidence-based information for informed decision-making.[77,] A multi-disciplinary group of experts has been convened to prepare recommendations for the upcoming 2025-2026 fall-winter respiratory season.[77,] CIDRAP will provide updates on the initiative's progress as they become available.[77,] For additional information see, https://www.cidrap.umn.edu/vaccine-integrity-project (https://www.cidrap.umn.edu/vaccine-integrity-project) .

# Dosage and Administration

## ▪ General

### *Dispensing and Administration Precautions*

Appropriate medications and supplies for managing allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following vaccine administration.[1,]

Syncope may occur following administration of injectable vaccines.[1,] Procedures should be in place to avoid injury from fainting; if syncope develops, patients should be observed until the symptoms resolve.[1,]

## ▪ Administration

Respiratory syncytial virus (RSV) vaccine (mRNA) should be administered *only* by IM injection.[1,]

### *IM Administration*

RSV vaccine (mRNA) is supplied in a prefilled syringe that contains a white- to off-white frozen suspension that must be thawed prior to administration.[1,] The syringes are supplied as a carton of 1 or 2 single-dose prefilled syringes or as a carton of 10 single-dose prefilled syringes.[1,]

Thaw each syringe before use, either in the refrigerator or at room temperature according to the manufacturer's instructions.[1,] Do not refreeze after thawing.[1,] Do not shake the syringe.[1,] Do not return the syringe to the refrigerator after standing at room temperature.[1,]

Store RSV vaccine (mRNA) frozen between -40 to -15°C prior to use.[1,] Prefilled syringes of the vaccine may be stored after thawing at 2-8°C for up to 90 days prior to use and at 8-25°C for a total of 24 hours after removal from refrigerated conditions.[1,] Discard the thawed prefilled syringe if not used within this time; total storage at 8-25°C must not exceed 24 hours.[1,] During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.[1,]

Thawed prefilled syringes may be transported at 2-8°C.[1,] Once prefilled syringes have been thawed and transported at this temperature, syringes should not be refrozen and should be stored at 2-8°C until use.[1,]

Before administration, visually inspect the suspension; it may contain visible white or translucent product-related particulates.[1,] Discard suspension if discoloration or other particulate matter is observed.[1,]

## ▪ Dosage

### *Adult Dosage*

#### Prevention of Lower Respiratory Tract Disease Caused by RSV in Older Adults.

For the prevention of lower respiratory tract disease caused by RSV in adults ≥60 years of age and adults 18-59 years of age at increased risk of RSV disease, a single 0.5 mL dose of RSV vaccine (mRNA) is administered by IM injection.[1,]

# Cautions

## ▪ Contraindications

History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.[1,]

## ▪ Warnings/Precautions

### *Preventing and Managing Allergic Vaccine Reactions*

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of respiratory syncytial virus (RSV) vaccine (mRNA).[1,]

### *Syncope*

Syncope (fainting) may occur in association with administration of injectable vaccines, including RSV vaccine (mRNA).[1,] Procedures should be in place to avoid injury from

fainting.[1,]

*Altered Immunocompetence*

Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to RSV vaccine (mRNA).[1,]

*Specific Populations*

Pregnancy.

RSV vaccine (mRNA) is not approved for use in persons <60 years of age.[1,] There are no human data to establish whether there is a vaccine-associated risk with use of RSV vaccine (mRNA) in pregnancy.[1,]

Lactation.

RSV vaccine (mRNA) is not approved for use in persons <60 years of age.[1,] It is not known whether the vaccine is distributed into human milk; no human or animal data are available to assess vaccine effects on the breastfed infant or on milk production.[1,] The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for vaccination and any potential adverse effects on the breastfed child from the vaccine or from the underlying maternal condition (the susceptibility to disease prevented by the vaccine).[1,]

Pediatric Use.

RSV vaccine (mRNA) is not approved for use in persons <18 years of age.[1,]

Geriatric Use.

RSV vaccine (mRNA) is approved for use in individuals ≥60 years of age.[1,] All individuals enrolled in the principal efficacy study were ≥60 years of age; 61.9% were 60-69, 30.1% were 70-79, and 7.9% were ≥80 years of age.[1,] Efficacy against RSV-related lower respiratory tract disease was 58.8% among participants 60 to 69 years of age and 78.0% among participants 70 to 79 years of age; insufficient cases were available to determine efficacy in patients ≥80 years of age.[1,]

### ▪ Common Adverse Effects

Commonly reported adverse reactions (≥10%) in individuals ≥60 years of age were injection-site pain, fatigue, headache, myalgia, arthralgia, axillary (underarm) swelling or tenderness, and chills.[1,]

Commonly reported (≥10%) adverse reactions in individuals 18 through 59 years who are at increased risk for LRTD caused by RSV were injection site pain, fatigue, headache, myalgia, arthralgia, chills, axillary (underarm) swelling or tenderness, and nausea/vomiting.[1,]

## Description

Respiratory syncytial virus (RSV) vaccine (mRNA) contains nucleoside modified mRNA, encoding the RSV F glycoprotein stabilized in the prefusion conformation (preF protein), that is encapsulated in lipid nanoparticles (LNPs).[1,3,]

The mechanism of action is based on delivery of the mRNA-LNPs into host cells to allow expression of the RSV preF protein.[1,3,] RSV F glycoprotein (in the pre-fusion, preF, conformation) mediates viral fusion and host-cell entry, elicits neutralizing antibodies, and is highly conserved across the 2 RSV subtypes (A and B).[3,] The vaccine elicits an immune response to the preF protein antigen, which protects against lower respiratory tract disease caused by RSV.[1,3,]

## Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from MedlinePlus (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus) (in English and Spanish; written at a 6th- to 8th-grade reading level).

Advise patients of the potential benefits and risks of respiratory syncytial virus (RSV) vaccine (mRNA).

Clinicians or individuals can report any adverse reactions that occur following vaccination to the Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 or https://vaers.hhs.gov/ (https://vaers.hhs.gov/) .

Advise patients to inform their clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs and dietary or herbal supplements, as well as any concomitant illnesses.[1,]

Advise patients to inform their clinician if they are or plan to become pregnant or plan to breast-feed.[1,]

Inform patients of other important precautionary information.[1,]

## Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for

informational purposes only. The manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

# Preparations

*Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.*

**Respiratory Syncytial Virus Vaccine (mRNA) (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Respiratory+Syncytial+Virus+Vaccine+%28mRNA%29&collapse=1)**

**Parenteral**

*Injectable suspension, for IM use only*

Each 0.5 mL contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation

**mRESVIA®** *(Supplied as a prefilled syringe that contains a frozen suspension)*, Moderna (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=LabelerName&ApptName=Moderna&collapse=1)

# Related Resources

AHFS Patient Medication Information (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)) and other related patient health topics (MedlinePlus)
ASHP Drug Shortages Resource Center (https://www.ashp.org/Drug-Shortages)
CCRIS (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+ccris:%%22Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)%%22) (Chemical Carcinogenesis Research Information System)
ChemID*plus* (https://chem.nlm.nih.gov/chemidplus/name/Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA))
Biochemical Data Summary (http://www.drugbank.ca/unearth/q?utf8=%%E2%%9C%%93&query=Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)&searcher=drugs&approved=1&vet_approved=1&nutraceutical=1&
(US and Canada)
Clinical Trials (https://www.clinicaltrials.gov/ct/search?submit=Search&term=Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA))
DailyMed (https://dailymed.nlm.nih.gov/dailymed/search.cfm?query=Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)) (drug labels)
DART (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+dart:%%22Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)%%22) (Developmental and Reproductive Toxicology Database)
Drugs@FDA (https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchType=BasicSearch&SearchTerm=Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)) (approval information)
European Medicines Agency (https://www.ema.europa.eu/en/search/search?search_api_views_fulltext=Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA))
FDA National Drug Code Directory (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)&collapse=1)
FDA Recalls, Market Withdrawals, and Safety Alerts (https://www.fda.gov/Safety/Recalls/default.htm)
HSDB (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:%%22Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)%%22) (Hazardous Substances Data Bank)
Inxight Drugs (https://drugs.ncats.io/substances?q=%%22Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)%%22) (National Center for Advancing Translational Sciences)
LactMed (drug effects on breastfeeding) (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+lactmed:@or+%%28@na+%%22Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)%%22+%%29)
New Drug Approvals (https://ahfs.ashp.org/drug-assignments.aspx)
Orange Book (https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?panel=0&drugname=Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)) (therapeutic equivalence)
PharmGKB (https://www.pharmgkb.org/search?connections&gaSearch=Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)&query=Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)&type=c
(Pharmacogenomic data from PharmGKB)
Pillbox (*beta*) (https://pillbox.nlm.nih.gov/pillimage/search_results.php?submit=Search&splid=&getingredient=Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)) (drug identification and images)
PubMed (https://www.ncbi.nlm.nih.gov/pubmed?DB=pubmed&term=Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)%%5BAll+Fields%%5D) (scientific journals)
Safety-related Labeling Changes (https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges) (FDA/CDER)
ToxLine (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+toxline:%%22Respiratory%20Syncytial%20Virus%20Vaccine%20(mRNA)%%22) (Toxicology Literature Online)

† Use is not currently included in the labeling approved by the US Food and Drug Administration.


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**About ASHP**
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**Contact Us**
ASHP
4500 East-West Highway, Suite 900
Bethesda, Maryland 20814

Customer Service
1-866-279-0681
custserv@ashp.org (mailto:custserv@ashp.org)
softwaresupport@ashp.org (mailto:softwaresupport@ashp.org)