RESPIRATORY SYNCYTIAL VIRUS VACCINE, ADJUVANTED

Respiratory Syncytial Virus Vaccine, Adjuvanted

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Introduction

Respiratory syncytial virus (RSV) vaccine, adjuvanted is a protein subunit vaccine that stimulates active immunity to RSV infection; the vaccine is a recombinant stabilized pre-fusion F protein (RSVpreF3) antigen with an $ASO1_E$ adjuvant (RSVpreF3-AS01).[1,2,8]

Uses

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

RSV PreF3-ASO1 is used for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals ≥60 years of age and in individuals 18–59 years of age who are at increased risk for LRTD caused by RSV.[1] RSV vaccine, adjuvanted is not indicated for use in pregnant individuals.[1]

Clinical Experience

Efficacy of RSV PreF3-ASO1 in adults ≥60 years of age is based principally on a randomized, placebo-controlled, observer-blinded, clinical study (NCT04886596) that was conducted in 17 countries from the Northern and Southern Hemispheres.[1,2] Data are available for up to 3 RSV seasons in this study.[1] Patients with medically stable chronic medical conditions (e.g., diabetes, hypertension, or cardiac disease) were allowed to participate; however, the study excluded patients who were immunocompromised due to disease or immunosuppressive treatments.[1,2] The primary vaccine efficacy endpoint was prevention of a first episode of confirmed RSV A- and/or B-associated LRTD during the first season.[1,2] Lower respiratory symptoms were defined as new or increased sputum, new or increased cough, new or increased dyspnea; lower respiratory signs were defined as new or increased wheezing, crackles/rhonchi, respiratory rate ≥20 respirations/minute, low or decreased oxygen saturation (O_2 saturation <95% or ≤90% if baseline is <95%), or need for oxygen supplementation.[1,2] LRTD was defined as at least 2 lower respiratory symptoms/signs, including at least 1 lower respiratory sign for at least 24 hours, or at least 3 lower respiratory symptoms for at least 24 hours.[1,2] A severe RSV-associated LRTD was defined as a PCR-confirmed RSV-associated LRTD with at least 2 lower respiratory signs, or preventing normal, everyday activities or requiring supportive therapy.[1]

Participants included in the study were randomized to receive either a single dose of RSV PreF3-ASO1 or placebo.[1,2] The median age of participants in the population evaluated for efficacy over the first RSV season was 69 years; 51.7% were female, 79.4% were white, 8.7% were Black, and 7.6% were Asian.[1] At baseline, 39.3% of participants had at least 1 comorbidity of interest; 19.7% of participants had an underlying cardiorespiratory condition (chronic obstructive pulmonary disease, asthma, any chronic respiratory/pulmonary disease, or chronic heart failure) and 25.8% of participants had endocrine and metabolic conditions (diabetes, advanced liver or renal disease).[1] Demographic and baseline characterstics among participants evaluated for efficacy over 2 and over 3 RSV seasons were similar to those evaluated over the first RSV season.[1] Participants were followed up to the end of the third RSV season (median follow-up of 30.6 months).[1,2]

Compared to placebo, RSV PreF3-ASO1 significantly reduced the risk of developing RSV-associated LRTD by 82.6% during the first RSV season in participants 60 years of age or older, which met the success criterion for the primary study objective; the vaccine also significantly reduced the risk of developing severe RSV-associated LRTD by 94.1% compared with placebo.[1,2] Vaccine efficacy against RSV A- and RSV B-associated LRTD cases was 84.6 and 80.9%, respectively.[1] Efficacy against RSV-related LRTD was 81% among participants 60 to 69 years of age and 93.8% among those 70 to 79 years of age; insufficient cases were available to reliably determine efficacy for patients ≥80 years of age.[2] In participants with at least 1 comorbidity of interest, vaccine efficacy over the first RSV season was 94.6%.[1] The study was not powered to estimate efficacy against hospitalization, severe RSV illness requiring respiratory support, or death.[2]

The efficacy analysis for RSV PreF3-ASO1 also included data up to the end of the second and third seasons in the Northern Hemisphere; participants 60 years of age or older who received a single dose of the RSV vaccine or placebo prior to season 1 were included in the cumulative analysis.[1] At a median follow-up of 17.8 months over 2 RSV seasons,

vaccine efficacy of 1 dose was 67.2%; at a median follow-up of 30.6 months over 3 RSV seasons, vaccine efficacy was 62.9%.[1,6] Vaccine efficacy over 2 RSV seasons was 65.4% among participants 60 to 69 years of age and 74.9% among those 70 to 79 years of age.[1] Vaccine efficacy over 3 RSV seasons was 60.3% among participants 60 to 69 years of age and 70.6% among those 70 to 79 years of age.[1] Insufficient cases were available to reliably determine efficacy for patients ≥80 years of age.[1] In participants with at least 1 comorbidity of interest, vaccine efficacy over 2 RSV seasons was 66.7% and vaccine efficacy over 3 RSV seasons was 64.7%.[1] Vaccine efficacy against severe RSV-associated LRTD was 78.8% over 2 RSV seasons and 67.4% over 3 RSV seasons in participants 60 years of age and older.[1] Vaccine efficacy against RSV-associated LRTD over the second RSV season was 56.1% with a median follow-up of 6.3 months and vaccine efficacy against RSV-associated LRTD over the third RSV season was 48% with a median follow-up of 7 months.[1]

The immunogenicity of RSV PreF3-ASO1 in adults 18 through 59 years of age at increased risk of LRTD caused by RSV was evaluated in 2 studies.[1] In the first study, individuals 50 through 59 years of age with certain underlying conditions were randomized to receive RSV PreF3-ASO1 or placebo.[1] In the second study, individuals 18 through 49 years of age with certain underlying conditions received a single dose of the vaccine.[1] Patients in these studies had an underlying chronic medical condition that increased their risk of severe RSV disease; these conditions included cardiopulmonary disorders, diabetes mellitus, chronic kidney disease, chronic liver disease, and nuerologic or neuromuscular conditions.[1] The effectiveness of RSV PreF3-ASO1 in both studies was assessed by a comparison of RSV neutralizing antibody responses induced by the vaccine in these age groups with the antibody responses induced by the vaccine in individuals 60 years of age and older at 1 month after vaccine administration.[1] The neutralizing antibody responses to RSV-A and RSV-B subtypes in individuals 50 through 59 years of age and individuals 18 through 49 years of age met the criteria for immunobridging; the difference in seroresponse rate was ≤10% for both RSV-A and RSV-B neutralizing titers, which demonstrated noninferiority to the response observed in adults 60 years of age and older.[1]

Clinical Perspective

RSV causes respiratory tract infections in individuals of all age groups.[3,4] 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.[4] Infection rates, intensive care unit (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., chronic obstructive pulmonary disease, congestive heart failure, asthma).[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 to prevent serious RSV infection and hospitalization.[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 or requiring treatment with insulin or a sodium-glucose cotransporter-2 (SGLT2) inhibitor, 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] There are 3 FDA-licensed RSV vaccines recommended for use in adults ≥50 years of age: CDC states there is no preference for which vaccine to use.[15] While FDA has approved RSV vaccines for use in adults 18-49 years of age at increased risk for RSV-associated lower respiratory tract infection, ACIP and CDC are continuing to review evidence for vaccination recommendations in this younger adult age group.[15] Eligible adults can receive an RSV vaccine at any time; however, the best time to vaccinate is in late summer and early fall before the start of the RSV season.[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 vaccines.[77] The Vaccine Integrity Project is an initiative dedicated to providing trusted, science-based information for informed vaccine choices.[77] A multi-disciplinary group of experts was convened by the Vaccine Integrity Project to independently review the available data on vaccine efficacy, effectiveness, and safety of COVID-19, influenza, and RSV immunizations for the 2025-2026 respiratory virus season.[77] A systematic review of 511 published studies (mostly observational) was conducted.[17] Results of the evidence review found that RSV vaccination (with RSV preF vaccine or RSV preF3-AS01 vaccine) in adults 60 years of age or older was associated with pooled vaccine effectiveness of 79% against hospitalization.[17,77] Among immunocompromised adults, vaccine effectiveness against hospitalization was 70-73%.[17,77] Effectiveness was higher among solid organ transplant recipients compared with hematopoietic stem cell transplant recipients.[17,77] There was limited information in younger adult age groups (18-59 years of age).[77] For additional information, see[Web] .

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.[1,5]

- Syncope may occur following administration of injectable vaccines.[1,5] Procedures should be in place to avoid injury from fainting; if syncope develops, patients should be observed until the symptoms resolve.[1,5]

■ Administration

IM Administration

Respiratory syncytial virus (RSV) vaccine, adjuvanted suspension for injection is administered only by IM injection.[1] IM injections should preferably be made into the deltoid muscle.[2,5]

The vaccine preparation is supplied as a single-dose vial of lyophilized antigen component to be reconstituted with a vial of adjuvant suspension component.[1] Prepare the vaccine by reconstituting the lyophilized antigen component (sterile white powder) with the accompanying adjuvant suspension component (opalescent, colorless to pale brownish sterile liquid).[1] Use only the supplied adjuvant suspension component for reconstitution.[1] Using aseptic technique, withdraw the entire contents of the vial containing the adjuvant suspension component (liquid) with a sterile needle and syringe.[1] Slowly transfer entire contents of the syringe into the lyophilized antigen component vial.[1] Gently swirl the vial until the powder is completely dissolved; do *not* shake vigorously.[1] The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid and should not be used if it is discolored or contains particulates.[1] After reconstitution, administer the vaccine immediately or store under refrigeration (2-8°C) or at room temperature (up to 25°C); protect from light and use within 4 hours.[1] Discard the reconstituted vaccine if not used within 4 hours.[1]

To administer a dose of the vaccine, withdraw 0.5 mL of reconstituted vaccine for IM injection.[1]

RSVpreF3-AS01 lyophilized antigen and adjuvant suspension component vials should be stored at 2–8°C in the original carton, protected from light, prior to use.[1] Do not freeze.[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 through 59 years of age at increased risk, a single 0.5 mL dose of RSVpreF3-AS01 should be administered by IM injection.[1]*

Cautions

■ Contraindications

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

■ Warnings/Precautions

Guillain-Barré Syndrome

Results of a postmarketing observational study suggest that the risk of Guillain-Barré syndrome (GBS) may be increased during the 42 days following vaccination with RSVpreF3-AS01.[1,10] The observational study used Medicare claims data to assess the risk of GBS following vaccination with the RSV vaccine in a self-controlled case series analysis using a risk window of 1 to 42 days post vaccination and control window of 43 to 90 days post vaccination.[1] An increased risk of GBS was observed during the 42 days following vaccination, with an incidence rate ratio of 2.46 and an estimated 7 excess cases of GBS per million doses administered to individuals 65 years of age and older.[1] Based on the totality of evidence including data from clinical trials, reports to the Vaccine Adverse Event Reporting System (VAERS), and the postmarketing study, FDA has determined that the current evidence suggests an increased risk of GBS with RSVpreF3-AS01, but the available evidence is insufficient to establish a causal relationship.[10]

Preventing and Managing Allergic Vaccine Reactions

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of RSVpreF3-AS01.[1]

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, including RSVpreF3-AS01.[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 RSVpreF3-AS01.[1]

Specific Populations

> #### Pregnancy
>
> *There are no data from clinical trials on the use of RSVpreF3-AS01 in pregnant individuals.[1]*
>
> *In a randomized, controlled trial that enrolled pregnant individuals, preterm births were higher in those who received an investigational unadjuvanted RSV vaccine that contained the same RSVPreF3 antigen as RSVpreF3-AS01 compared with those who received placebo.[1] The available data are insufficient to determine a causal relationship between preterm birth and RSVpreF3-AS01.[1]*
>
> *In an animal reproduction study, no adverse effects on female fertility or pre-weaning development up to postnatal day 35 were observed following IM administration of RSVpreF3-AS01 to female rabbits prior to mating and during gestation.[1]*

> #### Lactation

> *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
>
> *Evidence from animal models strongly suggests that RSVpreF3-AS01 is unsafe in children <2 years of age because of an increased risk of enhanced respiratory disease.[1] Safety and effectiveness of the vaccine in individuals 2 to 17 years of age have not been established.[1]*

> ### Geriatric Use
>
> *In the principal efficacy study, 55.8% of patients were 60-69 years of age, 36% were 70-79 years of age, and 8.2% were ≥80 years of age.[1,2] Efficacy against RSV-related lower respiratory tract disease was 81% among participants 60 to 69 years of age and 93.8% 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

The most common adverse reactions occurring in ≥10% of individuals 60 years of age and older receiving RSVpreF3-AS01d were injection site pain, fatigue, myalgia, headache, and arthralgia.[1]

The most common adverse reactions occurring in ≥10% of individuals 50 through 59 years of age receiving RSVpreF3-AS01 were injection site pain, fatigue, myalgia, headache, arthralgia, erythema, and swelling.[1]

The most common adverse reactions occurring in ≥10% of individuals 18–49 years of age receiving RSVpreF3-AS01 were injection site pain, myalgia, fatigue, headache, and arthralgia.[1]

Drug Interactions

■ Influenza Vaccine

In open-label studies, participants received a single dose of RSVpreF3-AS01 (Arexvy®) and quadrivalent influenza virus vaccine inactivated (Fluarix®) simultaneously or separated by 1 month.[1] There was no evidence of interference in the immune response to any of the antigens contained in both concomitantly administered vaccines.[1]

Description

Respiratory syncytial virus vaccine, adjuvanted (RSVpreF3-AS01) is a recombinant RSV glycoprotein F stabilized in pre-fusion conformation (RSVPreF3) with $AS01_E$ adjuvant.[1] The $AS01_E$-based adjuvant is composed of 3-*O*-desacyl-4'-monophosphoryl lipid A (MPL) from *Salmonella minnesota* and QS-21, a saponin purified from plant extract *Quillaja saponaria* Molina, combined in a liposomal formulation.[1]

RSVpreF3-AS01 stimulates an immune response against RSVPreF3 to protect against lower respiratory tract disease (LRTD) caused by RSV.[1] RSV F glycoprotein (pre-fusion and post-fusion) mediates viral fusion and host-cell entry, elicits neutralizing antibodies, and is highly conserved across the 2 RSV subtypes (A and B).[2] In animal studies, significantly higher neutralizing activity occurred following immunization with pre-fusion forms of the F protein antigen compared to post-fusion forms.[2] Following vaccination with $AS01_E$-adjuvanted formulations, RSV-specific CD4+ T-cell frequencies increased in older adults to similar levels to those observed in young adults.[2]

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 (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Advise patients of the potential benefits and risks of RSVpreF3-AS01 vaccination.[1]
- Advise patients about the potential for adverse reactions that have been observed following vaccine administration.[1]
- Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website ([Web]).[1]
- 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 [Web] .[1]
- 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, Adjuvanted

ROUTES	*FORMS*	*STRENGTHS*	*BRAND NAMES*	*MANUFACTURER*

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

Original Publication Date: May 25, 2023.
Database Extraction: 05/07/2026 19:31:22 +0000+

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