RESPIRATORY SYNCYTIAL VIRUS VACCINE

Respiratory Syncytial Virus Vaccine

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Introduction

Respiratory syncytial virus (RSV) vaccine is a protein subunit vaccine that stimulates active and passive immunity to RSV infection; the vaccine contains stabilized prefusion F (RSV preF) antigens from RSV A and RSV B.[1,8]

Uses

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

Immunization of Pregnant Individuals

RSV preF vaccine is used for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by RSV in infants from birth through 6 months of age.[1]

Efficacy of RSV preF vaccine for this indication was established in a randomized, double-blind, placebo-controlled, phase 3 study that assessed the effects of the vaccine in preventing RSV-associated LRTD in infants born to individuals vaccinated during pregnancy.[1,2] Pregnant women ≤49 years of age at 24 through 36 weeks' gestation were enrolled at various study sites in the northern and southern hemispheres and randomized to receive a single IM injection of the vaccine or placebo.[1,2] The primary efficacy end points were RSV-associated severe LRTD and RSV-associated LRTD in infants within 90, 120, 150, and 180 days of birth.[1,2] RSV-associated LRTD was defined as a confirmed RSV illness with one or more of the following respiratory symptoms: tachypnea (respiratory rate ≥60 breaths/minute [<2 months of age], ≥50 breaths/minute [≥2 to 12 months of age], or ≥40 breaths/minute [≥12-24 months of age]); SpO_2 measured in room air <95%; and/or chest wall indrawing.[1] RSV-associated severe LRTD was a subset defined as meeting the RSV LRTD criteria plus at least one of the following: tachypnea (respiratory rate ≥70 breaths/minute [<2 months of age], ≥60 breaths/minute [≥2 to 12 months of age], or ≥50 breaths/minute [≥12 to 24 months of age]); SpO_2 measured in room air <93%; high-flow nasal cannula or mechanical ventilation (invasive or noninvasive), intensive care unit (ICU) admission for >4 hours, and/or failure to respond/unconscious.[1]

RSV preF vaccine met the success criterion for vaccine efficacy with respect to reducing severe RSV-associated LRTD in infants at all timepoints evaluated (vaccine efficacy of 81.8% at 90 days, 73.9% at 120 days, 70.9% at 150 days, and 69.4% at 180 days).[1,2] Results did not meet statistical criterion for success for the other end point in reducing LRTD due to RSV; however, the vaccine had a clinically meaningful effect after 90 days through 180 days after birth by reducing the incidence of hospitalization for RSV-associated LRTD.[1,2]

Immunization of Adults

RSV preF vaccine is used for active immunization for the prevention of LRTD caused by RSV in adults 60 years of age and older.[1] RSV preF vaccine 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]

Efficacy of RSV preF vaccine in older adults (≥60 years of age) is based principally on an ongoing, multicenter, randomized, double-blind, placebo-controlled, phase 3 study (NCT05035212).[1,6] Individuals with stable chronic medical conditions including cardiopulmonary disease were allowed to participate; however, immunocompromised patients other than those with stable human immunodeficiency virus (HIV), hepatitis B virus, or hepatitis C virus infection were excluded.[1,6] Participants were randomized to receive a single IM injection of the vaccine or placebo.[1,6] Starting 14 days after vaccination, participants were monitored for the onset of acute respiratory illness symptoms (i.e., new or increased sore throat, nasal congestion, nasal discharge, cough, wheezing, sputum production, or shortness of breath) and tested for RSV if any symptoms developed.[1,6] RSV-associated LRTD was defined as confirmed RSV illness with ≥2 of the following respiratory symptoms within 7 days of symptom onset and lasting more than 1 day during the

same illness: new or increased cough, wheezing, sputum production, shortness of breath, or tachypnea (≥25 breaths/min or 15% increase from resting baseline).[1,6] RSV-associated severe LRTD was defined as meeting the RSV-LRTD criteria plus at least one of the following: hospitalization due to RSV-LRTD, new or increased oxygen supplementation, or mechanical ventilation including continuous positive airway pressure (CPAP).[1,6] The primary analysis of efficacy was conducted when 44 cases of a first episode of RSV-associated LRTD with at least 2 symptoms had accrued in the first RSV season.[1] The median duration of follow-up for efficacy was 7 months.[1] Vaccine efficacy for preventing a first episode of RSV-associated LRTD with at least 2 signs or symptoms was 66.7%, and vaccine efficacy for preventing a first episode of RSV-associated LRTD with at least 3 signs or symptoms (indicating a worse clinical disease presentation) was 85.7%.[1,6]

Safety and immunogenicity of RSV preF vaccine in adults 18–59 years of age at increased risk of LRTD caused by RSV were evaluated in a phase 3, multicenter, randomized, double-blind, placebo-controlled study.[1] The study included individuals with chronic medical conditions, including chronic pulmonary, cardiovascular, renal, hepatic, neurologic, hematologic, or metabolic disorders.[1] RSV neutralizing geometric mean titers (GMTs) and seroresponse rates were compared between the evaluable immunogenicity population from this study and a subset of individuals from the study in individuals 60 years of age or older.[1] At 1 month after vaccination, individuals 18–59 years of age who received a single dose of RSV preF vaccine had similar neutralizing antibody titers and seroresponse rates compared with adults 60 years of age or older without comorbid conditions.[1]

Safety and immunogenicity of RSV preF vaccine in immunocompromised adults ≥18 years of age were evaluated in a single-arm, open-label, multicenter study.[1,20] Participants were immunocompromised due to a solid organ transplant, an autoimmune inflammatory disorder being actively treated with immunomodulator therapy, end-stage renal disease requiring hemodialysis, or advanced non-small cell lung cancer.[1,20] The median age of participants was 60 years; the most common immunocompromising conditions were autoimmune inflammatory disorders and history of solid organ transplant.[1] Participants received 2 doses of the vaccine, 1 month apart.[1] A single dose of the RSV preF vaccine elicited robust neutralizing antibody responses 1 month after the dose with seroresponse rates of 70.2% for RSV A and 71.3% for RSV B; a second dose of RSV preF vaccine did not further enhance the immune response.[1,20]

Clinical Perspective

RSV causes respiratory tract infections in individuals of all age groups and is a common cause of LRTD in infants.[21] To protect against RSV disease in infants, either maternal RSV vaccination or infant immunization with a RSV monoclonal antibody is recommended.[18] Vaccination of pregnant persons with a single dose of RSV preF vaccine (Abrysvo®) at 32 to 36 weeks' gestation has demonstrated efficacy in preventing RSV-associated LRTD in infants <6 months of age.[21] The US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommends seasonal administration of maternal RSVpreF vaccine (i.e., during September through end of January in most of the continental US) in pregnant persons as a one-time dose at 32–36 weeks' gestation for prevention of RSV-associated LRTD in infants <6 months of age.[21] Alternatively, a long-acting RSV monoclonal antibody (nirsevimab or clesrovimab) may be administered to the infant.[21] Most infants will not need both maternal vaccination and infant RSV antibodies.[18] Healthcare providers should discuss these options with parents and consider patient preferences.[18]

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, 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] 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 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 of insulin or sodium-glucose cotransporter-2 (SGLT2) inhbitor, 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 RSV 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.[19] 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.[19,77] Among immunocompromised adults, vaccine effectiveness against hospitalization was 70-73%; effectiveness was higher among solid organ transplant recipients compared with hematopoietic stem cell transplant recipients.[19,77] There was limited information in younger adult age groups (18-59 years of age).[77] Results of the evidence review also found that maternal RSVpreF immunization was associated with an estimated 68% vaccine effectiveness (from a pooled analysis of 3 case-control studies) against infant hospitalization.[19,77] Additional data from a randomized controlled trial showed that RSVpreF vaccination during pregnancy had a vaccine efficacy of 55% against infant hospitalization within 180 days after birth.[19,77] When the vaccine was administered at the recommended timing of 32-36 weeks' gestation, no increased risk of preterm birth was observed.[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]

- 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.[5]

Administration

IM Administration

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

RSV preF vaccine solution for injection is available in 3 presentations.[1] In one presentation, the lyophilized antigen component and sterile water diluent component are contained in separate chambers in a single vial (Act-O-Vial Presentation).[1] In another presentation, the vaccine is supplied in a kit that includes a vial of lyophilized antigen component, a prefilled syringe containing sterile water diluent component, and a vial adapter (Vial and Prefilled Syringe Presentation).[1] In the last presentation, the vaccine is supplied in cartons that include vials of lyophilized antigen component and vials containing the sterile water diluent component (Vial and Vial Presentation).[1] For all presentations, reconstitute the lyophilized antigen component with the accompanying sterile water diluent as described in the manufacturer's prescribing information.[1] After the vaccine is reconstituted, a single dose is either approximately 0.5 mL (for the Vial and Prefilled Syringe Presentation) or 0.5 mL (for the Act-O-Vial and Vial/Vial Presentations).[1] Visually inspect the solution; the vaccine should be clear and colorless.[1] Discard if discoloration or particulate matter is observed.[1]

Prior to reconstitution, store at 2-8ºC in the original carton; do not freeze.[1] After the vaccine is reconstituted, administer immediately or store at room temperature (15–30°C) and use within 4 hours; discard the vaccine if not used within 4 hours.[1]

Dosage

Prevention of Lower Respiratory Tract Disease Caused by RSV

Immunization in Pregnant Individuals at 32 through 36 Weeks Gestational Age

The dosage of RSV preF vaccine for active immunization in pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) caused by RSV in infants from birth through 6 months of age is 0.5 mL administered as a single IM dose.[1]

The manufacturer states that safety and effectiveness of the vaccine in infants born to individuals vaccinated at <10 years of age not established.[1]

Immunization in Individuals ≥60 Years of Age and Individuals 18–59 Years of Age at Increased Risk of RSV Disease

The dosage of RSV preF vaccine for active immunization for the prevention of LRTD caused by RSV in adults ≥60 years of age and adults 18-59 years of age at increased risk of RSV disease is 0.5 mL administered as a single IM dose.[1]

Cautions

Contraindications

- History of severe allergic reaction (e.g., anaphylaxis) to any component of respiratory syncytial virus (RSV) 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 RSV preF vaccine.[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 RSV preF vaccine, with an incidence rate ratio of 2.02 and an estimated 9 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 RSV preF vaccine, but the available evidence is insufficient to establish a causal relationship.[10]

Potential Risk of Preterm Birth

A numerical imbalance in preterm births was observed in recipients of RSV preF vaccine compared to placebo recipients in 2 clinical studies.[1] Available data are insufficient to establish or exclude a causal relationship to the drug.[1]

To avoid the potential risk of preterm birth before 32 weeks of gestation, administer RSV preF vaccine as indicated in pregnant individuals at 32 through 36 weeks gestational age.[1] Pregnant individuals who were at increased risk of preterm birth were generally excluded from clinical studies of the vaccine.[1]

Preventing and Managing Allergic Vaccine Reactions

Anaphylaxis and other hypersensitivity reactions have been reported during postmarketing experience in individuals receiving RSV preF vaccine.[1] Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the RSV preF vaccine.[1]

Syncope

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

Altered Immunocompetence

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

Limitations of Vaccine Effectiveness

Vaccination with the RSV preF vaccine may not protect all recipients.[1]

Specific Populations

Pregnancy

There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to RSV preF vaccine during pregnancy.[1] Individuals who receive the vaccine during pregnancy are encouraged to contact, or have their healthcare provider contact 1-800-616-3791 to enroll in or obtain information about the registry.[1]

In a randomized controlled trial that enrolled pregnant individuals, preterm births were higher in those who received RSV preF vaccine at 24 through 36 weeks' gestation compared to those who received placebo; however, available data are insufficient to establish or exclude a causal relationship to the drug.[1] There was no evidence of a vaccine-associated increase in the risk of congenital anomalies or fetal deaths.[1] To avoid the potential risk of preterm birth with use of RSV preF vaccine before 32 weeks of gestation, administer the vaccine as indicated in pregnant individuals at 32 through 36 weeks gestational age.[1] RSV preF vaccine has not been studied in pregnant individuals <24 weeks gestational age, and those at increased risk for preterm birth.[1]

Results of a developmental toxicity study in animals showed no evidence of fetal harm or adverse effects on postnatal survival, growth, or development.[1]

Lactation

It is not known whether RSV preF vaccine is excreted in human milk.[1] Data are not available to assess the effects of the vaccine 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 the RSV preF vaccine and any potential adverse effects on the breastfed child from the vaccine or from the underlying maternal condition.[1] For preventative vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.[1]

Pediatric Use

The safety and effectiveness of RSV preF vaccine for prevention of RSV LRTD and severe RSV LRTD in infants born to individuals vaccinated at <10 years of age have not been established.[1]

The safety and effectiveness of RSV vaccine to prevent RSV LRTD in non-pregnant individuals <18 years of age via active immunization have not been established.[1]

Geriatric Use

In the principal efficacy study of RSV preF vaccine in individuals 60 years of age and older and an additional study in immunocompromised adults ≥18 years of age, 63% of the participants were 60-69 years of age, 32% were 70-79 years of age, and 5% were ≥80 years of age.[1]

■ Common Adverse Effects

The most common local and systemic adverse reactions in pregnant individuals (≥10%) were pain at the injection site, headache, muscle pain, and nausea.[1]

The most common local and systemic adverse reactions in individuals ≥60 years of age (≥10%) were fatigue, headache, pain at the injection site, and muscle pain.[1]

The most common local and systemic adverse reactions in individuals 18-59 years of age (≥10%) were pain at the injection site, muscle pain, joint pain, and nausea.[1]

Drug Interactions

■ Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed

No safety concerns were identified when non-pregnant women received the RSV preF vaccine and Tdap (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed) concomitantly.[1,7] Immune responses to RSV A, RSV B, diphtheria, and tetanus were non-inferior to those after separate administration; however, geometric mean antibody concentrations (GMCs) to the acellular pertussis antigens were lower when the RSV vaccine was administered concomitantly with Tdap compared to when Tdap was administered alone.[1,7]

Concomitant administration of Tdap with the RSV vaccine in pregnant individuals has not been studied.[1]

Description

Respiratory syncytial virus (RSV) preF vaccine is a bivalent RSV stabilized prefusion F protein-based (RSV preF) vaccine that stimulates active and passive immunity to RSV infection; the antigen component contains recombinant RSV preF A and RSV preF B proteins.[1] RSV preF vaccine induces an immune response against RSV preF that protects against lower respiratory tract disease (LRTD) caused by RSV.[1] The vaccine also induces passive immunization when antibodies to RSV antigens from individuals vaccinated in pregnancy are transferred transplacentally to protect infants <6 months of age against LRTD and severe LRTD caused by RSV.[1] RSV F glycoprotein (prefusion and postfusion) mediates viral fusion and host-cell entry, elicits neutralizing antibodies, and is highly conserved across the 2 RSV subtypes (A and B).[4]

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 vaccine recipients of the potential benefits and risks of vaccination with the respiratory syncytial virus (RSV) preF vaccine.[1]
- Advise vaccine recipients to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System at 1-800-822-7967 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

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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

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER

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

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