Centers for Disease Control and Prevention

Vaccine Safety

Vaccine Safety Home

Respiratory Syncytial Virus (RSV) Vaccine

Safety Information

About Respiratory Syncytial Virus (RSV)

Respiratory Syncytial Virus, or RSV, is a common respiratory virus that usually causes mild, cold-like symptoms. Most people recover in a week or two, but RSV can cause severe illness.

Anyone can be infected with RSV, but people who are at a higher risk for severe illness include:

- Infants and young children
- Adults 60 years of age and older
- Adults with chronic heart and lung disease
- Adults with weakened immune systems
- Adults with certain other chronic medical conditions
- Adults living in nursing homes or long-term care facilities

RSV usually spreads through direct contact from cough or sneeze droplets that can get into your eyes, nose, or mouth. RSV can survive on hard surfaces for many hours which means the virus can also spread if you touch a surface that has the virus on it, like a doorknob, and then touch your face before washing your hands.

To prevent the spread of RSV, cover your coughs and sneezes with a tissue or your shirt sleeve. Remember to wash your hands often with soap and water for at least 20 seconds. Clean frequently touched surfaces often such as doorknobs and mobile devices.

Learn more about RSV.

Vaccine Information Statements

Vaccine Information Statements (VISs) are information sheets produced by CDC that explain both the benefits and risks of a vaccine.

RSV

Respiratory Syncytial Virus

Child and Adult Immunization Schedules

Get CDC's official recommended immunization schedules for children, adolescents, and adults.

Available RSV Products and Package Inserts

Talk with your healthcare provider about vaccines.

They can answer questions and offer advice based on your specific health needs.

For older adults

There are two RSV vaccines approved for use in the United States for adults ages 60 years and older: Pfizer RSV vaccine (ABRYSVO) and GSK RSV vaccine (AREXVY). Both vaccines contain a part of the RSV virus and can protect older adults against respiratory disease if they are infected with RSV in the future. CDC recommends that adults ages 60 years and older may receive a single dose of an RSV vaccine using shared clinical decision-making, a process by which healthcare providers and patients work together to make decisions about the patient's care. A single dose of either the Pfizer RSV vaccine (ABRYSVO) or GSK RSV vaccine (AREXVY) vaccine may be used. The GSK and Pfizer RSV vaccines may be given at the same time as other vaccines for older adults.

For pregnant people (maternal RSV vaccine)

The Pfizer RSV vaccine (ABRYSVO) is the only RSV vaccine approved and recommended for use in pregnant people to prevent severe RSV illness in their babies. The Pfizer RSV vaccine (ABRYSVO) is recommended as a single dose for those who are 32 through 36 weeks pregnant during September through January in most of the continental United States. Some areas, where RSV season is slightly different, may have adjustments to the months when the Pfizer RSV vaccine is recommended. The GSK RSV vaccine (AREXVY) is not recommended for pregnant people. The Pfizer RSV maternal vaccine may be given at the same time as other routine vaccines for pregnant people.

For infants and certain young children

Nirsevimab (Beyfortus) is a monoclonal antibody (passive immunization) that is administered to infants and young children and helps protect them from severe RSV illness. Nirsevimab may be given at the same time as other recommended pediatric vaccines.

All infants are recommended to be protected against severe RSV through the use of either the maternal RSV vaccine or infant receipt of nirsevimab:

- CDC recommends that pregnant people receive a single dose of the Pfizer RSV vaccine (ABRYSVO) during 32 through 36 weeks' gestation to protect their babies from severe RSV from birth to 6 months of age, OR
- CDC recommends that infants younger than 8 months of age receive one dose of nirsevimab if they are born shortly before or are entering their first RSV season.

Administration of both products is not needed for most infants.

Nirsevimab is also recommended for young children ages 8-19 months who are at in increased risk of severe RSV who are entering their second RSV season to help protect them from severe disease from an RSV illness.

RSV Product Manufacturer Package Inserts

For older adults

ABRYSVO [PDF- 22 Pages] Pfizer : The Food and Drug Administration (FDA) approved this vaccine in 2023. Pfizer RSV vaccine (ABRYSVO) is approved for individuals ages 60 years and older to prevent lower respiratory tract disease (LRTD) caused by RSV.
AREXVY [PDF – 14 Pages] GSK : The Food and Drug Administration (FDA) approved this vaccine in 2023. GSK RSV vaccine (AREXVY) is only approved for individuals ages 60 years and older to prevent LRTD caused by RSV.

For pregnant people

ABRYSVO [PDF- 22 Pages] Pfizer : The Food and Drug Administration (FDA) approved this vaccine in 2023. Pfizer RSV vaccine (ABRYSVO) is approved for pregnant people at 32 through 36 weeks gestational age to protect their babies from LRTD and severe LRTD caused by RSV.

For infants and young children

Nirsevimab (Beyfortus) [PDF – 16 Pages] : The Food and Drug Administration (FDA) approved this injectable monoclonal antibody to prevent RSV LRTD. Nirsevimab is a passive immunization and is approved for infants born or entering their first RSV season and for some young children who are at increased risk for severe RSV disease and entering their second RSV season.

Common Side Effects

In clinical trials, the RSV vaccines and passive immunization (monoclonal antibody product) were shown to be safe and effective at preventing RSV-associated lower respiratory tract disease (LRTD). Vaccines and monoclonal antibody products, like any medicine, can have side effects.

- The most common side effects after RSV vaccination for older adults are usually mild or moderate, like a sore arm in the area where the shot was given, fatigue, headache, and muscle or joint pain.
- The most common side effects after Pfizer RSV vaccination (ABRYSVO) for pregnant people are usually mild or moderate, like pain at injection site, headache, muscle pain, and nausea.
- The most common side effects after RSV passive immunization with nirsevimab in infants and young children are rash, pain, swelling, or hardness at the injection site.

Severe allergic reactions following vaccination are rare but can be life threatening.
Symptoms of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness.

If any of these reactions occur, seek immediate medical attention.

Pfizer RSV Vaccine (ABRYSVO)

Common Side Effects

- Pain where the shot is given
- Fatigue (feeling tired)
- Headache

- Muscle pain
- Nausea

Who Should Not Get the Pfizer RSV Vaccine
This vaccine is not intended for individuals ages 59 years and younger who are not pregnant.

People should not get the Pfizer RSV vaccine if they:
Have had a history of severe allergic reaction, such as anaphylaxis, to any component of the vaccine.

People should talk to their healthcare provider before getting the Pfizer RSV vaccine if they:

- Have moderate or severe acute illness with or without fever,
- Have had any severe, life-threatening allergies.

In some cases, the healthcare provider may decide to postpone Pfizer RSV vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting an RSV vaccine.

GSK RSV Vaccine (AREXVY)

Common Side Effects

- Pain where the shot is given
- Fatigue (feeling tired)
- Muscle and joint pain
- Headache

Who Should Not Get the GSK RSV Vaccine
This vaccine is not intended for individuals ages 59 years and younger. The GSK RSV vaccine is not approved for use during pregnancy and is not recommended for pregnant people.

People should not get the GSK RSV vaccine if they:
Have had a history of severe allergic reaction, such as anaphylaxis, to any component of the vaccine.

People should talk to their healthcare provider before getting the GSK RSV vaccine if they:

- Have moderate or severe acute illness with or without fever,
- Have had had any severe, life-threatening allergies.

In some cases, the healthcare provider may decide to postpone GSK RSV vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting an RSV vaccine.

RSV Passive Immunization (Nirsevimab)

Common Side Effects

- Pain, redness, or swelling where shot is given
- Rash

Who Should Not Get the RSV Passive Immunization
This passive immunization is not recommended for use in children aged 20 months or older.

Children should not get the RSV passive immunization if they:
Have had a history of severe allergic reaction, such as anaphylaxis, after a previous dose or to any component of the nirsevimab passive immunization.

Parents should talk to their healthcare provider before their child receives the RSV passive immunization if the child:

- Has moderate or severe acute illness,
- Has had any severe, life-threatening allergies,
- Has a bleeding disorder.

In some cases, the healthcare provider may decide to postpone RSV passive immunization to a future visit.

Children with minor illnesses, such as a cold, may be vaccinated. Children who are moderately or severely ill should usually wait until they recover before getting an RSV passive immunization .

More Information

RSV Vaccination: what everyone should know

Learn more about the safety of RSV vaccine.

Who Should NOT Get These Vaccines?

Some people should not get certain vaccines or should wait before getting them. Read the CDC guidelines for each vaccine.

RSV Vaccines – ACIP Recommendations and Guidance

Official guidance on RSV vaccines from the Advisory Committee on Immunization Practices (ACIP).

RSV Vaccines for Healthcare Professionals

Information for healthcare professionals: how to recommend and answer questions about RSV vaccination.

A Closer Look at the Safety Data

Which adverse events are considered "serious?"

By the Code of Federal Regulations (CFR) Title 21, an adverse event is defined as serious if it involves any of the following outcomes:

- Death
- A life-threatening adverse event
- A persistent or significant disability or incapacity
- A congenital anomaly or birth defect
- Hospitalization, or prolongation of existing hospitalization

Learn more about adverse events.

Both RSV vaccines and the monoclonal antibody passive immunization (nirsevimab) have been shown to be safe and effective in clinical trials when used according to the approved indications and recommendations. CDC and FDA continue to monitor the safety of the RSV vaccines and the passive immunization and will share findings with the public as they become available.

For older adults
In May 2023, the U.S. Food and Drug Administration (FDA) approved the first two vaccines for the prevention of lower respiratory tract disease (LRTD) caused by RSV (AREXVY GSK and ABRYSVO Pfizer vaccines) in adults aged 60 years and older.

In clinical trials assessing the safety of the GSK (AREXVY) and Pfizer (ABRYSVO) RSV vaccines in adults ages 60 years and older, the frequency of serious adverse events (SAEs) was similar in the vaccine and placebo groups. In clinical trials in adults ages 60 years and older, a small number of people developed serious neurologic conditions, such as Guillain-Barre syndrome (GBS), after RSV vaccination. Given the small number, it is unclear whether the vaccine caused these events, or whether they occurred due to chance. GBS is a rare condition in which your immune system attacks your nerves, causing symptoms such as weakness.

For pregnant people
In August 2023, the Pfizer RSV vaccine (ABRYSVO) was also approved for use in pregnant people at 32 through 36 weeks' gestational age to prevent LRTD and severe LRTD from RSV in infants from birth through 6 months of age.

The Pfizer RSV vaccine (ABRYSVO) was studied in clinical trials in pregnant people at 24 through 36 weeks' gestation. SAEs in pregnant people and infants were balanced between the vaccine and placebo group. Clinical trials in pregnant people who received the Pfizer RSV vaccine (ABRYSVO) vaccinated at 24 through 36 weeks' gestation identified a small increase in the number of preterm births in vaccinated pregnant people after receipt of the Pfizer RSV vaccine. When the rate of preterm birth was assessed during the approved dosing interval (32–36 weeks' gestation), 4.2% of infants were born preterm in the Pfizer RSV vaccine group (68 participants) versus 3.7% in the placebo group (59 participants). It is not clear if this is a true safety problem related to RSV vaccine or if this occurred for reasons unrelated to vaccination. Also, 1.8% of vaccinated pregnant people in the clinical trials developed a dangerous high blood pressure condition called pre-eclampsia (compared to 1.4% of pregnant people who received a placebo) during 24 through 36 weeks' gestation. Additional studies are being conducted to look more closely at the potential risk for preterm birth and pregnancy-related high blood pressure issues in mothers, including pre-eclampsia. ACIP judged the benefits of maternal Pfizer RSV (ABRYSVO) vaccination at 32–36 weeks' gestation to outweigh the potential risks for preterm birth and hypertensive disorders of pregnancy.

For infants and young children
In July 2023, FDA approved the nirsevimab monoclonal antibody product to prevent lower respiratory tract disease caused by RSV in infants and young children. Nirsevimab is a passive immunization and is administered as an injection. Nirsevimab is not a vaccine.

No safety concerns were observed during the clinical trials for infants and young children who received the nirsevimab passive immunization. The incidence of serious adverse events was not increased in infants receiving nirsevimab compared with those receiving placebo.

How CDC Monitors the Safety of RSV Vaccines

CDC and FDA monitor the safety of vaccines after they are approved. If a problem is found with a vaccine, CDC and FDA will inform health officials, health care providers, and the public.

Related Scientific Articles

2023

Advisory Committee on Immunization Practices (ACIP) RSV slides. 2023 Sep 22.

- RSVpreF Vaccine Safety Surveillance in Pregnancy from The Vaccine Safety Datalink [PDF – 19 Pages]
- Maternal RSV vaccine safety monitoring in the VAERS and V-safe [PDF – 10 Pages]
- Proposed clinical considerations for maternal RSVPreF [PDF – 19 Pages]

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Melgar M, Britton A, Roper LE, Talbot HK, Long SS, Kotton CN, Havers FP. Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices – United States, 2023. *MMWR Morb Mortal Wkly Rep.* 2023 Jul 21;72(29);793-801.

Last Reviewed: January 2, 2024