

IMMUNIZATION INFORMATION STATEMENT

Respiratory Syncytial Virus (RSV) Preventive Antibody: *What You Need to Know*

Why get immunized with a RSV preventive antibody?

A respiratory syncytial virus (RSV) preventive antibody can prevent severe lung disease caused by RSV.

RSV is a common respiratory virus that usually causes mild, cold-like symptoms but can also affect the lungs. Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing.

Anyone can become infected by RSV, and almost all children get an RSV infection by the time they are 2 years old. While most children recover from an RSV infection in a week or two, RSV infection can be dangerous for infants and some young children, causing difficulty breathing, low oxygen levels, and dehydration. In the United States, RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lungs) and pneumonia (infection of the lungs) in children younger than 1 year of age. Children who get sick from RSV may need to be hospitalized, and some might even die.

RSV Preventive Antibodies

The RSV preventive antibody (generic name nirsevimab, trade name Beyfortus) is a shot that prevents severe RSV disease in infants and young children. Antibodies are proteins that the body's immune system uses to fight off harmful germs. Like traditional vaccines, preventive antibodies are immunizations that provide protection against a specific pathogen. While both are immunizations, the way they provide immunity is different. Nirsevimab is an immunization that provides antibodies directly to the recipient. Traditional vaccines are immunizations that stimulate the recipient's immune system to produce antibodies.

Infants born during the RSV season (typically fall through spring) should receive a single dose of the RSV Immunization within 1 week after birth. Most infants whose mothers got the RSV vaccine don't need to get nirsevimab, too. Both protect infants from severe RSV by providing antibodies, either from the mother to the infant or directly to the infant. Most infants will likely only need protection from either the maternal RSV vaccine or nirsevimab (not both). However, there may be some situations in which nirsevimab would be recommended for an infant after the mother received an RSV vaccine.

Infants born outside of the RSV season who are younger than 8 months should receive a single dose of the RSV Immunization shortly before their first RSV season (typically the fall), but infants who are younger than 8 months who have not yet received a dose may receive a dose at any time during the season.

Some infants and young children who are at increased risk for severe RSV disease may need a single dose of the RSV antibody before or during their second RSV season.

RSV preventive antibodies can be given at the same time as vaccines routinely recommended for infants and young children.



Talk with your health care provider

Tell your health care provider if the person getting the preventive antibody has a:

- History of serious allergic reactions to an RSV preventive antibody (nirsevimab) or any of its components,
- Bleeding disorder, or
- Moderate or severe acute illness.

In some cases, your child's health care provider may decide to postpone giving RSV preventive antibodies until a future visit.

People who have a minor illness, such as a cold, can safely receive an RSV preventive antibody. People who are moderately or severely ill should usually wait until they recover.

Your health care provider can give you more information.

Risks of a reaction to RSV preventive antibodies

After getting an RSV preventive antibody, your child might have temporary pain, redness, swelling where the injection was given, or a rash.

As with any medicine, there is a very remote chance that RSV Immunization could cause a severe allergic reaction, other serious injury, or death.

An allergic reaction could occur after your child leaves the hospital or clinic. If you see signs of a severe allergic reaction (for example, hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call 9-1-1 and get your child to the nearest hospital.

Call your health care provider if you see any other symptoms that concern you.

What if there is a serious problem?

If your child got an RSV preventive antibody without getting a vaccine at the same time, and you suspect an adverse reaction, you or your health care provider can submit a report through <https://www.fda.gov/medwatch> or by phone at 1-800-FDA-1088.

If your child got an RSV preventive antibody and a vaccine at the same time and you suspect an adverse reaction, you or your health care provider should report it to the [Vaccine Adverse Event Reporting System \(VAERS\)](https://vaers.hhs.gov/) <https://vaers.hhs.gov/> or call [1-800-822-7967](https://vaers.hhs.gov/). In your report, note that your child got an RSV Immunization along with a vaccine.

Note: MedWatch and VAERS are only for reporting reactions. MedWatch and VAERS staff members do not give medical advice.

How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit U.S. Food and Drug Administration website at [Drugs@FDA: FDA-Approved Drugs](https://www.fda.gov/oc/ohrt/).
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - [Visit the CDC website https://www.cdc.gov/rsv/about/prevention.html](https://www.cdc.gov/rsv/about/prevention.html)





**Addendum to Respiratory Syncytial Virus (RSV)
Preventive Antibody: *What You Need to Know*
Immunization Information Statement (IIS)**

1. I agree that the person named below will get the preventive antibody checked below.
2. I received or was offered a copy of the Immunization Information Statement (IIS) for the preventive antibody listed above.
3. I know the risks of the disease this preventive antibody prevents.
4. I know the benefits and risks of the preventive antibody.
5. I have had a chance to ask questions about the disease the preventive antibody prevents, the antibody, and how the antibody is given.
6. I know that the person named below will have the preventive antibody put in his/her body to prevent the disease this preventive antibody prevents.
7. I am an adult who can legally consent for the person named below to get the preventive antibody. I freely and voluntarily give my signed permission for this preventive antibody..

Preventive antibody to be given: Respiratory Syncytial Virus (RSV) Preventive Antibody

Information about person to receive preventive antibody (Please print)				
Name: Last	First	Middle Initial	Birthdate (mm/dd/yy)	Sex (circle one)
				M F
Address: Street	City	County	State TX	Zip
Signature of person to receive preventive antibody or person authorized to make the request (parent or guardian):				
x _____			Date: _____	
x _____			Date: _____	
Witness				

PRIVACY NOTIFICATION - With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. See <http://www.dshs.texas.gov> for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, 559.003, and 559.004)

Privacy Notice: I acknowledge that I have received a copy of my immunization provider's HIPAA Privacy Notice.

For Clinic / Office Use Only

Clinic / Office Address:	Date Preventive Antibody Administered:
	Preventive Antibody Manufacturer:
	Preventive Antibody Lot Number:
	Site of Injection:
	Title of Preventive Antibody Administrator:
	Signature of Preventive Antibody Administrator:
	Date IIS Given:

Notice: Alterations or changes to this publication is prohibited.

Instructions: File this consent statement in the patient's chart.