RSV

maternal vaccine | abrysvo

monoclonal antibody | nirsevimab

Trade Name: ABRYSVO™ **Generic Name:** Respiratory Syncytial Virus Vaccine

---------- INDICATIONS AND USAGE----------

ABRYSVO is a vaccine indicated 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 respiratory syncytial virus (RSV) in infants from birth through 6 months of age. (1.1)
- Active immunization for the prevention of LRTD caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. (1.2)

Ingredients:

The antigen component contains recombinant RSV preF A and RSV preF B.

The RSV preF A and RSV preF B recombinant proteins are expressed in genetically engineered Chinese Hamster Ovary cell lines grown in suspension culture using chemically-defined media, without antibiotics or animal-derived components. The recombinant proteins are purified through a series of column chromatography and filtration steps followed by formulation, filling into vials, and lyophilization.

After reconstitution, each dose of ABRYSVO is approximately 0.5 mL. The vaccine is formulated to contain 120 mcg of RSV stabilized prefusion F proteins (60 mcg RSV preF A and 60 mcg RSV preF B) per 0.5 mL. ABRYSVO also contains the following buffer ingredients: 0.11 mg tromethamine, 1.04 mg tromethamine hydrochloride, 11.3 mg sucrose, 22.5 mg mannitol, 0.08 mg polysorbate 80, and 1.1 mg sodium chloride per 0.5 mL. ABRYSVO is a sterile, clear, and colorless solution.

ABRYSVO contains no preservatives. Each dose may also contain residual amounts of host cell proteins (≤0.1% w/w) and DNA (<0.4 ng/mg of total protein) from the manufacturing process.

5.5 Limitations of Vaccine Effectiveness

Vaccination with ABRYSVO may not protect all vaccine recipients.

SOURCES FROM FDA + PFIZER

The safety and effectiveness of ABRYSVO to prevent RSV LRTD and severe RSV LRTD in infants born to individuals vaccinated at younger than 10 years of age have not been established.

The safety and effectiveness of ABRYSVO to prevent RSV LRTD in non-pregnant individuals younger than 18 years of age via active immunization have not been established.

Warnings + Precautions:

5.1 Potential Risk of Preterm Birth

A numerical imbalance in preterm births in ABRYSVO recipients was observed compared to placebo recipients in two clinical studies *[see Adverse Reactions 6.1]*. Available data are insufficient to establish or exclude a causal relationship between preterm birth and ABRYSVO. To avoid the potential risk of preterm birth with use of ABRYSVO before 32 weeks of gestation, administer ABRYSVO as indicated in pregnant individuals at 32 through 36 weeks gestational age. Pregnant individuals who were at increased risk of preterm birth were generally excluded from clinical studies of ABRYSVO.

Manufacturer-listed Adverse Reactions for Pregnant Individuals:

+ Pain at injection site
+ Headache
+ Muscle Pain
+ Nausea

Section 6.2 for Post-marketing adverse reactions is missing, even with over 1.7k adverse reactions reported on VAERS.

Drug Interactions:

In Study 4 in a concomitant administration study of ABRYSVO and a Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap) in non-pregnant women, no safety concerns were identified. Immune responses to RSV A, RSV B, diphtheria, and tetanus were non-inferior to those after separate administration. Lower geometric mean antibody concentrations (GMCs) to the acellular pertussis antigens (pertussis toxin [PT], filamentous hemagglutinin (FHA), and pertactin [PRN]) were measured when ABRYSVO was administered concomitantly with Tdap compared to pertussis GMCs when Tdap was administered alone *[see Clinical Studies (14.3)]*.

Concomitant administration of Tdap with ABRYSVO in pregnant individuals has not been studied.

Clinical Considerations:

Maternal Adverse Reactions
In Study 1, 3,682 pregnant individuals received ABRYSVO and 3,676 received placebo. Local and systemic adverse reactions occurred with greater frequency in the ABRYSVO group. Serious adverse reactions observed in pregnant individuals at a higher rate in the ABRYSVO group compared to the placebo group included pre-eclampsia (1.8% versus 1.4%) and gestational hypertension (1.1% versus 1.0%) *[see Adverse Reactions (6.1)]*.

ABRYSVO has not been studied in pregnant individuals less than 24 weeks gestational age, and those at increased risk for preterm birth.

Study 1 enrolled 7,358 pregnant individuals who were randomized 1:1 and received ABRYSVO or placebo (0.5 mL dose, containing the same buffer ingredients in the same quantities as in a single dose of ABRYSVO

https://www.cdc.gov/vaccine-safety/vaccines/rsv.html

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. [6]

It is not known whether ABRYSVO is excreted in human milk. Data are not available to assess the effects of ABRYSVO on the breastfed infant or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ABRYSVO and any potential adverse effects on the breastfed child from ABRYSVO or from the underlying maternal condition.

https://www.cdc.gov/rsv/hcp/vaccine-clinical-guidance/pregnant-people.html

Misadministration alert

In the 2023–2024 RSV season, CDC received reports of GSK's Arexvy being administered in error to pregnant people.

Pfizer's Abrysvo is the only RSV vaccine recommended for pregnant people. **GSK's Arexvy and Moderna's mResvia are NOT approved for use during pregnancy.**

monoclonal antibody for newborns

Trade Name: BEYFORTUS **Generic Name:** nirsevimab-alip

---------- INDICATIONS AND USAGE ----------

BEYFORTUS is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease in:

- Neonates and infants born during or entering their first RSV season. (1)
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. (1)

Ingredients:

Nirsevimab-alip, a respiratory syncytial virus F protein-directed fusion inhibitor, is a human immunoglobulin G1 kappa (IgG1κ) monoclonal antibody produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology.

Each 0.5 mL contains 50 mg nirsevimab-alip, arginine hydrochloride (8 mg), histidine (1.1 mg), L-histidine hydrochloride monohydrate (1.6 mg), polysorbate 80 (0.1 mg), sucrose (21 mg), and water for injection (USP). The pH is 6.0.

Each 1 mL contains 100 mg nirsevimab-alip, arginine hydrochloride (17 mg), histidine (2.2 mg), L-histidine hydrochloride monohydrate (3.3 mg), polysorbate 80 (0.2 mg), sucrose (41 mg), and water for injection (USP). The pH is 6.0.

Table 1 Recommended Dosage of BEYFORTUS in Neonates and Infants Born During or Entering Their First RSV Season

Body Weight at Time of Dosing	Recommended Dosage
Less than 5 kg	50 mg by IM injection
5 kg and greater	100 mg by IM injection

SOURCES FROM FDA + ASTRAZENECA + SANOFI PASTEUR

Warnings + Precautions:

5.1 Hypersensitivity Including Anaphylaxis

Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human immunoglobulin G1 (IgG1) monoclonal antibodies. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, initiate appropriate medications and/or supportive therapy.

5.2 Use in Individuals with Clinically Significant Bleeding Disorders

As with any other IM injections, BEYFORTUS should be given with caution to infants and children with thrombocytopenia, any coagulation disorder, or to individuals on anticoagulation therapy.

Note: Both U.S licensed vaccines for Hepatitis B (Engerix-b, RECOMBIVAX HB®) list "Thrombocytopenia" as a potential adverse reaction, and are recommended during the same time as Beyfortus.

NIH https://medlineplus.gov/ency/article/000586.htm

Thrombocytopenia means there is an abnormally low amount of platelets. Platelets are parts of the blood that help blood to clot. This condition is sometimes associated with abnormal bleeding.

Severe bleeding (hemorrhage) is the main complication. Bleeding may occur in the brain or gastrointestinal tract.

In addition to Beyfortus and the Hepatitis B vaccine, the CDC also recommends the synthetic Vitamin K injection (AquaMEPHYTON) due to coagulation concerns for newborns. If this is a concern at birth, why are products that can potentially contribute to significant bleeding disorders safe for newborns?

Manufacturer-listed Adverse Reactions:

+ Injection site reactions (swelling/hardness)
+ Rash
+ Pain

Section 6.2 for Post-marketing adverse reactions is missing.

These are not all of the possible side effects of BEYFORTUS.

Vaccines: There is limited experience with co-administration of BEYFORTUS with vaccines. In clinical trials, when BEYFORTUS was given concomitantly with routine childhood vaccines, the safety and reactogenicity profile of the co-administered regimen was similar to the childhood vaccines given alone.

CDC https://www.cdc.gov/rsv/hcp/vaccine-clinical-guidance/infants-young-children.html

Adverse reactions might occur after the coadministration of nirsevimab with a vaccine; these reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS), and reports should specify that the patient received nirsevimab on the VAERS form in Section 9: "Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination."

In other words, if an adverse reaction occurs after an infant receives Beyfortus and another vaccine, then Beyfortus should be listed in the report to VAERS.

Clinical Considerations:

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis, mutagenesis and reproductive toxicity studies have not been performed with BEYFORTUS.

Your child may still get RSV disease after receiving BEYFORTUS. Talk to your child's healthcare provider about what symptoms to look for.

According to the manufacturer, your child can still get RSV after receiving Beyfortus.