

CDC Recommendation for ABRYSVO® to Help Protect Older Adults From RSV1





CDC recommended as a single dose for:

All adults 75+ and 60-74 with certain chronic medical conditions at increased risk for severe RSV*†

with certain chronic medical

*Patient attestation is sufficient evidence of the presence of a risk factor. Vaccinators should not deny RSV vaccination to a person because of lack of medical documentation.

Chronic medical conditions and risk factors for severe RSV disease in older adults aged 60-74 years*



Cardiovascular disease (e.g., heart failure, coronary artery disease, or congenital heart disease [excluding isolated hypertension])



Chronic lung or respiratory disease (e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, or cystic fibrosis)



End-stage renal disease or dependence on hemodialysis or other renal replacement therapy



Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end-organ damage, or requiring treatment with insulin or sodium-glucose cotransporter-2 (SGLT2) inhibitor



Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness (e.g., poststroke dysphagia, amyotrophic lateral sclerosis, or muscular dystrophy [excluding history of stroke without impaired airway clearance)



Chronic liver disease (e.g., cirrhosis)



Chronic hematologic conditions (e.g., sickle cell disease or thalassemia)



Severe obesity (body mass index ≥40 kg/m²)



Moderate or severe immune compromise



Residence in a nursing home



Other chronic medical conditions or risk factors that a healthcare provider determines would increase the risk for severe disease due to viral respiratory **infection** (e.g., frailty, situations in which healthcare providers have concern for presence of undiagnosed chronic medical conditions, or residence in a remote or rural community where transportation of patients with severe RSV disease for escalation of medical care is challenging)

†Eligible older adults who have not previously received an RSV vaccine may be vaccinated any time of the year, but the optimal timing is just before the RSV season during August-October.

INDICATIONS

ABRYSVO is a vaccine indicated for

- active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older
- active immunization for the prevention of LRTD caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV

IMPORTANT SAFETY INFORMATION

- Do not administer ABRYSVO to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of ABRYSVO
- The results of a postmarketing observational study suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination with ABRYSVO
- In clinical trials with adults aged 60+, the most commonly reported (≥10%) adverse reactions were fatigue (15.7%), headache (12.9%), pain at the injection site (10.7%), and muscle
- In clinical trials with adults aged 18-59, the most commonly reported (≥10%) adverse reactions were pain at the injection site (35.3%), muscle pain (24.4%), joint pain (12.4%), and nausea (11.8%) (continued on next page)

CDC = Centers for Disease Control and Prevention; RSV = respiratory syncytial virus.

Please see full Prescribing Information for ABRYSVO.

Help Protect Infants Against RSV From Birth Through 6 Months With Maternal Vaccination





ABRYSVO® is CDC recommended for pregnant persons as a one-time dose for prevention of RSV-associated LRTI in infants aged <6 months²

- at 32 weeks and 0 days' gestation through 36 weeks and 6 days' gestation
- √ during September through January in most of the US*

Scan this QR code to help estimate the potential ABRYSVO vaccination window



This digital tool will help estimate a patient's vaccine eligibility based on ABRYSVO's approved indication (32-36 weeks gestation) and the RSV seasonal guidance provided by the CDC.

CDC's Routine Recommended Maternal Administration Schedule^{2*}

VACCINE	SEP	ОСТ	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG
ABRYSVO® Respiratory Syncytial Virus Vaccine approved to help protect infants)	Routine recommended				Providers should follow local guidance from February-August*							

*In jurisdictions with RSV seasonality that differs from most of the US (Alaska, southern Florida, Guam, Hawaii, Puerto Rico, US-affiliated Pacific Islands, and US Virgin Islands), providers should follow state, local, or territorial guidance on timing of ABRYSVO.

INDICATION

ABRYSVO is a vaccine indicated for

 active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age

IMPORTANT SAFETY INFORMATION (continued)

- A numerical imbalance in preterm births was observed compared to placebo in 2 clinical studies. Data are insufficient to establish or exclude a causal relationship between
 preterm birth and ABRYSVO. To avoid potential risk of preterm birth with use of ABRYSVO before 32 weeks of gestation, administer to pregnant individuals at 32 through 36 weeks
 gestational age
- Appropriate medical treatment must be available in case of an anaphylactic reaction
- · Syncope (fainting) may occur in association with administration of injectable vaccines, including ABRYSVO. Procedures should be in place to avoid injury from fainting
- Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to ABRYSVO
- Vaccination with ABRYSVO may not protect all vaccine recipients
- In clinical trials with pregnant individuals, the most commonly reported (≥10%) adverse reactions were pain at the injection site (40.6%), headache (31.0%), muscle pain (26.5%), and nausea (20.0%)
- In clinical trials with infants born to pregnant individuals, low birth weight (5.1% ABRYSVO versus 4.4% placebo) and neonatal jaundice (7.2% ABRYSVO versus 6.7% placebo) were observed

Individuals who received ABRYSVO during pregnancy are encouraged to contact 1-800-616-3791 to enroll in a Pregnancy Exposure Registry.

CDC = Centers for Disease Control and Prevention; LRTD = lower respirtory tract disease; LRTI = lower respiratory tract infection; ; RSV = respiratory syncytial virus.

Please see full Prescribing Information for ABRYSVO.

1. Britton A, et al. MMWR Morb Mortal Wkly Rep. 2024;73(32):696-702. 2. Fleming-Dutra KE, et al. MMWR Morb Mortal Wkly Rep. 2023;72:1115-1122.

