Help protect against RSV-LRTD

Start with ABRYSVO™

ABRYSVO is a bivalent vaccine indicated for active immunization of pregnant individuals from 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.[1]

> The only RSV vaccine indicated for the prevention of LRTD caused by RSV in infants from birth through 6 months (by immunizing pregnant individuals)[2]*

RSV: respiratory syncytial virus; LRTD: lower respiratory tract disease; SOGC: Society of Obstetricians and Gynaecologists of Canada

*Comparative clinical significance has not been established.

MATERNAL VACCINATION WITH RSVpreF IS PART OF THE NEW SOGC RECOMMENDATIONS ON RSV IMMUNIZATION[3]

See the complete statement

SAFETY INFORMATION[1]

Clinical use:
Safety and efficacy have not been established in pediatrics (< 18 years of age). Limited data are available in pregnant adolescents and their infants.

Contraindications:
- Patients with a known hypersensitivity to the active substance or to any component of the vaccine

Relevant warnings and precautions:
- Medical treatment should be available in case of a rare anaphylactic event following the administration of ABRYSVO
- Syncope (fainting) may occur with administration of injectable vaccines
- As with any vaccine, ABRYSVO will not protect 100% of those who receive it
- Postpone in those with acute febrile illness
- As with other vaccines administered intramuscularly, use with caution in those with thrombocytopenia or a coagulation disorder
- Immunocompromised individuals may have diminished response to ABRYSVO

For more information:
Consult the Product Monograph at https://www.pfi.sr/abrysvo-pm for important information relating to adverse reactions, drug interactions, and dosing that has not been discussed in this piece. The Product Monograph is also available by calling 1-800-463-6001.

References: 1. ABRYSVO Product Monograph. Pfizer Canada ULC. May 29, 2024. **2.** Data on file. Pfizer Canada ULC. January 22, 2024. **3.** Society of Obstetricians and Gynaecologists of Canada. SOGC statement on RSV immunization to prevent infant RSV infection. Accessed July 31, 2024. https://sogc.org/common/Uploaded%20files/Position%20Statements/SOGC%20Statement%20RSV_07182024_EN.pdf. **4.** Government of Canada. Respiratory syncytial virus (RSV) vaccines: Canadian Immunization Guide. Accessed August 13, 2024. https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/respiratory-syncytial-virus.html#a2.2. **5.** Centers for Disease Control and Prevention (CDC). RSV in infants and young children. Accessed September 10, 2024. https://www.cdc.gov/rsv/infants-young-children/?CDC_AAref_Val=https://www.cdc.gov/rsv/high-risk/infants-young-children.html. **6.** Government of Canada. Respiratory syncytial virus (RSV): for health professionals. Accessed January 24, 2024. https://www.canada.ca/en/public-health/services/diseases/respiratory-syncytial-virus-rsv/health-professionals.html. **7.** Parikh RC et al. Chronologic age at hospitalization for respiratory syncytial virus among preterm and term infants in the United States. *Infect Dis Ther*. 2017;6(4):477–486.

ABRYSVO™
Respiratory Syncytial Virus Stabilized Prefusion F Subunit Vaccine

ABRYSVO™
Pfizer Canada ULC

Kirkland, Quebec H9J 2M5

PP-A1G-CAN-0110-EN

Maternal vaccination with RSVpreF is part of the new SOGC recommendations on RSV immunization[3]

INFANTS ARE AT INCREASED RISK OF SEVERE RSV DISEASE DURING THEIR FIRST RSV SEASON[4,5*†]

Infants at increased risk include:

- Infants 6 months and younger are at increased risk of severe RSV disease
  - The younger the child, the higher the risk of hospitalization
- All premature infants (i.e. born at less than 37 wGA)
- Infants with:
  - Congenital lung disease
  - Cystic fibrosis
  - Congenital heart disease
  - Severe immunodeficiency
  - Severe congenital airway anomalies
  - Neuromuscular disease

RSV hospitalizations in infants*

Hospitalization rates are the highest in infants, especially within **the first 2 months of life**[6]

> 50% of hospitalizations were found to be in the first 3 months of life[7‡]

> 75% of hospitalizations were found to be in the first 6 months of life[7‡]

2 months

3 months

6 months

50%

75%

RSV: respiratory syncytial virus; wGA: weeks' gestational age; LRTD: lower respiratory tract disease; CI: confidence interval; MA: medically attended

*ABRYSVO is not indicated to prevent RSV-associated hospitalization/death. ABRYSVO did not have a statistically significant result in the hospitalization endpoint in the maternal/infant indication.

†During first RSV season.

‡A study designed to combine available data from literature and databases to determine the effect of chronologic age on RSV hospitalizations among US preterm and term infants.[7]

DEMONSTRATED POWERFUL PREVENTION AGAINST RSV-LRTD[1]

In infants from birth through 6 months of age (via active immunization of pregnant individuals)[¶§]

81.8% reduction at 90 days

(99.5% CI: 40.6, 96.3; case counts: ABRYSVO n=6/3,495**; placebo n=33/3,480)

73.9% reduction at 120 days

(97.58% CI: 45.6, 88.8; case counts: ABRYSVO n=12/3,495**; placebo n=46/3,480)

70.9% reduction at 150 days

(97.58% CI: 44.5, 85.9; case counts: ABRYSVO n=16/3,495**; placebo n=55/3,480)

69.4% reduction at 180 days

(97.58% CI: 44.3, 84.1; case counts: ABRYSVO n=19/3,495**; placebo n=62/3,480)

> ABRYSVO demonstrated statistically significant reduction in the relative risk of severe MA RSV-LRTD at all timepoints through 180 days vs. placebo

¶MATISSE: A Phase 3, multicentre, randomized, double-blind, placebo-controlled global study comparing ABRYSVO (n=3,695) to placebo (n=3,697) in infant participants born to pregnant individuals ≤ 49 years of age receiving one dose (0.5 mL) of ABRYSVO (120 mcg [60 mcg each of subgroup A and B, without an adjuvant $Al(OH)_3$]) or placebo intramuscularly. The study objective was assessment of VE, defined as the RRR of the endpoint in the ABRYSVO group compared to the placebo group. There were two primary efficacy endpoints, assessed in parallel: severe RSV-positive medically attended LRTD and RSV-positive MA-LRTD, occurring within 90/120/150/180 days after birth. The statistical criterion for success was defined as a CI lower bound > 20%.

§Severe MA RSV-LRTD was defined as meeting the RSV-LRTD criteria plus ≥ 1 of the following: fast breathing, low oxygen saturation (SpO_2 < 93%), high-flow nasal cannula or mechanical ventilation, ICU admission for > 4 hours, and/or failure to respond/unconsciousness. RSV-LRTD was defined as a medically attended visit with an RT-PCR–confirmed RSV illness with ≥ 1 of the following respiratory symptoms: fast breathing, low oxygen saturation (SpO_2 < 95% and chest wall indrawing).

**Evaluable efficacy population.

The prespecified success criterion was not met for MA RSV-LRTD at 90 days (co-primary endpoint).

57.1% reduction at 90 days

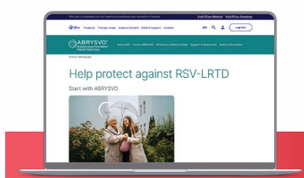
(99.5% CI: 14.7, 79.8; case counts: ABRYSVO n=24/3,495**; placebo n=56/3,480**)

The trial did not demonstrate a statistically significant reduction in hospitalizations due to RSV at 360 days (secondary endpoint).

33.3% reduction at 360 days

(99.17% CI: -17.6, 62.9; case counts: ABRYSVO n=38/3,495; placebo n=57/3,480)

The trial included pregnant individuals who were between 24 and 36 weeks of gestation. ABRYSVO is only indicated in pregnant individuals at 32–36 weeks' gestation.



Learn more about ABRYSVO