NOW APPROVED - RSV MATERNAL VACCINE[1,2]

INFANTS via maternal immunisation

ABRYSVO®

Recombinant respiratory syncytial virus pre-fusion F protein vaccine

EVERY *BREATH* MATTERS.

The first vaccine to help protect infants, via maternal immunisation, against lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV).[1,2]

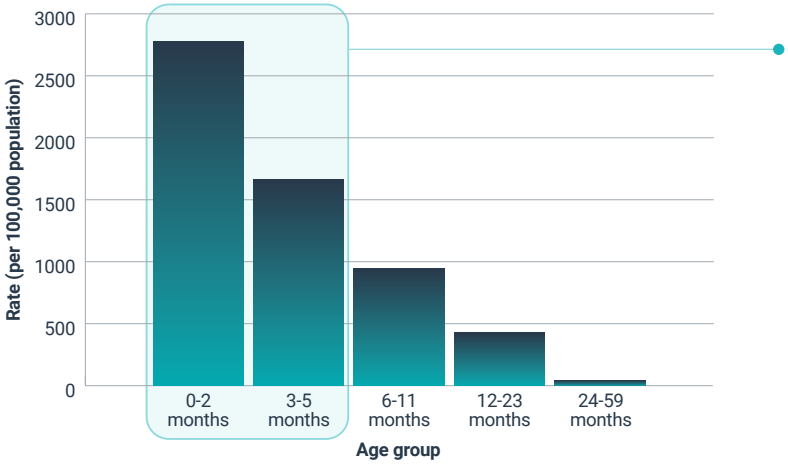
You can now offer protection to pregnant women for their newborns, helping to prevent the serious consequences of RSV-associated LRTD from birth through to 6 months of age.[1,2]

ABRYSVO is indicated for:

Active immunisation of pregnant women between 24–36 weeks' gestation for the prevention of LRTD caused by RSV, in **infants from birth through to 6 months of age**.[1]

RSV is a major cause of lower respiratory tract disease (LRTD) in infants and young children[3,4]

Paediatric hospitalisation rate for RSV as a principal diagnosis
(per 100,000 population)



Adapted from Saravanos GL, *et al.* 2019.[6]

LRTD due to RSV is a leading cause of hospitalisation in infants, with most hospitalisations in Australia occurring in infants aged under 6 months.[5,6]

- Infants are **more than 12x** as likely to be admitted to hospital with RSV as children aged 1–4 years.[6]
- RSV is responsible for **8x as many hospitalisations** as influenza in children <5 years.[7]
- In **indigenous children under 6 months old**, the rate of hospitalisation due to RSV is **almost double** that of non-indigenous children.[6]

Maternal immunisation with ABRYSVO is designed to help provide protection immediately from birth through to 6 months of age[1,8]

ABRYSVO administered

Pregnant individual receives ABRYSVO at **24–36 weeks' gestation**.[1]

RSV maternal antibodies

Pregnant individual's **immune system produces antibodies**, which are passed through the placenta to the foetus.[1,8]

Protection from birth

Infant is **born with maternal antibodies**, which help protect against RSV from birth, through to 6 months.[1,8]

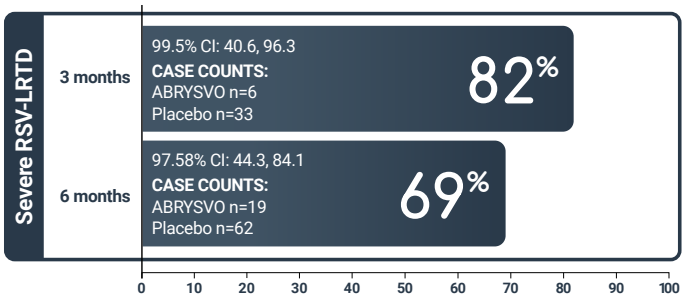
Don't let RSV take her baby's breath away.

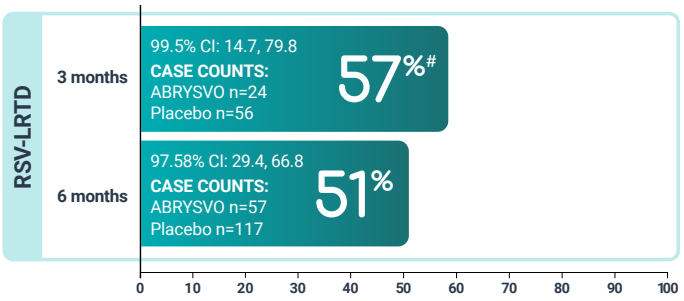
Scan the QR code to view the Australian Immunisation Handbook (AIH) and stay up to date with the latest recommendations.

ABRYSVO: The first opportunity to protect infants against LRTD caused by RSV*[1,2]

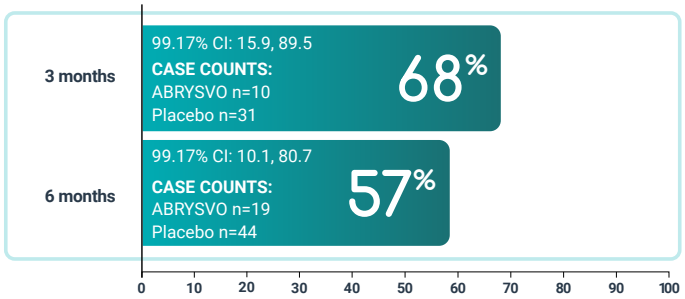
*Via maternal immunisation.[1]

ABRYSVO was effective at protecting infants from severe RSV-LRTD and RSV-LRTD, from birth†[1,8]





Adapted from Kampmann B, *et al*. 2023.[8]



Adapted from Kampmann B, *et al*. 2023.[8]

> ABRYSVO was effective at protecting infants from RSV-related hospitalisation§[1,8]

In infants, there were no safety signals detected, from birth through to 24 months[1,8]

Infant safety

The incidences of adverse events (AEs) reported within 1 month after birth in infants (n=3,568 and n=3,558 in ABRYSVO and placebo arms, respectively) were similar in the ABRYSVO group (37%) and the placebo group (35%).[1,8]

In maternal participants, safety was similar to placebo, with most local and systemic reactions mild to moderate in severity[1,8]

Maternal safety

- Most adverse reactions resolved within 2–3 days of onset.[1]
- The most frequently reported adverse reactions (≥1/10) were: fatigue (46%), vaccination site pain (41%), headache (31%), myalgia (27%), nausea (20%), joint pain (12%) and diarrhoea (11%).

> Choose ABRYSVO to help protect infants against RSV, from first breath through to 6 months of age[1,8]

† VE results met the statistical criterion for success (a CI lower bound >20%) for reducing severe medically attended lower respiratory tract illness due to RSV at all timepoints through 180 days.[8]

VE results did not meet the statistical criterion for success (a CI lower bound >20%) at 90 days for reducing medically attended lower respiratory tract illness due to RSV; however, clinically meaningful efficacy was observed from 90 days through 180 days after birth.[8]

§ VE results met the statistical criterion for success (a CI lower bound >0%) for hospitalization due to RSV in infants at all timepoints through 180 days.[8]

Learn more about the impact of RSV and ABRYSVO on PfizerPro

Special warnings and precautions for use:

· Do not administer ABRYSVO to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of ABRYSVO.[1]

· Appropriate medical treatment must be available in case of an anaphylactic reaction.[1]

If you have questions regarding ABRYSVO please contact **Pfizer Medical Information** on **1800 675 229**.

A one-time sign-up to any of our websites will connect you to our range of digital services for healthcare professionals.

Visit www.pfi.sr/abrysvopfizerpro for additional resources, including:

· How to reconstitute and administer ABRYSVO.

· Information about upcoming educational events.

· Podcasts and videos to help you learn more about RSV.

· Resources to download for you and your patients.

ABRYSVO Instructions for Use Video

Watch this short 3 min video for instructions on how to use ABRYSVO.

WATCH THE VIDEO

Take A Breath

An educational series discussing the diagnosis and management of respiratory infections.

LISTEN TO THE PODCAST

Medical Information Specialists

Access our tools and resources online, plus speak to our Medical Information Specialists (Mon-Fri 9am-5pm AEST).

ACCESS MEDICAL INFORMATION

▼ This vaccine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

PBS Information: ABRYSVO is not listed on the National Immunisation Program (NIP) or the PBS.

Before prescribing, please review the approved Product Information **by scanning the QR code.** ABRYSVO should be used in accordance with local recommendations.

Minimum Product Information: ABRYSVO® (recombinant respiratory syncytial virus pre-fusion F protein) 120 micrograms/0.5 mL bivalent vaccine powder for injection vial and diluent syringe.

Indications: Active immunisation of pregnant women (24-36 weeks gestation) for preventation of lower respiratory tract disease caused by RSV in infants (birth through 6 months); Active immunisation of individuals (60 years and above) for prevention of lower respiratory tract disease caused by RSV. Use ABRYSVO in accordance with official recommendations. **Contraindications:** Hypersensitivity to the active ingredient or to any of the excipients. **Precautions:** Appropriate treatment and supervision must be readily available in case of a rare anaphylactic reaction. Consider the risks of intramuscular injection in thrombocytopenia or coagulation disorders. Postpone in acute febrile illness. Anxiety-related reactions including syncope can occur following/before any vaccination. Immunocompromised individuals, including individuals receiving immunosuppressant therapy, may have a diminished immune response. No studies in pregnant individuals <24 weeks gestation. Protection may not be conferred in all individuals. Not for active immunisation in children. See PI for details. **Interactions with other Medicines:** Can be administered concomitantly, at different injection sites, with seasonal influenza vaccine and COVID-19 mRNA vaccines. Immunogenicity data indicated non-inferiority in immune response to RSV, diphtheria and tetanus components compared to ABRYSVO or dTpa administered alone. Immune response to the pertussis component of dTpa was lower in concomitant administration than dTpa administered alone. The clinical relevance of this is unknown. See PI for details. **Adverse Effects:** Headache, myalgia, vaccination site pain, vaccination site redness, vaccination site swelling, Guillain-Barré syndrome, hypersensitivity. See PI for details. **Dosage and Administration:** Single (0.5 mL) dose. For intramuscular use only. See PI for details. V10324.

References: 1. ABRYSVO Approved Product Information. **2.** ARTG Public Summary for Abrysvo, 20/03/2024. **3.** Bracht M, *et al. Drugs R D*. 2011 Sep 1;11(3):215–226. **4.** World Health Organization (2023) Respiratory Syncytial Virus (RSV) Disease. Available at https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/vaccine-standardization/respiratory-syncytial-virus-disease. Accessed: May 2024. **5.** Parikh RC, *et al. Infect Dis Ther*. 2017;6(4):477–486. **6.** Saravanos GL, *et al. Med J Aust*. 2019;210(10):447–453. **7.** Nazareno AL, *et al. Influenza Other Respir Viruses*. 2022;16(6):1082–1090. **8.** Kampmann B, *et al. N Engl J Med*. 2023;388(16):1451–1464.