Respiratory Syncytial Virus (RSV) Vaccine ABRYSVO™ Supplier: Pfizer Canada ULC

RECOMMENDED BY THE NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION BUT NOT PROVIDED FREE IN BC:

Strong recommendation:

- Adults 75 years of age and older
- Adults 60 years of age and older who are residents of nursing homes and other chronic care facilities

Discretionary recommendation:

- Other adults 60 to 74 years of age
- Pregnant people 18 years of age and older (32-36 weeks gestation)

This vaccine is only approved for the individuals indicated above.

DOSES AND SCHEDULE:

• 1 dose given as 0.5 mL IM.

ADMINISTRATION:

- Product needs to be reconstituted. Use the diluent provided with the vaccine.
- This product comes with a vial adapter. Details and a diagram on how to reconstitute are contained in the <u>product monograph</u> and the accompanying text is reproduced here. Connect the vial adapter with the vial with a straight downward push. Do not push the vial adapter in at an angle as it may result in leaking. Connect the syringe's Luer lock adapter to the vial adapter. Inject the entire contents of the syringe into the vial, hold the plunger rod down and gently swirl the vial until the powder is completely dissolved. Do not shake. Invert the vial and withdraw dose into syringe.
- Administer the entire volume of the reconstituted product.

BOOSTER DOSES:

No booster doses are recommended at this time.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of any RSV vaccine or to any component of ABRYSVO[™].

PRODUCT COMPONENTS:

Potential allergens: polysorbate 80.

Other components: mannitol, sodium chloride, sucrose, tromethamine, trometamol hydrochloride.

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PRECAUTIONS:

• Some studies have found an increase in preterm births among recipients of ABRYSVO™ compared to placebo recipients. This was not observed in high-income countries like Canada. It is unclear whether there is a causal relationship with the vaccine; the currently available data are inconclusive. By limiting vaccine administration to 32 through 36 weeks gestation, the potential risk of preterm birth is reduced.

SPECIAL CONSIDERATIONS:

- ABRYSVO[™] is administered during pregnancy to protect the infant through the passive transfer of maternal antibodies. Although BEYFORTUS[™] ^A administration in infants is preferred, limited quantities of BEYFORTUS[™] are available in BC for the 2024-25 RSV season. BEYFORTUS[™] is only available through the BC Infant Respiratory Syncytial Virus (RSV) Immunoprophylaxis Program and is not available for private purchase. If it is not anticipated that the infant will receive BEYFORTUS[™], administration of ABRYSVO[™] between 32 and 36 weeks gestation may be considered in advance of, or during RSV season to protect infants expected to be born during the RSV season.^B ABRYSVO[™] is optimally administered at least 2 weeks before birth to allow for the transplacental transfer of protective antibodies.
- ABRYSVO[™] can be administered concomitantly or at any time before or after the administration of other vaccines.^c
- ABRYSVO[™] in pregnancy is not expected to provide added benefit for healthy infants who will receive RSV monoclonal antibody (BEYFORTUS[™]).
- At this time, no data are available on the efficacy or safety of additional doses of ABRYSVO[™] given during subsequent pregnancies.
- The duration of protection of RSV vaccines is not yet known and it is unclear if the protection offered by vaccination can be boosted by subsequent doses of vaccine. Therefore, individuals 60-74 years of age who are not at increased risk of severe disease may want to discuss deferring vaccination with their health care provider to a future time when they may be at greater risk of severe disease.

ADVERSE EVENTS:

Local: pain, redness, swelling.

Systemic: fever, fatigue, headache, myalgia, arthralgia, nausea, diarrhea, vomiting.

Although data are limited, early safety data suggest a potential increased rate of atrial fibrillation events and inflammatory neurologic events, including Guillain-Barré syndrome, after administration of RSV vaccines in adults 60 years of age and older.

^A BEYFORTUS[™] (nirsevimab) is a long-acting monoclonal antibody that protects against RSV infection.

^B The RSV season is typically between mid-fall to early spring, though this may vary by geographic region.

^c A single study found that co-administration of Abrysvo[™] and Tdap vaccine may result in a lower immune response to the pertussis component compared to Tdap vaccine given alone; however, the clinical relevance of this is not known. Some studies suggest that concurrent administration of the RSV and influenza vaccines in adults may result in a lower immune response, but the clinical significance of this is unknown.