

Respiratory Syncytial Virus Vaccine (RSV)

BIOLOGICAL PAGE

Section 7	Biological Product Information	Standard # 07.316
Created and approved by	Provincial Immunization Program Standards and Quality	
Approval date	October 9, 2024	Revised

ABRYSVO	
Manufacturer	Pfizer Canada ULC
Classification	Subunit
Indications for Provincially Funded Vaccine	<p>Individuals who have not previously received any dose of RSV vaccine and are:</p> <ul style="list-style-type: none"> Residents of continuing care homes and senior supportive living accommodations that are 60 years of age and older. Community dwelling seniors 75 years of age and older.
Schedule	<p>1 dose</p> <ul style="list-style-type: none"> If an individual received a previous dose of any RSV vaccine, they are considered up to date and no additional doses are recommended at this time.
Preferred Use	N/A
Dose	0.5 mL
Route	IM
Contraindications/ Precautions	<p>Contraindications:</p> <ul style="list-style-type: none"> Known severe hypersensitivity to any component of the vaccine. Anaphylactic or other allergic reaction to a previous dose of Abrysvo. <p>Precautions:</p> <ul style="list-style-type: none"> There is no data on the use of Abrysvo in individuals who are immunocompromised. Immunocompromised individuals, including those taking immunosuppressant therapy, may have a diminished immune response.
Possible Reactions	<p>Reactions reported in individuals 60 years of age and older.</p> <p>Common:</p> <ul style="list-style-type: none"> Pain, erythema, swelling at the injection site Fatigue, headache Myalgia, arthralgia Fever Nausea, Diarrhea. <p>Uncommon:</p> <ul style="list-style-type: none"> Vomiting. <p>Rare:</p> <ul style="list-style-type: none"> Anaphylaxis. <p>Unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.</p>

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Pregnancy	<p>Not recommended during pregnancy at this time.</p> <ul style="list-style-type: none"> The National Advisory Committee on Immunization (NACI) does not recommend an immunization program for individuals who are pregnant, even though vaccine is licensed for use in the third trimester (32-36 weeks). Abrysvo has been studied in pregnant individuals from 24-36 weeks gestation. <p>Note:</p> <p>Monoclonal antibodies are recommended for infants in the prevention of RSV infection.</p>
Lactation	<p>Do not use for people who are breast/chest feeding.</p> <ul style="list-style-type: none"> There is no data on the excretion of Abrysvo in human or animal milk.
Composition	<p>Each 0.5 mL dose contains:</p> <ul style="list-style-type: none"> Lyophilized powder containing 120 mcg of RSV stabilized prefusion F protein: <ul style="list-style-type: none"> 60 mcg Subgroup A 60 mcg Subgroup B. Non-medicinal Ingredients: <ul style="list-style-type: none"> 22.5 mg mannitol 0.08 mg polysorbate 80 1.1 mg sodium chloride 11.3 mg sucrose 0.11 mg tromethamine 1.04 mg trometamol hydrochloride sterile water as the diluent.
Blood/Blood Products	Does not contain any human blood/blood products.
Bovine/Porcine Products	Does not contain bovine or porcine products.
Latex	Does not contain latex.
Interchangeability	N/A
Administration with Other Products	<p>Do not give at the same time as other vaccines.</p> <ul style="list-style-type: none"> Limited efficacy and safety studies have been conducted on giving RSV vaccine at the same time as other vaccines. <ul style="list-style-type: none"> Some studies suggest that giving RSV vaccine and other vaccines at the same time may not produce as strong of an immune response. The clinical significance of this is unknown and more evidence is required to understand if this is a risk. Space RSV vaccine from other vaccines to adequately monitor vaccine safety and to ensure that adverse events following immunization are not attributed to another vaccine. <p>Spacing recommendations:</p> <ul style="list-style-type: none"> Prioritize giving seasonal influenza and seasonal COVID-19 vaccines first during respiratory season. Space RSV vaccine by 2 weeks before or after seasonal influenza and/or seasonal COVID-19 vaccines. <ul style="list-style-type: none"> Space RSV vaccine by 6 weeks before or after any other non-seasonal vaccines. Consider the dose valid if RSV vaccine is inadvertently administered without the recommended 2-or 6-week spacing interval.
Appearance	Final reconstituted solution is clear and colourless.
Storage/Preparation	<p>Un-reconstituted vaccine:</p> <ul style="list-style-type: none"> Store in a refrigerator between 2°C and 8°C. Store in the original carton to protect from light.

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	<ul style="list-style-type: none"> Do not freeze. <p>Reconstituted vaccine:</p> <ul style="list-style-type: none"> Once reconstituted, administer promptly. <ul style="list-style-type: none"> If a delay in administration, store reconstituted vaccine between 15°C and 30°C and administer within 4 hours. Do not store under refrigerated conditions (2°C to 8°C). Do not freeze. <p>Preparation:</p> <ul style="list-style-type: none"> Please see product monograph for detailed information regarding reconstitution.
Vaccine Code	RSV
Antigen Code	RSV-F
Licensed for	<ul style="list-style-type: none"> 60 years of age and older Individuals who are pregnant in the third trimester (32-36 weeks)
Notes	<ul style="list-style-type: none"> 2024 October 7: Introduced Respiratory Syncytial Virus (RSV) Vaccine into the routine immunization program for residents of continuing care homes and senior supportive living accommodations that are 60 years of age and older and community dwelling seniors 75 years of age.
Related Resources	Respiratory Syncytial Virus (RSV) Vaccine Information Sheet
<p>References</p> <p>Alberta Health. (2024, October 1). Respiratory Syncytial Virus Vaccine (RSV). In <i>Alberta Immunization Policy: Biological Products</i>. Government of Alberta.</p> <p>National Advisory Committee on Immunization. (2024, July 12). <i>Statement on the prevention of respiratory syncytial virus disease in older adults. An advisory committee statement</i>. Public Health Agency of Canada.</p> <p>Public Health Agency of Canada. (2024, August). <i>Respiratory syncytial virus (RSV) vaccines</i>. In <i>Canadian Immunization Guide: Part 4: Immunizing agents</i>. Government of Canada.</p> <p>Pfizer Canada ULC. (2023, December 21). ABRYSVO Respiratory Syncytial Virus Stabilized Prefusion F Subunit Vaccine. Health Canada drug product database. https://pdf.hres.ca/dpd_pm/00073900.PDF</p>	