

Ministry of Health

Respiratory Syncytial Virus (RSV) Fact Sheet for Health Care Providers

Version 2.0 – December 18, 2023

This question-and-answer sheet for health care professionals provides basic information only. It is not intended to provide or take the place of medical advice, diagnosis, or treatment. For more information about the Arexvy vaccine, please refer to the [product monograph](#) authorized by Health Canada.

1. What is Respiratory Syncytial Virus?

Respiratory Syncytial Virus (RSV) is a major cause of lower respiratory illness, particularly among infants, children, and older adults.

Older adults, particularly those with existing comorbid conditions, are more susceptible to severe disease and have an increased risk of RSV-related hospitalization and mortality. In Ontario, most deaths from RSV have occurred in those aged 60 years and older. Older adults in long-term care and retirement homes also have longer hospital stays than the general population due to RSV.

During peak RSV season, hospitals have seen a surge in emergency room visits and admissions of young children and older adults requiring medical care, putting a strain on hospital resources, including beds, staffing, and specialized units.

2. What RSV vaccine products are available for use in Canada?

GSK received Health Canada authorization on August 4, 2023, for their RSV vaccine, Arexvy. Arexvy is an adjuvanted vaccine containing a recombinant subunit prefusion RSV F glycoprotein antigen (RSVPreF3) combined with GSK's proprietary AS01_E adjuvant. Additional RSV vaccines are expected to be authorized in the Canadian market in the coming year.

3. Who is eligible to receive the publicly funded RSV vaccine in Ontario for the 2023-2024 RSV season?

Ontario's publicly funded RSV prevention program is targeted for high risk individuals and settings. The program includes individuals 60 years and older who are:

- Living in long-term care homes
- Living in Elder Care Lodges
- Residents of retirement homes licensed to provide dementia care
- Patients in hospital receiving alternate level of care (ALC)
- Patients receiving hemodialysis or peritoneal dialysis
- Recipients of solid organ or hematopoietic stem cell transplants
- Individuals experiencing homelessness
- Individuals who identify as First Nations, Inuit, or Métis

4. How to order RSV Vaccine?

Vaccine Provider	Ordering Process
Toronto providers	Email your RSV vaccine orders to vaccineorder@toronto.ca using the Toronto Provider RSV Vaccine Order Form. Please contact Toronto Public Health for more information.
Providers outside of Toronto	Local PHU using the appropriate PHU vaccine order process. Please contact your local PHU for more information.

5. How can I reduce vaccine wastage?

For information on vaccine waste reduction best practices, please refer to the [Vaccine Storage and Handling Guidelines](#). Furthermore, there is a limited quantity of Arexvy in the 1-pack format. Thus, it is recommended that vaccinators tailor which product formats they order to reduce vaccine wastage (e.g., if you require 25 doses of RSV vaccine, please order two 10-packs and five 1-packs versus ordering twenty-five 1-packs).

6. What is the recommended indication, dose and immunization schedule for Arexvy?

Arexvy is indicated for the prevention of lower respiratory tract disease (LRTD) caused by RSV in adults 60 years of age and older. This vaccine must be reconstituted and administered intramuscularly (IM) as a single dose of 0.5 mL, containing both antigen and adjuvant components.

The need for future doses is unknown at this time.

7. Who should NOT receive the RSV vaccine?

Those who have a history of severe allergic reaction to any of the vaccine ingredients, including non-medicinal ingredients or any materials found in the vaccine's packaging (such as the vial cap, aluminum seal, or synthetic rubber stopper). Please refer to the [product monograph](#) for detailed information on contraindications and precautions.

8. What is the efficacy of the RSV vaccine?

Vaccine efficacy was 94.1% (95% CI, 62.4 to 99.9) against severe RSV-related lower respiratory tract disease and 71.7% (95% CI, 56.2 to 82.3) against RSV-related acute respiratory infection. Efficacy overall was 82.6% and still retained at 77.3% by the second season (1 year later).

9. What are the side effects of the RSV vaccine?

Like any other vaccine or medication, the RSV vaccine may have some side effects, which in most cases are mild and last only a few days. Common side effects after the RSV vaccine can include pain, redness, and swelling where the shot is given, fatigue (feeling tired), fever, headache, nausea, diarrhea, and muscle or joint pain.

Serious neurologic conditions, including Guillain-Barré syndrome, have been reported very rarely after RSV vaccination in clinical trials. It is unclear whether the vaccine caused these events.

Please refer to the [product monograph](#) for more information.

As a new vaccine, post-market surveillance of vaccine safety will continue to provide details on the product.

10. What information should be provided to individuals related to potential adverse events following immunization (AEFI) with the RSV vaccine?

As per s.38 of the *Health Protection and Promotion Act*, those administering this vaccine should ensure that the vaccine recipients or their substitute decision-makers are aware of the need to immediately report AEFIs to their health care provider. Vaccine recipients should be advised to go to the nearest emergency department if severe reactions develop, including the following:

- Hives
- Swelling of the mouth or throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Seizures
- Other serious reactions

Health care providers (e.g., physicians, nurses and pharmacists) are required by law (i.e., *Health Protection and Promotion Act*, s.38) to report AEFIs associated with the RSV vaccine to their local public health unit. Reports should be made using the [Ontario AEFI Reporting Form](#) and faxed to the local public health unit.

11. Who can administer the RSV vaccine?

- Currently, physicians, nurse practitioners, registered nurses (RNs) and registered practical nurses (RPNs) can administer the RSV vaccine.
- Currently, RNs and RPNs can administer the RSV vaccine based on a medical directive or a direct order.
- At this time, pharmacy professionals (pharmacists, registered pharmacy students, interns, and pharmacy technicians) are not authorized to administer the RSV vaccine.

12. Can the RSV vaccine be given at the same time as other vaccines?

[As per the Ontario Immunization Advisory Committee \(OIAC\)](#), routine co-administration with other vaccines is not recommended at this time as a precaution. This is not due to any safety signals but instead to enable proper surveillance of potential vaccine effects. It is recommended to wait 14 days before or after the administration Arexvy and other vaccines.

There may be scenarios where co-administration may be considered in situations where, in the provider's best judgment, the benefits outweigh the risks, including:

- When there is an outbreak of RSV, COVID-19 or influenza within the home or nearby;
- If community activity of COVID-19, influenza and/or RSV is high and increasing;
- When there is a risk that the individual otherwise will not receive the recommended vaccine doses.

13. Can the RSV vaccine be given to individuals who are ill?

It is dependent on the severity of symptoms. Those with a severe acute illness with or without a fever should wait until symptoms have subsided before being vaccinated. The presence of a minor illness, such as a cold, should not result in the deferral of vaccination.

14. How long after RSV infection should an individual be offered the RSV vaccine?

If an individual has had an RSV infection, they may be offered vaccination against RSV once they are clinically well. There is no specific interval that is recommended between RSV infection and RSV vaccination.

15. How long should the observation period be following RSV immunization?

Vaccine recipients should be kept under observation for at least 15 minutes after immunization; 30 minutes is a preferred interval when there is a specific concern about a possible vaccine allergy.

16. How is the RSV vaccine packaged?

Arexvy is packaged in either a 10-pack or 1-pack container. Each 10-pack includes ten single-dose vials of the **lyophilized antigen (powder)** in a type 1 glass with a mustard-coloured vial cap and butyl rubber stopper and ten vials of the **adjuvant (suspension)** in a type 1 glass with a brown vial cap and butyl rubber stopper. Each 1-pack includes one single-dose vial of **lyophilized antigen (powder)** and one vial of the **adjuvant (suspension)**.

17. How is Arexvy stored?

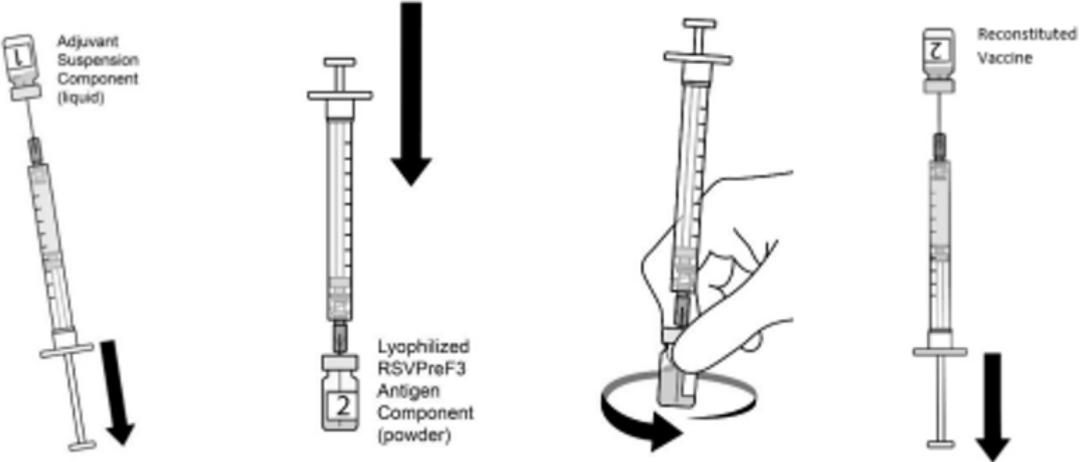
To ensure optimal protection, Arexvy (both the lyophilized antigen powder and adjuvant) must be maintained at a temperature between +2°C and +8°C and this temperature must always be monitored to ensure cold chain is maintained. Please refer to the [product monograph](#) for more information on Arexvy storage and handling. For additional information on provincial vaccine storage and handling requirements, please refer to the [Vaccine Storage and Handling Guidelines](#).

18. How is Arexvy prepared?

Arexvy must be reconstituted prior to administration. Arexvy is a suspension for injection supplied as a lyophilized antigen (white powder) that is reconstituted with the accompanying adjuvant suspension. ***A single dose after reconstitution is 0.5 mL.***

*As per the GSK [Product Monograph](#)

Reconstitution Instructions:



Step 1. Cleanse both vial stoppers. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the adjuvant suspension component (liquid) by slightly tilting the vial. Vial 1 of 2 (brown cap vial).

Step 2. Slowly transfer entire contents of syringe into the lyophilized RSVPreFe antigen component vial (powder). Vial 2 of 2 (mustard-coloured cap vial).

Step 3. Gently swirl the vial until powder is completely dissolved. **Do not shake vigorously.**

Step 4. After reconstitution, using a new needle of suitable gauge and length for intramuscular vaccination, withdraw 0.5 mL of the reconstituted vaccine into the syringe and administer **intramuscularly.**

The reconstituted vaccine should be opalescent (colourless to pale brownish liquid).

*Always inspect for particulate matter and/or variation of appearance (e.g., discolouration) prior to administration. If either of these conditions exists, the vaccine should **not** be administered.

19. Where can health care providers find more information about the RSV vaccine?

Health care providers looking for more information about RSV, the RSV vaccine or the province's RSV vaccination program can refer to the ministry's [RSV website](#) and the [product monograph](#).

20. Where can members of the public and vaccine recipients get more information about the RSV vaccine?

Health care providers can direct patients/residents to the ministry's [RSV website](#). Providers can also direct patients/residents to the RSV fact sheet for patients.

LTC, Elder Care Lodges and RHs are also encouraged to provide information to residents and substitute decision-makers/caregivers.

21. Where can individuals find information about the infant RSV prevention program?

Individuals can find information about the infant RSV prevention program at the ministry's [RSV website](#).

22. Additional Resources

- [Arexvy Product Monograph](#)
- [Respiratory Syncytial Virus](#)