

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

AREXVY

Respiratory Syncytial Virus (RSV) vaccine (recombinant, AS01_E adjuvanted)

Reconstituted Suspension for Intramuscular Injection

Read this carefully as it provides important information about **AREXVY**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **AREXVY**.

What is AREXVY used for?

AREXVY is a vaccine that helps to protect adults 60 years of age and older from lower lung disease caused by respiratory syncytial virus (RSV).

RSV is a common highly contagious respiratory virus, causing infections of the lungs and breathing passages. RSV causes yearly outbreaks of respiratory infections in Canada from late fall to early spring.

RSV infection can happen at any age, and usually causes mild, cold-like symptoms. But it can also cause more serious respiratory illness, as well as make some illnesses and conditions worse in older adults. Older adults who experience a natural decrease in immunity due to aging, adults with weakened immune systems, and adults with underlying chronic conditions such as respiratory (such as asthma, COPD), heart, metabolic (such as diabetes) and advanced liver or kidney diseases) are at higher risk of severe outcomes from RSV such as pneumonia, new or worsening of underlying chronic conditions (such as asthma, COPD, congestive heart failure), heart attack and stroke that can lead to hospital stays or even death.

Speak with your healthcare professional to understand your risk of RSV.

How does AREXVY work?

AREXVY helps the body make antibodies and white blood cells to significantly reduce the chance of getting a RSV lower lung infection caused by RSV-A or RSV-B subtypes in adults aged 60 years and older.

As AREXVY does not contain the RSV virus, it cannot cause an infection.

As with all vaccines, AREXVY may not fully protect all people who are vaccinated.

What are the ingredients in AREXVY?

Medicinal ingredient: Each dose (0.5 mL) of AREXVY contains 120 micrograms of RSVPreF3 powder.

The AS01_E adjuvant is used to improve the body's response to the vaccine and is composed of the plant extract *Quillaja saponaria* Molina, fraction 21 (QS-21) (25 micrograms) and 3-O-desacyl-4'-monophosphoryl lipid A (MPL) from *Salmonella minnesota* (25 micrograms).

Non-medicinal ingredients: Each dose (0.5 mL) of AREXVY contains cholesterol, dioleoyl phosphatidylcholine, dipotassium phosphate, disodium phosphate anhydrous, MPL, polysorbate 80, potassium dihydrogen phosphate, QS-21, sodium chloride, trehalose dihydrate, and water for injection.

AREXVY comes in the following dosage forms:

AREXVY is available as a suspension for intramuscular injection. AREXVY comes in two (2) single-dose vials to be mixed together to prepare a single-dose (0.5 mL) injection.

Do not use AREXVY if you are allergic (hypersensitive) to any of the ingredients contained in AREXVY (see What are the ingredients in AREXVY). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

To help avoid side effects and ensure proper use, talk to your healthcare professional before AREXVY is given to you. Talk about any health conditions or problems you may have, including if you have:

- A severe infection with a high temperature. In these cases, the vaccination may be postponed until recovery. A minor infection such as a cold, including mild fever, should not be a problem, tell your healthcare professional first.
- A bleeding problem or bruise easily.
- Fainted with a previous injection or before receiving any needle injection.

Other warnings you should know about:

- Do not drive or use machines if you are feeling unwell.

Pediatrics (< 18 years of age):

- AREXVY is not indicated for use in infants, children and adolescents under 18 years old.

Pregnancy and breast-feeding:

- There is no information on the use of AREXVY in pregnant or breast-feeding women.
- AREXVY is not recommended for use in pregnancy or in breast-feeding women.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following may interact with AREXVY:

- Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, or have recently received any other vaccine.

How to take AREXVY:

AREXVY must be reconstituted prior to administration. The reconstituted vaccine is an opalescent, colourless to pale brownish liquid.

- AREXVY is given as a single injection of 0.5 mL into a muscle (usually in the upper arm).
- AREXVY may be given at the same time as an inactivated seasonal influenza vaccine.
- If AREXVY is given at the same time as another vaccine, a different injection site will be used for each vaccine.

Usual dose:

AREXVY is given as a single dose of 0.5 mL as an injection.

Overdose:

Contact a healthcare professional, hospital emergency department, or regional poison control centre immediately.

What are possible side effects from using AREXVY?

Like all medicines, AREXVY can cause side effects, although not everyone gets them.

The following side effects may occur after receiving AREXVY. Most side effects are mild and moderate, and do not last long (usually 1 to 2 days). These are not all the possible side effects you may have when taking AREXVY.

Very common (these may occur with more than 1 in 10 doses of the vaccine):

- pain at the injection site
- tiredness
- headache
- muscle pain (myalgia) and joint pain (arthralgia)

Common (these may occur with up to 1 in 10 doses of the vaccine):

- redness and swelling at the injection site, fever, chills
- runny nose (rhinorrhea)

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):

- injection site itching (pruritus), pain, generally feeling unwell
- swelling of lymph nodes (lymphadenopathy)
- allergic reaction such as rash
- feeling sick (nausea), stomach pain

If any of the side effects get serious or becomes bad enough to interfere with your daily activities, you have a troublesome symptom or side effect that is not listed here, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and GlaxoSmithKline Inc. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store AREXVY in the original package to protect from light, in a refrigerator at 2°C to 8°C (do not freeze).

Keep out of reach and sight of children.

If you want more information about AREXVY:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this

Patient Medication Information by visiting the Health Canada website:
(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.gsk.ca], or by calling the manufacturer at 1-800-387-7374.

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