AREXVY

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about receiving this vaccine, speak to your doctor, nurse or pharmacist.

▼ This vaccine is new. Please report side effects. See the full CMI for further details.

1. Why am I being given AREXVY?

AREXVY is a vaccine that helps to protect individuals against Respiratory Syncytial Virus (RSV) infection in adults over the age of 60, and adults 50 through 59 who are at increased risk of RSV disease. RSV is a highly contagious respiratory virus that causes infections of the lungs and breathing passages. Infection can occur at any age. It usually causes mild, cold-like symptoms in adults. RSV can also cause more serious respiratory illnesses in infants and older adults.

For more information, see Section 1. Why am I being given AREXVY? in the full CMI.

2. What should I know before I am given AREXVY?

You should not be given AREXVY if you have ever had an allergic reaction to any of the ingredients listed at the end of the CMI.

Talk to your doctor or nurse if you are currently unwell, have any other medical conditions or take any other medicines. AREXVY is not intended to be used in pregnant or breastfeeding women but talk to your doctor if you are meant to receive this vaccine when you are pregnant, intending to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given AREXVY? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AREXVY and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is AREXVY given?

- Your doctor or nurse will give you AREXVY as a single injection into a muscle (usually in the upper arm).

More instructions can be found in Section 4. How is AREXVY given? in the full CMI.

5. What should I know when being given AREXVY?

Things you should do	• Remind the person who is giving you your vaccination if you are taking other medicines. • Keep a record of your immunisation history.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how AREXVY affects you.
Looking after your vaccine	• AREXVY will normally be stored at the doctor's surgery or in the pharmacy. • If you need to store AREXVY, it is important to keep it in the pack to protect it from light. • Store AREXVY in the refrigerator between 2°C and 8°C. • Do not freeze.

For more information, see Section 5. What should I know when being given AREXVY? in the full CMI.

6. Are there any side effects?

Side effects which have been reported following administration of AREXVY include itching, pain, redness or swelling at the injection site, fever, chills, tiredness, headache, muscle pain, joint pain, a runny nose, generally feeling unwell, nausea, stomach pain and swelling of the lymph nodes. Allergic reactions have also occurred following administration of AREXVY. Allergy is rare and severe reactions will usually occur within the first few hours of vaccination. There is also a very rare (estimated 7 excess cases of per million doses administered as observed in a study conducted in the US in people aged 65 years and older) risk of Guillain-Barré syndrome, an autoimmune syndrome affecting the nerves resulting in weakness of muscles. This event has not been definitively linked to the use of AREXVY. If this occurs go to the Emergency Department of the nearest hospital immediately.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This vaccine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

AREXVY

Active ingredient: *Recombinant Respiratory Syncytial Virus pre-fusion F protein (RSVPreF3)*

Consumer Medicine Information (CMI)

This leaflet provides important information about AREXVY. **You should also speak to your doctor or nurse if you would like further information or if you have any concerns or questions about AREXVY.**

Where to find information in this leaflet:

1. Why am I being given AREXVY?
2. What should I know before I am given AREXVY?
3. What if I am taking other medicines?
4. How is AREXVY given?
5. What should I know when being given AREXVY?
6. Are there any side effects?
7. Product details

1. Why am I being given AREXVY?

AREXVY is a vaccine that contains the active ingredient Recombinant Respiratory Syncytial Virus pre-fusion F protein (RSVPreF3). It is mixed with an adjuvant suspension to form the vaccine that you will receive.

The adjuvant is used to improve the body's response to the vaccine.

AREXVY helps to protect individuals against Respiratory Syncytial Virus (RSV) infection in adults over the age of 60, and in adults 50 through 59 who are at increased risk of RSV disease.

RSV is a highly contagious respiratory virus that causes infections of the lungs and breathing passages. It usually causes mild, cold-like symptoms in healthy adults. However, it can also cause more serious respiratory illnesses and complications, such as infection of the lungs (pneumonia), in older adults and adults with underlying medical conditions.

RSV infection may also worsen some existing conditions such as long-term respiratory conditions or heart disease.

The vaccine works by helping your body make antibodies and special white blood cells to reduce your chances of experiencing a serious illness due to RSV infection.

AREXVY does not contain the RSV virus and it cannot cause lung infection.

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

2. What should I know before I am given AREXVY?

Warnings

Do not receive AREXVY if:

- you are allergic to AREXVY, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this vaccine.

Check with your doctor, nurse or pharmacist if you:

- have any other medical conditions
- have lowered immunity
- have a bleeding problem or bruise easily
- take any medicines for any other condition
- currently have a severe infection with a high temperature.

Your doctor, nurse or pharmacist may decide to delay vaccination with AREXVY until the illness has passed. A minor infection such as a cold is not usually a reason to delay vaccination but talk to your doctor about this before being vaccinated.

If you are unwell and cannot receive AREXVY, talk to your doctor or nurse about when you can receive it.

You may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

AREXVY is not recommended during pregnancy or breast-feeding. Talk to your doctor, nurse or pharmacist if you are pregnant or intend to become pregnant or are breastfeeding.

Fainting

Fainting can occur following, or even before, any needle injection. Tell the person giving you your injection if you have ever fainted with a previous injection.

Multiple vaccinations

AREXVY can be given at the same time as standard dose, high dose and adjuvanted influenza (flu) vaccines.

If AREXVY is given at the same time as another vaccine, a different injection site will be used for each injection.

3. What if I am taking other medicines?

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with AREXVY and affect how it works.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AREXVY.

4. How is AREXVY given?

How much is given

- Your doctor, nurse or pharmacist will give you AREXVY as an injection.
- The dosage is 0.5 mL.

How it is given

- AREXVY is generally injected into a muscle (usually in the upper arm).

If you are given too much AREXVY

If you think that you have been given too much AREXVY, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know when being given AREXVY?

Things you should do

If applicable, remind the person who is giving you your vaccination that you are taking other medicines.

Keep a record of this vaccination for your medical history.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AREXVY affects you.

However, you should not drive or use machines if you are feeling unwell.

Looking after your vaccine

- AREXVY will usually be stored at the doctor's clinic or at the pharmacy.
- If you need to store AREXVY it is important to keep it in the pack to protect it from light.
- Store AREXVY in the refrigerator between 2°C and 8°C.
- DO NOT FREEZE AREXVY.

Follow the instructions in the carton on how to take care of your vaccine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this vaccine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• itching or pain at the injection site • redness and swelling at the injection site • fever • chills • tiredness • headache • muscle pain • joint pain • runny nose • generally feeling unwell • nausea, stomach pain • swelling of the lymph nodes	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Allergic reaction Signs of an allergic reaction include: swelling of the limbs, face, eyes, inside of the nose, mouth or throat shortness of breath, breathing or swallowing difficulties hives, itching (especially of the hands or feet), reddening of the skin (especially around the ears) or severe skin reactions unusual tiredness or weakness that is sudden and severe **Allergy to AREXVY is rare. Severe reactions will usually occur within the first few hours of vaccination. If this occurs go to the Emergency Department of the nearest hospital immediately.**	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
Guillain-Barré syndrome (GBS) A very rare autoimmune syndrome affecting the nerves resulting in weakness of muscles. GBS may cause tingling of the hands or feet, or sudden numbness or weakness in the legs or arms, or problems swallowing or breathing. Tell your doctor or pharmacist if you have any of these side effects.	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

Always make sure you speak to your doctor or nurse before you decide to stop taking any of your medicines.

7. Product details

This vaccine is only available from a healthcare professional.

What AREXVY looks like

Each dose of AREXVY is made up of 2 components:

- Vial containing the RSV powder which is white.
- Vial or pre-filled syringe containing the $AS01_E$ adjuvant suspension which is an opalescent, colourless to pale brownish liquid. The adjuvant is used to improve the body's response to the vaccine.

The contents of both components are mixed prior to vaccination.

AREXVY is available as either a single dose (2 vials) or a 10 dose (20 vials) multipack (AUST R 400657).

AREXVY is also available as either a single dose (1 vial and 1 pre-filled syringe) or 10 dose (10 vials and 10 pre-filled syringes) multipack (AUST R 523373).

Not all presentations and pack sizes may be marketed.

What AREXVY contains

Active ingredient **(main ingredient)**	RSV vial: Respiratory syncytial virus (RSV) glycoprotein F stabilised in the pre-fusion conformation (RSVPreF3) Adjuvant vial or pre-filled syringe: plant extract *Quillaja saponaria* saponin (QS-21) 3-O-desacyl-4'-monophosphoryl lipid A (MPL) from *Salmonella minnesota*
Other ingredients **(inactive ingredients)**	RSV vial: trehalose dihydrate polysorbate 80 monobasic potassium phosphate dibasic potassium phosphate Adjuvant vial or pre-filled syringe: dioleoylphosphatidylcholine cholesterol sodium chloride dibasic sodium phosphate monobasic potassium phosphate water for injections

Do not receive this vaccine if you are allergic to any of these ingredients.

Who distributes AREXVY

GlaxoSmithKline Australia Pty Ltd

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www.gsk.com.au

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