Package leaflet: Information for the user

Arexvy powder and suspension for suspension for injection
Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)

▼This medicine 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Arexvy is and what it is used for

Arexvy is a vaccine that helps to protect adults aged 60 years and older against a virus called 'respiratory syncytial virus' (RSV).
RSV is a respiratory virus that spreads very easily.
- RSV can cause lower respiratory tract disease - infections of the lungs and other parts of the body that help you breathe.

RSV infection can happen at any age, and usually causes mild, cold-like signs in adults. But it can also:
- cause more serious respiratory illness in infants and older adults
- make some illnesses worse, such as long-term respiratory or heart diseases.

How Arexvy works

Arexvy helps your body's natural defences make antibodies and special white blood cells. These protect you against RSV.

Arexvy does not contain the virus. This means it cannot cause an infection.

2. What you need to know before you receive Arexvy

Do not use Arexvy

- if you are allergic to the active substances or any of the other ingredients of this vaccine (listed in section 6).

Do not use Arexvy if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you receive Arexvy if:

- you have ever had a severe allergic reaction after the injection of any other vaccine
- you have a severe infection with a high temperature (fever). If this happens, the vaccination may be delayed until you feel better. A minor infection such as a cold should not be a problem but talk to your doctor first
- you have a bleeding problem or bruise easily
- you have fainted with a previous injection - fainting can happen before or after any needle injection.

If any of the above apply to you, or you are not sure, talk to your doctor or pharmacist before you have Arexvy.

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

Other medicines/vaccines and Arexvy

Tell your doctor or pharmacist if:

- you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription.
- you have recently received any other vaccine.

Arexvy may be given at the same time as a flu vaccine.

If Arexvy is given at the same time as another injectable vaccine, a different injection site will be used for each vaccine, which means a different arm for each injection.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this vaccine.
Arexvy is not recommended during pregnancy or breast-feeding.

Driving and using machines

Some of the effects mentioned below in section 4 “Possible side effects” (e.g. feeling tired) may temporarily affect the ability to drive or use machines. Do not drive or use machines or tools if you are feeling unwell.

Arexvy contains sodium and potassium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

This medicine contains less than 1 mmol (39 mg) potassium per dose, i.e. essentially ‘potassium-free’.

3. How Arexvy is given

Arexvy is given as a single dose injection of 0.5 mL into a muscle. It is usually given into the upper arm.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The following side effects may happen after receiving Arexvy:

Very common (these may occur with more than 1 in 10 doses of the vaccine):
- pain at the injection site
- feeling tired (fatigue)
- headache
- muscle pain (myalgia)
- joint pain (arthralgia)

Common (these may occur with up to 1 in 10 doses of the vaccine):
- redness and swelling where the injection is given
- fever
- chills

Uncommon (these may occur with up to 1 in 100 doses of vaccine)
- itching at the injection site
- pain
- generally feeling unwell (malaise)
- enlarged lymph nodes, or swollen glands in the neck, armpit or groin (lymphadenopathy)
- allergic reactions such as rash
- feeling sick (nausea)
- vomiting
- stomach pain

Tell your doctor or pharmacist if you get any of the side effects listed above. Most of these side effects are mild to moderate in intensity and do not last long.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Arexvy

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Store in a refrigerator (2 °C – 8 °C).
- Do not freeze.
- Store in the original package in order to protect from light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Arexvy contains

- The active substances are:

  After reconstitution, one dose (0.5 mL) contains:

  RSVPreF3[1] antigen[2,3]
  120 micrograms

  [1] Respiratory Syncytial Virus recombinant glycoprotein F stabilised in the pre-fusion conformation = RSVPreF3

  [2] RSVPreF3 produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology

  [3] adjuvanted with $AS01_E$ containing:
  plant extract Quillaja saponaria Molina, fraction 21 (QS-21) 25 micrograms
  3-O-desacyl-4'-monophosphoryl lipid A (MPL) from Salmonella minnesota

  25 micrograms

  The RSVPreF3 is a protein present in the Respiratory Syncytial Virus. This protein is not infectious.

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

- The other ingredients are:
  - **Powder** (RSVPreF3 antigen): Trehalose dihydrate, polysorbate 80 (E 433), potassium dihydrogen phosphate (E 340), dipotassium phosphate (E 340).
  - **Suspension**: Dioleoyl phosphatidylcholine (E 322), cholesterol, sodium chloride, disodium phosphate anhydrous (E 339), potassium dihydrogen phosphate (E 340) and water for injections.

  See Section 2 "Arexvy contains sodium and potassium".

What Arexvy looks like and contents of the pack

- Powder and suspension for suspension for injection.
- The powder is white.
- The suspension is an opalescent, colourless to pale brownish liquid.

One pack of Arexvy consists of:
- Powder (antigen) for 1 dose in a vial
- Suspension (adjuvant) for 1 dose in a vial

Arexvy is available in a pack size of 1 vial of powder plus 1 vial of suspension or in a pack size of 10 vials of powder plus 10 vials of suspension.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

GlaxoSmithKline Biologicals SA
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Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only).

Please be ready to give the following information:
Product name Arexvy
Reference number 19494/0316

This is a service provided by the Royal National Institute of Blind People.
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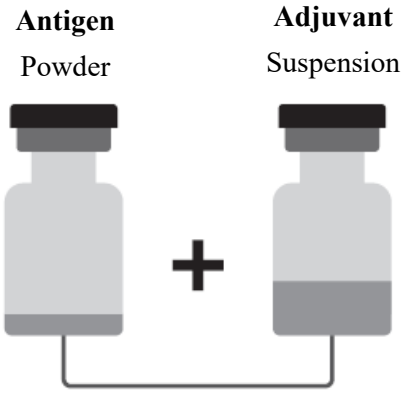
The following information is intended for healthcare professionals only:

Arexvy is presented as a vial with a mustard green flip-off cap containing the powder (antigen) and a vial with a brown flip-off cap containing the suspension (adjuvant).

The powder and the suspension must be reconstituted prior to administration.



1 dose (0.5 mL)

The powder and suspension should be inspected visually for any foreign particulate matter and/or variation of appearance. If either is observed, do not reconstitute the vaccine.

How to prepare Arexvy

Arexvy must be reconstituted prior to administration.

1. Withdraw the entire contents of the vial containing the suspension into the syringe.
2. Add the entire contents of the syringe into the vial containing the powder.
3. Gently swirl until the powder is completely dissolved.

The reconstituted vaccine is an opalescent, colourless to pale brownish liquid.

The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of appearance. If either is observed, do not administer the vaccine.

Chemical and physical in-use stability has been demonstrated for 4 hours at 2 °C – 8 °C or at room temperature up to 25 °C.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 4 hours.

Before administration

1. Withdraw 0.5 mL of the reconstituted vaccine into the syringe.
2. Change the needle so that you are using a new needle.

Administer the vaccine intramuscularly.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.