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Arexvy (*Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)*)

An overview of Arexvy and why it is authorised in the EU

What is Arexvy and what is it used for?

Arexvy is a vaccine used to protect adults 60 years of age and older against lower respiratory tract disease (LRTD, diseases of the lungs such as bronchitis or pneumonia) caused by respiratory syncytial virus (RSV).

It can also be used in adults from 50 to 59 years old who are at increased risk for RSV disease.

Arexvy contains a version of a protein found on the surface of the virus called RSVPreF3.

How is Arexvy used?

The recommended dose is a single injection into a muscle, preferably into the muscle of the upper arm.

The vaccine can only be obtained with a prescription and should be used according to official recommendations issued at national level by public health bodies.

For more information about using Arexvy, see the package leaflet or contact your doctor or pharmacist.

How does Arexvy work?

Arexvy works by preparing the immune system (the body's natural defences) to defend itself against a LRTD caused by RSV. Arexvy contains a protein from the surface of RSV. When a person is given the vaccine, the immune system treats the virus protein as 'foreign' and makes defences against it. If, later on, the vaccinated person comes into contact with the virus, the immune system will recognise the protein and be prepared to attack it. This will help to protect the person against LRTD caused by RSV.

What benefits of Arexvy have been shown in studies?

In a study in over 25,000 adults aged 60 years and above, people who received Arexvy had a 83% reduction in their risk of getting LRTD caused by RSV compared with those who had a dummy injection.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

In the group that received Arexvy, 7 out of 12,466 people got LRTD, while in the group that received a dummy injection, 40 out of 12,494 people got the disease.

A second study involved 386 people aged 50 to 59 years at increased risk of LRTD caused by RSV. Following vaccination with Arexvy, the immune response in these people was comparable to that seen in people 60 years old and above.

What are the risks associated with Arexvy?

For the full list of side effects and restrictions with Arexvy, see the package leaflet.

The most common side effects with Arexvy (which may affect more than 1 in 10 people) include injection site pain, tiredness, muscle pain, headache and joint pain. These side effects are usually mild or moderate in intensity and resolve within a few days after vaccination.

Why is Arexvy authorised in the EU?

At the time of authorisation of Arexvy, there was no vaccine to prevent RSV and no treatment other than supportive care for people 60 years of age and older and adults between 50 and 59 years of age who are at increased risk for RSV disease.

Arexvy was found to be effective in preventing LRTD caused by RSV in people 60 years of age and older. By preventing LRTD caused by RSV, the vaccine is also expected to reduce the risk of severe RSV disease in these people. In addition, data in adults aged 50 to 59 years of age showed a comparable immune response to that seen in people 60 years old and above. The vaccine is therefore expected to protect against LRTD caused by RSV in this group of people. There are no serious safety concerns with Arexvy and the European Medicines Agency therefore decided that it’s benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Arexvy?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Arexvy have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Arexvy are continuously monitored. Suspected side effects reported with Arexvy are carefully evaluated and any necessary action taken to protect patients.

Other information about Arexvy

Arexvy received a marketing authorisation valid throughout the EU on 6 June 2023.

Further information on Arexvy can be found on the Agency’s website: ema.europa.eu/medicines/human/EPAR/arexvy.

This overview was last updated in 08-2024.