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Arexvy® (active substance: respiratory syncytial virus (RSV) pre-fusion F protein)

Authorisation in Switzerland: 2 May 2024

Powder and suspension to make a suspension for injection for active immunisation for prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 60 years of age and older .

About the medicinal product

Arexvy contains the active substance respiratory syncytial virus (RSV) pre-fusion F protein (RSVPreF3 antigen).
Arexvy is a vaccine and is used for active immunisation for prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults 60 years of age and older.
RSV causes acute respiratory diseases that can affect people in all age groups. The diseases are particularly severe in infants, older adults, and immunocompromised individuals.

Effect

The vaccine Arexvy causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the RS virus, thereby affording protection against diseases of the lower respiratory tract.

For a detailed explanation of the mode of action of protein vaccines, we recommend the Swissmedic video

Administration

Arexvy is available only on prescription and consists of a powder and a suspension to make a suspension for injection.
After reconstitution, 1 dose of Arexvy contains 120 micrograms of the active substance in 0.5 mL of solution.

Vaccination with Arexvy is performed in accordance with the currently valid vaccination strategy. The vaccination is administered by a person with appropriate medical training.
Arexvy is injected into a muscle, preferably of the upper arm.

Efficacy

The efficacy of Arexvy against RSV-associated LRTD in adults 60 years of age and over was investigated in the pivotal trial RSV OA=ADJ-006.
The 24,960 participants, adults 60 years of age and over, received either a dose of Arexvy or placebo (dummy medicine).
When the primary efficacy analysis[1] was performed, the participants had been observed for a period of up to 10 months (median[2] 6.7 months) for the development of an RSV-associated LRTD.

Compared with placebo, Arexvy significantly reduces the risk of an RSV-associated LRTD by 82.6%. This efficacy was also consistent in subgroup analyses, including in participants with at least 1 pre-existing disease, in whom 94.6% efficacy was observed.

Although the absolute incidence of 47 RSV-confirmed cases in approx. 24,000 patients was low as a result of COVID-19 measures, the results overall demonstrated that the vaccine was clearly effective.

Precautions, undesirable effects, & risks

Arexvy must not be used in those who are hypersensitive to the active substance or any of the excipients.

Like all vaccines, Arexvy can also produce side effects, although not necessarily in everyone. The most common undesirable effects (affecting more than 1 in 10 users) are headache, muscle pain, joint pain, and pain at the injection site.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

Respiratory syncytial virus (RSV) causes acute respiratory tract diseases in people in all age groups and is a major, frequently unidentified cause of LRTD in older and immunocompromised adults that can also be fatal. When the authorisation application for Arexvy was reviewed, palivizumab was the only preventive treatment against RSV authorised in Switzerland. However, this medicine is only authorised for infants with a high risk of severe RSV diseases. There is therefore a medical need for medicinal products to treat and prevent RSV in older adults and immunocompromised individuals.

The efficacy of a single dose of the vaccine Arexvy in the prevention of RSV-confirmed LRTD in adults 60 years of age and over was demonstrated in the trial RSV OA=ADJ-006.

The clinical benefits and the good safety profile of the medicinal product, in combination with the unmet medical need, result in a positive benefit-risk assessment. Swissmedic has therefore authorised the medicinal product Arexvy, containing the active substance RSV pre-fusion F protein, for use in Switzerland.

[1] Primary efficacy analysis: The primary analysis takes place when the primary endpoint of a clinical trial is reached. The primary endpoint is the main objective of the study determined before the trial starts. If the primary endpoint is reached or exceeded, the trial proves that a treatment is effective. Secondary endpoints, on the other hand, refer to other effects that do not clearly prove efficacy or that do not allow any clear conclusions to be drawn about the actual target criterion (primary endpoint).

[2] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Arexvy®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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