swissmedic

Summary report on authorisation dated 4 February 2025

Abrysvo® (active substance: RSV subgroup A stabilised prefusion F antigen and RSV subgroup B stabilised prefusion F antigen)

Authorisation in Switzerland: 23 August 2024

Powder and solvent for solution for injection for passive immunisation of infants up to 6 months of age following maternal immunisation between weeks 32 and 36 of pregnancy, and for active immunisation of individuals 60 years of age and older for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

About the medicinal product

The active substance in Abrysvo is a surface protein of the RSV subgroup A and subgroup B prefusion F antigens.

The medicinal product Abrysvo is a vaccine and is used

- for passive immunisation of infants from birth up to the age of 6 months following immunisation of the mother between weeks 32 and 36 of pregnancy.

- for active immunisation of individuals 60 years of age and older.

The vaccine is authorised for the prevention of lower respiratory tract disease (LRTD) caused by RSV.

RSV causes acute respiratory diseases that can affect people in all age groups. The diseases are particularly severe in infants up to 6 months of age, adults 65 years of age and older, and immunocompromised individuals.

Abrysvo has been authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control. In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland. The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

Swissmedic adopted parts of the review findings of the European Medicines Agency (EMA; Procedure

No. EMEA/H/C/006027/00004863362) for the authorisation of Abrysvo in Switzerland, and only carried out its own limited scientific assessment for the indication "passive immunisation of infants up to 6 months of age".

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the public Assessment Report issued by the reference authority, the EMA: www.ema.europa.eu

Mode of action

The vaccine Abrysvo causes the immune system (the body's natural defences) to produce antibodies that neutralise RSV. This allows the Abrysvo vaccine to provide protection against lower respiratory tract disease caused by RSV.

Older people 60 years of age and over are actively immunised by vaccination with Abrysvo and thus protected against lower respiratory tract disease caused by RSV.

Immunisation of a pregnant woman produces elevated levels of antibodies against RSV in her blood, which are transferred to the unborn child via the placenta (passive immunisation). This protects infants against lower respiratory disease caused by RSV.
For a detailed explanation of the mode of action of protein vaccines, we recommend the following video: Swissmedic video

Use

Abrysvo is available only on prescription and consists of a powder and a solvent to make a solution for injection.
One dose of Abrysvo contains 60 micrograms of RSV antigens in 0.5 mL of solution.

Abrysvo is used in accordance with official immunisation recommendations and is administered by an individual with appropriate medical training.
Abrysvo is administered by injection into the muscle of the upper arm.
The vaccine Abrysvo must not be mixed with other vaccines or medicinal products.

Efficacy

The efficacy of Abrysvo in the prevention of RSV-associated LRTD in infants born to mothers vaccinated between weeks 32 and 36 of pregnancy was investigated in study C3671008.

The pregnant women in the study were given either 1 dose of Abrysvo or placebo (dummy drug). The study showed that Abrysvo reduced the risk of RSV-associated LRTD in newborns and children up to 6 months of age compared with placebo.

The efficacy of Abrysvo in adults 60 years of age and over was investigated in the study C3671013. The results of the study demonstrated its efficacy in preventing an initial episode of RSV-associated lower respiratory tract disease with 2 or more symptoms.

Precautions, undesirable effects, & risks

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

Like all vaccines, Abrysvo can also produce side effects, although not necessarily in everyone. The most common undesirable effects are pain at the injection site, headache, and muscle pain.

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

Why the medicinal product has been authorised

RSV causes potentially severe acute lower respiratory tract disease in individuals in all age groups, and is a major cause of LRTD in infants and older and immunocompromised adults.

There is therefore a medical need for medicinal products to treat and prevent RSV in infants and older adults.

The efficacy of a single dose of the vaccine Abrysvo in the prevention of RSV-LRTD in infants up to the age of 6 months and adults 60 years of age and over was demonstrated in the clinical trials that were performed.

The clinical benefits and the acceptable safety profile of the vaccine Abrysvo result in a positive benefit-risk assessment. Swissmedic has therefore authorised the medicinal product Abrysvo, containing the active substance RSV subgroup A and subgroup B prefusion protein F, for Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Abrysvo®

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 Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.