swissmedic

Summary report on authorisation dated 15 September 2026

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

Indication extension in Switzerland: 30 October 2025

Powder and solvent for solution for injection for active immunisation of adults aged 18 to 59 years to prevent lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

About the medicinal product

Abrysvo is a vaccine containing a surface protein of the RSV subgroup A and subgroup B prefusion F antigens as an active substance.

Abrysvo was first authorised by Swissmedic on 23 August 2024. The vaccine protects infants from birth up the age of 6 months when the mother is vaccinated between weeks 32 and 36 of pregnancy. It is also authorised for immunisation of adults aged 60 years and older.

The vaccine Abrysvo is indicated for the prevention of lower respiratory tract disease (LRTD) caused by the respiratory syncytial virus (RSV).

RSV causes acute respiratory tract diseases that affect people in all age groups and can be particularly severe in immunocompromised individuals.

This indication extension means that Abrysvo can now also be used for adults aged between 18 and 59 years who have an increased risk of a lower respiratory tract disease caused by RSV.

Mode of action

The vaccine Abrysvo causes the immune system (the body's natural defences) to produce antibodies that neutralise RSV.

Adults aged between 18 and 59 years who have an increased risk of a lower respiratory tract disease caused by RSV are actively immunised by vaccination with Abrysvo and thus protected against lower respiratory tract diseases triggered by RSV.

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

Administration

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 a person with appropriate medical training.

The vaccine Abrysvo is administered as a single dose of 0.5 mL by injection into the muscle of the upper arm.

The vaccine Abrysvo must not be mixed with other vaccines or medicinal products.

Efficacy

In the pivotal study C3671013, the vaccine demonstrated a comparable immune response in adults aged 18 to 59 years who have increased risk of severe RSV diseases due to chronic underlying diseases to that in older adults. Similar protection against RSV-related lower respiratory tract diseases is therefore also expected in this younger adult population who are at increased risk, as demonstrated in study C3671013.

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, fatigue, and muscle pain.

The available safety data did not indicate any new risks or safety concerns.

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 acute respiratory tract diseases in individuals in all age groups and is a major cause of LRTD in immunocompromised adults.

There is therefore a medical need for medicinal products to prevent RSV in adults aged 18 to 59 years who have a high risk of a severe course of RSV due to chronic underlying diseases.

Based on study results, it is assumed that the vaccine protects against RSV LRTD just as well in younger adults aged between 18 and 59 years as in older individuals.

The clinical benefits and the acceptable safety profile of the vaccine Abrysvo result in a positive benefit-risk assessment.

Swissmedic has therefore authorised the indication extension in Switzerland for the medicinal product Abrysvo, containing the active substance RSV subgroup A and subgroup B prefusion protein F, for adults aged between 18 and 59 years who have increased risk of lower respiratory tract disease caused by RSV.

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.