swissmedic

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Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report
Extension of therapeutic indication

Abrysvo

International non-proprietary name: RSV subgroup A stabilised prefusion F antigen, RSV subgroup B stabilised prefusion F antigen

Pharmaceutical form: powder and solvent for solution for injection

Dosage strength(s): 60 µg/60 µg per dose

Route(s) of administration: intramuscular use

Marketing authorisation holder: Pfizer AG

Marketing authorisation no.: 69691

Decision and decision date: extension of therapeutic indication approved on 30.10.2025

Note:

This assessment report is as adopted by Swissmedic with all information of a commercially confidential nature deleted.

SwissPARs are final documents that provide information on submissions at a particular point in time. They are not updated after publication.

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1 Terms, Definitions, Abbreviations

ADA	Anti-drug antibody
ADME	Absorption, distribution, metabolism, elimination
AE	Adverse event
ALT	Alanine aminotransferase
API	Active pharmaceutical ingredient
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area under the plasma concentration-time curve
$AUC_{0\text{-}24h}$	Area under the plasma concentration-time curve for the 24-hour dosing interval
CHMP	Committee for Medicinal Products for Human Use
CI	Confidence interval
C_{max}	Maximum observed plasma/serum concentration of drug
COVID-19	Coronavirus disease 2019
CYP	Cytochrome P450
DDI	Drug-drug interaction
FCV	Federal Commission for Vaccination
EMA	European Medicines Agency
ERA	Environmental risk assessment
FDA	Food and Drug Administration (USA)
FOPH	Federal Office of Public Health
GBS	Guillain-Barré syndrome
GI	Gastrointestinal
GLP	Good Laboratory Practice
GMFR	Geometric mean fold rise
GMT	Geometric mean titre
HPLC	High-performance liquid chromatography
IC/EC_{50}	Half-maximal inhibitory/effective concentration
ICH	International Council for Harmonisation
Ig	Immunoglobulin
INN	International non-proprietary name
ITT	Intention-to-treat
LoQ	List of Questions
LRTD	Lower respiratory tract disease
LRTI	Lower respiratory tract infection
MAH	Marketing authorisation holder
Max	Maximum
Min	Minimum
MRHD	Maximum recommended human dose
N/A	Not applicable
NO(A)EL	No observed (adverse) effect level
PBPK	Physiology-based pharmacokinetics
PD	Pharmacodynamics
PIP	Paediatric investigation plan (EMA)
PK	Pharmacokinetics
PopPK	Population pharmacokinetics
PSP	Pediatric study plan (US FDA)
RMP	Risk management plan
RNA	Ribonucleic acid
RSV	Respiratory syncytial virus
SAE	Serious adverse event
SARS-COV-2	Severe acute respiratory syndrome coronavirus 2

SwissPAR	Swiss Public Assessment Report
TEAE	Treatment-emergent adverse event
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)
URTI	Upper respiratory tract infection

2 Background information on the procedure

2.1 Applicant's request(s) and information regarding procedure

Extension(s) of the therapeutic indication(s)
The applicant requested the addition of a new therapeutic indication or modification of an approved one in accordance with Article 23 TPO.

2.2 Indication and dosage

2.2.1 Requested indication

Active immunisation of individuals 18 years of age and older for the prevention of lower respiratory tract disease caused by RSV.

2.2.2 Approved indication

Active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by RSV in:
o adults 18-59 years of age who are at increased risk for LRTD caused by RSV.

2.2.3 Requested dosage

Summary of the requested standard dosage:

Individuals 18 years of age and older
A single dose of 0.5 mL should be administered.

2.2.4 Approved dosage

(see appendix)

2.3 Regulatory history (milestones)

Application	04.11.2024
Formal control completed	18.11.2024
List of Questions (LoQ)	14.03.2025
Response to LoQ	09.05.2025
Preliminary decision	15.07.2025
Response to preliminary decision	14.09.2025
Final decision	30.10.2025
Decision	approval

3 Medical context

The human respiratory syncytial virus (RSV) causes acute respiratory tract illness in persons of all ages. RSV is a single-stranded, negative-sense ribonucleic acid (RNA) virus. Two subtypes, A and B, are simultaneously present in most outbreaks, with A subtypes typically causing more severe disease. Several distinct genotypes within these subtypes predominate within a community; the dominant strains shift yearly, perhaps accounting for frequent reinfections.

The clinical manifestation of the RSV infection varies with age and health status.
Almost all children are infected by 2 years of age, and reinfection is common. RSV infection is usually a self-limited process that results in no apparent long-term pulmonary sequelae.
RSV bronchiolitis is the most common lower respiratory tract infection in infants and leads to the hospitalisation of 1-2% of the annual birth cohort because of respiratory insufficiency and/or inadequate fluid intake.
Young children, particularly infants below 6 months, and adults over 65 years of age, are the most affected by severe RSV-associated disease.
Healthy adults are infected with RSV repeatedly throughout their lives and typically have symptoms restricted to the upper respiratory tract.
In older adults and younger adults with underlying chronic medical conditions considered as risk factors and in immunocompromised adults, RSV is an important and often unrecognised cause of lower respiratory tract infection (LRTI).

Therapy for RSV LRTI is primarily supportive. Supportive care includes frequent monitoring of clinical status and provision of fluid and respiratory support, as necessary. Standard strategies to reduce the risk of a viral infection include hand hygiene, avoiding contact, and minimising passive smoking.

RSV typically causes seasonal outbreaks throughout the world. In the Northern Hemisphere, these usually occur from October/November to April/May, with a peak in January or February.

In Switzerland, two RSV vaccines, Abrysvo and Arexvy were approved at the time of this review for the active immunisation of individuals 60 years and older. Abrysvo is also indicated for the passive immunisation of infants through immunisation of the mother during pregnancy.

The Federal Office of Public Health (FOPH) and the Federal Commission for Vaccination (FCV) recommend RSV vaccination for all subjects 75 years and above and for subjects between 60-75 years of age with higher risk for severe RSV disease (including chronic underlying diseases and patients living in long-term care facilities).
Additionally, for subjects between 18-59 years of age with severe immune deficiency or with very high risk for a severe RSV disease.[1]
At the time of the submission, there were no licensed vaccines to prevent RSV-associated respiratory disease in adults 18 through 59 years of age in Switzerland. During the review process, an indication extension concerning adults aged 50-59 years at increased risk of RSV was accepted for Arexvy.

[1] BAG-Bulletin 47/2024

4 Nonclinical aspects

The applicant did not submit new nonclinical studies to support the requested extension of the indication for Abrysvo. This was considered acceptable.
Based on the ERA, the extension of the indication will not be associated with a significant risk for the environment.
From the nonclinical point of view, there are no objections to approval of the proposed extension of indication.

5 Clinical aspects

5.1 Clinical pharmacology

No clinical pharmacology studies were conducted in support of this application. This is acceptable as clinical pharmacology studies are not routinely conducted as part of the evaluation of vaccines and is in line with the CHMP “Guideline on Clinical Evaluation of New Vaccines” (EMEA/CHMP/VWP/164653/2005).

5.2 Dose finding and dose recommendation

The approved dose for the vaccination of the elderly and pregnant mothers (for the passive protection of their newborns) was proposed and used for the immunobridging, which is acceptable.

5.3 Efficacy

A clinical efficacy study was not provided in support of this application. The efficacy is proposed to be inferred from older adults through the demonstration of non-inferior immunogenicity. This immunobridging approach can be considered acceptable and it is also in line with the EMA Guideline on respiratory syncytial virus (RSV).

C3671023 Substudy A was a multicentre, randomised, double-blinded, placebo-controlled Phase 3 study which investigated the safety, tolerability, and immunogenicity of Abrysvo in adults 18 through 59 years of age considered to be at increased risk for RSV disease due to certain chronic medical conditions, such as chronic obstructive pulmonary disease, asthma, and chronic heart failure.

The study assessed immunobridging between C3671023 Substudy A and Study C3671013, which was the pivotal efficacy study in adults ≥ 60 years of age supporting the initial marketing approval for this population.

It was demonstrated that the immune responses elicited by Abrysvo in adults 18 through 59 years of age with high-risk chronic medical conditions in C3671023 Substudy A were noninferior to the immune responses in selected vaccinated adults ≥ 60 years of age (N: 410) in the C3671013 efficacy study. This was based on GMTs for RSV A and B serum neutralising titres and seroresponses to RSV A and B using strict non-inferiority margins. For a detailed tabular presentation of the immunogenicity data please refer to Table 6 in the attached Information for healthcare professionals.

Based on the demonstrated non-inferior immunogenicity, the effectiveness can be inferred for adults 18-59 years of age with underlying chronic conditions considered to be risk factors for severe RSV disease.

Substudy A excluded immunocompromised subjects, however open-label Substudy B included subjects with such conditions.

Results for Substudy B showed the neutralising antibody responses measured by GMTs, GMFRs, and seroresponse rates after a single dose of Abrysvo in immunosuppressed adults 18 to < 60 years and ≥ 60 years of age. The immune responses did not further increase with a second dose received 1 month after the first dose.

In addition, supportive immunogenicity data from Study C3671013 in participants ≥ 60 years of age with and without chronic medical conditions were provided, which suggested similar immune responses in subjects with and without medical conditions.

Furthermore, immunogenicity results from lot consistency study C3671014 conducted in healthy participants 18 to 49 years of age showed immune responses similar (similar range of GMFRs) to

those observed in the pivotal study. However, this similar immunogenicity was not based on dedicated, statistically proven clinical data. Cross-study comparison with assays performed at different time points with differences in the used reagents are not considered conclusive. The similar immune response is not unexpected, as younger adults generally induce a stronger immune response to vaccine antigens.

The clinical efficacy demonstrated in the elderly for the prevention of LRTD cannot be inferred generally for the younger adult population, as in healthy younger adults RSV mostly causes URTI. Morbidity is not negligible in this age group but is lower than the morbidity rates for influenza or SARS-COV-2 infections, even though the exact incidence of RSV disease in this age group is not well known.

Furthermore, the associated risk of Guillain-Barré syndrome (GBS) observed in the post-marketing setting impacts the benefit/risk in the proposed age group as the risk of severe disease is generally low. Thus, the indication was restricted to adults 18-59 years of age at increased risk for severe RSV disease.

5.4 Safety

Safety findings are based on data from 5417 subjects 18-59 years of age exposed to Abrysvo, including 453 subjects from Study C3671023 Substudy A, 200 subjects from Substudy B and 4964 subjects from the pooled analyses.

Safety findings from the pivotal study, based on 453 subjects exposed to Abrysvo, were generally in line with the already known safety profile, although the limited population does not allow a firm conclusion.
The safety results from Substudy B in 200 immunocompromised adults did not raise any safety concerns, and findings were consistent with previous results.
No Guillain-Barré syndrome (GBS) was observed in study C3671023 or in the pooled analysis.

Further, a pooled analysis of 4964 subjects (3844 subjects with at least 6-month follow-up) from previous clinical studies also did not raise any new safety concerns. As the pooled analysis included mostly pregnant women (males: 5.4%) aged 18-49 years of age, the generalisability of the safety findings to the proposed population, especially to males, is somewhat questionable.

5.5 Final clinical benefit risk assessment

Immunological non-inferiority was shown for adults 18 through 59 years of age who are at high risk for severe RSV disease due to underlying chronic medical conditions compared to a subset of elderly subjects above 60 years of age with proven efficacy data. Thus, effectiveness similar to that previously demonstrated in the elderly for the prevention of LRTI caused by RSV is assumed in the younger high-risk population.
Based on the provided safety data, no new findings or concerns were identified, although the database from the immunobridging studies is limited and the pooled analysis included mostly pregnant women and subjects younger than 50 years of age.

The benefit of Abrysvo in adults 18-59 years of age at increased risk for severe RSV disease outweighs its potential risks.

6 Risk management plan summary

The RMP summaries contain information on the medicinal products′ safety profiles and explain the measures that are taken to further investigate and monitor the risks, as well as to prevent or minimise them.
The RMP summaries are published separately on the Swissmedic website. It is the responsibility of the marketing authorisation holder to ensure that the content of the published RMP summaries is accurate and correct. As the RMPs are international documents, their summaries might differ from the content in the Information for healthcare professionals / product information approved and published in Switzerland, e.g. by mentioning risks that occur in populations or indications not included in the Swiss authorisations.

7 Appendix

Approved Information for healthcare professionals

Please be aware that the following version of the Information for healthcare professionals for Abrysvo was approved with the submission described in the SwissPAR. This Information for healthcare professionals may have been updated since the SwissPAR was published.

Please note that the valid and relevant reference document for the effective and safe use of medicinal products in Switzerland is the Information for healthcare professionals currently authorised by Swissmedic (see www.swissmedicinfo.ch).

Note:
The following Information for healthcare professionals has been translated by the MAH. It is the responsibility of the authorisation holder to ensure the translation is correct. The only binding and legally valid text is the Information for healthcare professionals approved in one of the official Swiss languages.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected new or serious adverse reactions. See the «Undesirable effects» section for advice on the reporting of adverse reactions.

Abrysvo®

Composition

Active substances

Antigenum F praefusionis stabilitum RSV subgrupi A[1,2], antigenum F praefusionis stabilitum RSV subgrupi B[1,2].

[1]glycoprotein F stabilised in the prefusion conformation.

[2]produced from genetically modified Chinese Hamster Ovary cells.

Excipients

Trometamolum, trometamoli hydrochloridum, saccharum, mannitolum, polysorbatum 80, natrii chloridum (corresp. 0.43 mg sodium per dose), acidum hydrochloridum (q.s. ad pH), aqua ad iniectabile.

Pharmaceutical form and active substance quantity per unit

Powder and solvent for solution for injection, intramuscularly.

After reconstitution 1 dose (0.5 ml) contains 60 µg of each RSV antigen: RSV subgroup A stabilised prefusion F antigen and RSV subgroup B stabilised prefusion F antigen. The powder is white. The solvent is a clear, colourless liquid.

Indications/Uses

Abrysvo is indicated for:

- Passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following immunisation of pregnant individuals from a gestational age of 32 0/7 up to and including 36 0/7 weeks of pregnancy (see «Warnings and precautions» and «Properties/Effects»).

- Active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by RSV in:
    - adults 60 years of age and older.
    - adults 18-59 years of age who are at increased risk for LRTD caused by RSV.

The use of this vaccine should be in accordance with official recommendations.

Dosage/Administration

Pregnant individuals

A single dose of 0.5 ml should be administered to pregnant individuals from a gestational age of 32 0/7 up to and including 36 0/7 weeks of pregnancy (see «Warnings and precautions» and «Properties/Effects»).

The need for revaccination with subsequent pregnancies has not been established.

Individuals 18 years of age and older

A single dose of 0.5 ml should be administered.

The need for revaccination has not been established.

Paediatric population

The safety and efficacy of Abrysvo in children (from birth to less than 18 years of age) have not yet been established. Very limited data are available in pregnant adolescents and their infants (see «Properties/Effects»).

Mode of administration

Abrysvo is for intramuscular injection into the deltoid region of the upper arm.

The vaccine should not be mixed with any other vaccines or medicinal products.

For instructions on reconstitution and handling of the medicinal product before administration, see «Instructions for handling».

Traceability

To ensure traceability of biotechnological medicinal products, it is recommended that the trade name and batch number should be documented for each vaccination.

Contraindications

Hypersensitivity to the active substances or to any of the excipients (see «Composition»).

Warnings and precautions

The results of a postmarketing observational study suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination with Abrysvo (see section «Undesirable effects»).

Hypersensitivity and anaphylaxis

Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Potential risk of premature birth

A numerical imbalance in preterm births in Abrysvo recipients was observed compared to placebo recipients in the two clinical studies conducted in pregnant women. Available data are insufficient to establish or exclude a causal relationship between preterm birth and Abrysvo. To avoid the potential risk of preterm birth with use of Abrysvo before 32 weeks of gestational age, administer Abrysvo as indicated in pregnant individuals from a gestational age of 32 0/7 up to and including 36 0/7 weeks of pregnancy. Pregnant individuals who were at increased risk of preterm birth were generally excluded from clinical studies of Abrysvo (see «Pregnancy, lactation» and «Undesirable effects»).

Anxiety-related reactions

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from fainting.

Concurrent illness

Vaccination should be postponed in individuals suffering from an acute febrile illness. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

Thrombocytopenia and coagulation disorders

Abrysvo should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding or bruising may occur following an intramuscular administration to these individuals.

Immunocompromised individuals

Immunocompromised individuals, including individuals receiving immunosuppressant therapy, may have a diminished immune response to Abrysvo. Available data are included in sections «Undesirable effects» and «Properties/Effects».

Individuals before a gestational age of 24 weeks

Abrysvo has not been studied in pregnant individuals who have not yet reached a gestational age of 24 weeks.

Limitations of vaccine effectiveness

As with any vaccine, a protective immune response may not be elicited after vaccination.

Excipients of particular interest

This medicinal product contains less than 1 mmol sodium (23 mg) per 0.5 ml dose, i.e. it is almost «sodium-free».

Interactions

Use with other vaccines

In a randomised study in adults 65 years of age and older (N=1‘403, randomised 1:1) the concomitant administration of Abrysvo with a seasonal influenza vaccine (QIV, surface antigen, inactivated, adjuvanted) was investigated. The criteria for non-inferiority of the immune responses in the co administration versus the separate administration group were met. However, numerically lower RSV A and B neutralising titres and numerically lower influenza A and B haemagglutination inhibition (HAI) titres were observed when Abrysvo and influenza vaccine were co-administered than when they were administered separately. The clinical relevance of this finding is unknown.

In a randomised study in adults 65 years of age and older, Abrysvo and bivalent Original/Omicron BA.4/BA.5 COVID-19 mRNA vaccine were studied with or without concomitant administration of a high dose quadrivalent influenza vaccine. The predefined non-inferiority criterion regarding the RSV A

and RSV B neutralising titres (NT) and SARS CoV-2 Omicron BA.4/BA.5 strain and reference strain, and each of the four strain specific HAI titres were met. For information on local and systemic reactions following concomitant administration, see «Undesirable effects».

The concomitant administration of Abrysvo with a tetanus-diphtheria-acellular pertussis vaccine (Tdap) was investigated in healthy, non-pregnant women (N=141) aged 18-49 years. There were no safety concerns in the population studied when Abrysvo was co-administered with Tdap. Immune responses to RSV A, RSV B, diphtheria and tetanus on co-administration were non-inferior to those after separate administration. However, the immune responses to the pertussis components were lower on co-administration compared to separate administration; non-inferiority was not shown for any of the acellular pertussis antigens (pertussis toxoid [PT], filamentous hemagglutinin [FHA], and pertactin [PRN]) as the lower bound of the 95% CI for the GMC ratios of the co-administration group to the separate administration group did not exceed 0.67. The lower limit of the 95% CI for the GMC ratio was 0.64 for PT, 0.50 for FHA, and 0.48 for PRN. The clinical relevance of this finding is unknown.

A minimum interval of two weeks is recommended between administration of Abrysvo and administration of a tetanus, diphtheria and acellular pertussis vaccine (Tdap).

Data on concomitant administration of Abrysvo and vaccines other than those listed above are not available.

Different injectable vaccines should always be given at different vaccination sites.

Do not mix Abrysvo with other vaccines/medicinal products in the same syringe.

The concomitant administration of Abrysvo with Tdap, COVID-19 mRNA vaccines or influenza vaccines has not been studied in pregnant women.

Pregnancy, lactation

Pregnancy

Data on pregnant women (more than 4‘000 exposed outcomes) indicate no malformative nor feto/neonatal toxicity.

Results from animal studies with Abrysvo do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see «Preclinical data»).

In a phase 3 study (Study C3671008), maternal adverse events reported within 1 month after vaccination were similar in the Abrysvo group (13.8%) and the placebo group (13.1%). Serious adverse reactions observed in pregnant individuals in the Abrysvo group and the placebo group included pre-eclampsia (1.8% versus 1.4%), hypertension (0.4% versus 0.2%), gestational hypertension (1.2% versus 1.1%), premature rupture of membranes (0.4% versus 0.4%), preterm

premature rupture of membranes (0.4% versus 0.3%), maternal death (<0.1% versus 0%) and foetal death (0.3% versus 0.3%).

No safety signals were detected in infants up to 24 months of age. The incidences of adverse events reported within 1 month after birth in infants were similar in the Abrysvo group (38%) and the placebo group (35%).

Major birth outcomes assessed in the Abrysvo group compared to placebo included premature birth (207 [6%] and 172 [5%], respectively), low birth weight (186 [5%] and 158 [4%], respectively) and congenital anomalies (205 [6%] and 245 [7%], respectively).

Available data are insufficient to establish or exclude a causal relationship between preterm birth and Abrysvo (see «Warnings and precautions» and «Undesirable effects»).

To minimize any potential risk of preterm birth Abrysvo should be given to pregnant individuals from a gestational age of 32 0/7 up to and including 36 0/7 weeks of pregnancy.

Lactation

It is unknown whether Abrysvo is excreted in human milk. No adverse effects of Abrysvo have been shown in breastfed newborns of vaccinated mothers.

Fertility

No human data on the effect of Abrysvo on fertility are available.

Animal studies do not indicate direct or indirect harmful effects with respect to female fertility (see «Preclinical data»).

Effects on ability to drive and use machines

Abrysvo has no or negligible influence on the ability to drive and use machines.

Undesirable effects

Summary of the safety profile

The safety of administering a single dose of Abrysvo to pregnant women at 24-36 weeks of gestation (n=3‘698), individuals 60 years of age and older (n=18‘574) and individuals 18 through 59 years of age at high risk of lower respiratory tract disease caused by RSV (n=453) was evaluated in phase 3 clinical trials.

Pregnant individuals

In pregnant women at 24-36 weeks of gestation the most frequently reported adverse reactions were vaccination site pain (41%), headache (31%) and myalgia (27%). The majority of local and systemic reactions in maternal participants were mild to moderate in severity and resolved within 2-3 days of onset.

Individuals 60 years of age and older

In individuals 60 years of age and older the most frequently reported adverse reaction was vaccination site pain (11%). The majority of reactions were mild to moderate in severity and resolved within 1-2 days of onset.

Individuals 18 through 59 years of age

In individuals 18 through 59 years of age, based on a study in individuals at high risk of lower respiratory tract disease caused by RSV, the most frequently reported adverse reactions were vaccination site pain (35%) and myalgia (24%). The majority of reactions were mild to moderate in severity and resolved within 1-2 days of onset.

List of adverse reactions

The adverse reactions are arranged according to MedDRA system organ classes and the conventional frequencies as follows: «very common» (≥1/10), «common» (≥1/100, <1/10), «uncommon» (≥1/1'000, <1/100), «rare» (≥1/10'000, <1/1'000), «very rare» (<1/10'000), «not known» (frequency cannot be estimated from the available data).

Table 1 Adverse reactions following administration of Abrysvo

System Organ Class	*Adverse Drug Reactions Pregnant individuals ≤49 years*	*Adverse Drug Reactions Individuals ≥18 years*
Blood and lymphatic system disorders		
Lymphadenopathy	Rare	Rare
Immune system disorders		
Hypersensitivity reactions[a]	Rare	Rare
Anaphylaxis		Very rare
Nervous system disorders		
Headache	Very common (31.0%)	Very common (19.5%)
Guillain-Barré syndrome		Very rare
Musculoskeletal and connective tissue disorders		

System Organ Class	*Adverse Drug Reactions Pregnant individuals ≤49 years*	*Adverse Drug Reactions Individuals ≥18 years*
Myalgia	Very common (26.6%)	Very common (16.4%)
Arthralgia		Common
General disorders and administration site conditions		
Fatigue		Very common (23.5%)
Vaccination site pain	Very common (40.7%)	Very common (18.9%)
Vaccination site redness	Common	Common
Vaccination site swelling	Common	Common

[a] Hypersensitivity reactions include rash and urticaria.

Description of specific adverse reactions and additional information

Guillain-Barré-Syndrome

In a study in individuals 60 years of age and older, one case of Guillain-Barré syndrome (with diagnosis later revised to chronic inflammatory demyelinating polyneuropathy) and one case of Miller Fisher syndrome were reported with onset of 7 and 8 days, respectively, after receiving Abrysvo and assessed by the investigator as possibly related to the administered vaccine. Both cases had either confounding factors or an alternative aetiology.

The association between vaccination with Abrysvo and GBS was evaluated in individuals 65 years of age and older in the USA using claims data, between May 2023 through July 2024. Vaccinations with Abrysvo and potential cases of hospitalized GBS among recipients of Abrysvo were identified through procedural and drug codes, and International Classification of Diseases (ICD) codes, respectively. GBS diagnoses in claims data were confirmed by medical record review when available.

The risk of GBS following vaccination with Abrysvo was assessed in self-controlled case series analyses using a risk window of 1 to 42 days post-vaccination and a control window of 43 to 90 days post-vaccination. The analyses of all GBS cases based on claims data suggest an increased risk of GBS during the 42 days following vaccination with Abrysvo, with an incidence rate ratio (GBS cases in the risk window/control window) of 2.02 (95% CI: 0.93, 4.40) and an estimated 9 excess cases of GBS per million doses administered to individuals 65 years of age and older. The background risk of GBS in a study population influences the excess GBS case estimate and may differ between studies, precluding direct comparison to excess GBS case estimates from other vaccine studies or populations.

The analyses of GBS diagnoses in claims data were supported by analyses of GBS cases confirmed by medical record review and by analyses of GBS cases in individuals who received Abrysvo alone, without other concomitantly administered vaccines.

Preterm births in clinical studies

A numerical imbalance in preterm births in Abrysvo recipients compared to placebo recipients was observed in two clinical studies conducted in pregnant women vaccinated between the 24-36 gestational weeks.

Study C3671003 was a phase 2, randomized, placebo-controlled, observer-blinded study that investigated the safety of two dose levels (120 µg and 240 µg) of Abrysvo administered to pregnant individuals. Abrysvo (120 µg) was administered to 115 maternal participants, and 114 infants were born to these maternal participants. In this study preterm births occurred in 5.3% (6 out of 114) in the Abrysvo group and 2.6% (3 out of 116) in the placebo group.

In the subsequent phase 3 study C3671008, preterm birth events occurred in 5.7% [95% CI: 4.9, 6.5] (207 out of 3‘659) in the Abrysvo group and 4.7% [95% CI: 4.1, 5.5] (172 out of 3‘646) in the placebo group. In infants born preterm, 84 infants in the Abrysvo group and 81 infants in the placebo group remained hospitalized or were readmitted to the hospital in the neonatal period (up to 30 days after birth). Available data are insufficient to establish or exclude a causal relationship between preterm birth and Abrysvo. A numerical imbalance in preterm births was also observed in study C3671008 among the subgroup of infants born to participants who were vaccinated at 32 through 36 weeks gestation, with 4.3% (71/1‘667) in the Abrysvo group and 3.7% (60/1‘640) in the placebo group (see «Warnings and precautions» and «Pregnancy, lactation»).

Special Populations

Immunocompromised individuals 18 years of age and older

The safety of Abrysvo in 203 immunocompromised individuals 18 years of age and older was evaluated in a Phase 3 clinical trial. All solicited local reactions were mild to moderate in severity and the majority had a median duration of 1-3 days. Reporting of local reactions trended lower after dose 1 than dose 2. Pain at the injection site was the most frequently reported local reaction. Solicited systemic reactions were mostly mild to moderate in severity and the majority had a median duration of 1-4 days, with reporting of any systemic reaction similar after each dose. The most frequently reported systemic reaction was fatigue. Severe systemic reactions were reported in 2% and 6% of participants 18 to <60 years and ≥60 years of age, respectively, after any dose.

Concomitant administration with a COVID-19 vaccine or with a COVID-19 vaccine and a seasonal influenza vaccine

Solicited local and systemic reactions, within 7 days following vaccine administration, were reported more frequently by participants who received the concomitantly administered vaccines compared with Abrysvo given alone. The most commonly reported solicited reactions (≥20%) in the Abrysvo and

bivalent Original/Omicron BA.4/BA.5 COVID-19 mRNA vaccine (COVID-19 vaccine) (n=157), the Abrysvo with COVID-19 vaccine and high dose quadrivalent influenza vaccine group (n=158), and the Abrysvo alone group (n=152) were injection site pain at any vaccination site (56.7%, 53.8%, and 10.5%, respectively), fatigue (38.9%, 46.8%, and 24.3%, respectively) and headache (24.2%, 19.0% and 19.1%, respectively). Other, less commonly reported local and systemic reactions (10 – 15%) in the Abrysvo and COVID-19 Vaccine (n=157), the Abrysvo with COVID-19 vaccine and high dose quadrivalent influenza vaccine group (n=158), and the Abrysvo alone group (n=152) included redness (12.7%, 8.9% and 2.6%, respectively), swelling (12.7%, 7.0% and 3.3%, respectively), chills (10.2%, 10.8% and 3.9%, respectively), muscle pain (14.0%, 14.6% and 9.9%, respectively) and joint pain (10.2%, 9.5% and 5.9% respectively).

Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online via the ElViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

Overdose with Abrysvo is unlikely due to its single dose presentation.

There is no specific treatment for an overdose with Abrysvo. In the event of an overdose, the individual should be monitored and provided with symptomatic treatment as appropriate.

Properties/Effects

ATC code

J07BX05

Mechanism of action

Abrysvo contains two recombinant stabilised RSV prefusion F antigens representing subgroups RSV A and RSV B. Prefusion F is the primary target of neutralising antibodies that block RSV infection. Following intramuscular administration, the prefusion F antigens elicit an immune response, which protects against RSV associated lower respiratory tract disease.

In infants born to mothers who were vaccinated with Abrysvo during pregnancy, protection against RSV-associated lower respiratory tract disease is due to transplacental transfer of RSV neutralising antibodies. Adults 18 years of age and older are protected by active immunisation.

Pharmacodynamics

No information.

Clinical efficacy

Infants from birth through 6 months of age by active immunisation of pregnant individuals

Study C3671008 was a phase 3, multicentre, randomised (1:1), double-blind, placebo-controlled study to assess the efficacy of a single dose of Abrysvo in the prevention of RSV associated lower respiratory tract disease in infants born to pregnant individuals vaccinated between weeks 24 and 36 of gestation.

In this study, 3‘711 pregnant individuals with uncomplicated, singleton pregnancies were randomised to the Abrysvo group and 3‘709 to placebo.

Of the pregnant women who received Abrysvo, 65% were White, 20% were Black or African American and 29% were Hispanic/Latino. The median age was 29 years (range 16-45 years); 0.2% of participants were under 18 years of age and 4.3% were under 20 years of age. The median gestational age at vaccination was 31 weeks and 2 days (range 24 weeks and 0 days to 36 weeks and 4 days). The median infant gestational age at birth was 39 weeks and 1 day (range 27 weeks and 3 days to 43 weeks and 6 days).

Vaccine efficacy (VE) was defined as the relative risk reduction of the endpoint in the Abrysvo group compared to the placebo group for infants born to pregnant individuals who received the assigned intervention. At the primary analysis, there were two primary efficacy endpoints, assessed in parallel, severe RSV positive medically attended lower respiratory tract illness and RSV positive medically attended lower respiratory tract illness, occurring within 90, 120, 150 or 180 days after birth.

RSV-associated lower respiratory tract illness was defined as a medically attended visit with a reverse transcription-polymerase chain reaction (RT-PCR) confirmed RSV illness with one or more of the following respiratory symptoms: fast breathing (respiratory rate ≥60 bpm for <2 months of age [<60 days of age], ≥50 bpm for ≥2 months to <12 months of age, or ≥40 bpm for ≥12 months to 24 months of age), low oxygen saturation (SpO_2 <95%) and chest wall indrawing. RSV-associated severe lower respiratory tract illness was defined as an illness that met the lower respiratory tract illness RSV criteria plus at least one of the following: very fast breathing (respiratory rate ≥70 bpm for <2 months of age [<60 days of age], ≥60 bpm for ≥2 months to <12 months of age, or ≥50 bpm for ≥12 months to 24 months of age), low oxygen saturation (SpO_2 <93%), high-flow oxygen supplementation via nasal cannula or mechanical ventilation, ICU admission for >4 hours and/or failure to respond/unconscious.

In the population studied, the VE results met the statistical criterion for success (a CI lower bound >20%) for reducing severe medically attended lower respiratory tract illness illness due to RSV, at all timepoints to within 180 days. The VE results did not meet the statistical criterion for success for reducing medically attended lower respiratory tract illness illness due to RSV; however, clinically meaningful efficacy was observed after 90 days through 180 days after birth.

Vaccine efficacy in infants from birth to 180 days of age whose mothers were vaccinated from a gestational age of 32 0/7 up to and including 36 0/7 weeks of pregnancy was based on a post-hoc analysis. Vaccine efficacy is presented in Tables 2 and 3.

Table 2 Vaccine efficacy of Abrysvo against severe medically attended lower respiratory tract illness caused by RSV in infants from birth through 6 months of age by active immunisation of pregnant individuals from a gestational age of 32 0/7 up to and including 36 0/7 weeks of pregnancy – Study C3671008[a]

Time period	*Abrysvo Number of cases N=1‘572[b]*	*Placebo Number of cases N=1‘539[b]*	*VE % (CI)[c]*
90 days	1	11	91.1 (38.8, 99.8)
180 days	6	25	76.5 (41.3, 92.1)

CI = confidence interval; VE = vaccine efficacy
[a] This post-hoc descriptive subgroup analysis was not controlled for multiple comparisons; results from 90 days and 180 days are presented.
[b] Evaluable efficacy population.
[c] 95% CI

Table 3 Vaccine efficacy of Abrysvo against medically attended lower respiratory tract illness caused by RSV in infants from birth through 6 months of age by active immunisation of pregnant individuals from a gestational age of 32 0/7 up to and including 36 0/7 weeks of pregnancy – Study C3671008 [a]

Time period	*Abrysvo Number of cases N=1‘572[b]*	*Placebo Number of cases N=1‘539[b]*	*VE % (CI)[c]*
90 days	14	21	34.7 (-34.6, 69.3)
180 days	24	55	57.3 (29.8, 74.7)

CI = confidence interval; VE = vaccine efficacy
[a] This post-hoc descriptive subgroup analysis was not controlled for multiple comparisons; results from 90 days and 180 days are presented.
[b] Evaluable efficacy population.
[c] 95% CI

Active immunisation of individuals 18 years of age and older

Clinical efficacy in individuals 60 years and older

Study C3671013 was a phase 3, multicentre, randomised, double blind, placebo-controlled study to assess the efficacy of Abrysvo in the prevention of RSV-associated lower respiratory tract illness in individuals 60 years of age and older.

RSV-associated lower respiratory tract illness was defined as RT-PCR confirmed RSV illness with two or more or three or more of the following respiratory symptoms within 7 days of symptom onset and lasting more than 1 day during the same illness: new or increased cough, wheezing, sputum production, shortness of breath or tachypnoea (≥25 breaths/min or 15% increase from resting baseline).

Participants were randomised (1:1) to receive Abrysvo (n=18‘487) or placebo (n=18‘479). Enrolment was stratified by age 60-69 years (63%), 70-79 years (32%) and ≥80 years (6%). Subjects with stable chronic underlying conditions were eligible for this study and 52% of participants had at least one prespecified condition; 16% of participants were enrolled with stable chronic cardiopulmonary conditions such as asthma (9%), chronic obstructive pulmonary disease (7%) or congestive heart failure (2%). Immunocompromised individuals were ineligible.

Of the participants who received Abrysvo, 51% were male and 80% were White, 12% were Black or African American and 42% were Hispanic/Latino. The median age of participants was 67 years (range 59-95 years).

The primary objective was assessment of vaccine efficacy (VE), defined as the relative risk reduction of first episode of RSV-associated lower respiratory tract illness in the Abrysvo group compared to the placebo group in the first RSV season.

At the end of the first RSV season the analysis demonstrated statistically significant efficacy for Abrysvo for reduction of RSV-associated lower respiratory tract illness with ≥2 symptoms and with ≥3 symptoms compared to placebo.

Vaccine efficacy information at the end of the first RSV season with a median follow-up period of 7.4 months is presented in Table 4.

Table 4 Analysis of vaccine efficacy of Abrysvo against RSV lower respiratory tract disease at the end of the first RSV season and by subgroup[a] (Study C3671013)

Efficacy endpoint		*Abrysvo Number of cases n/N*	*Placebo Number of cases n/N*	*VE (%) (95% CI)*
First RSV Season				
First episode of RSV-associated lower respiratory tract illness with ≥2 symptoms	Total	15/18‘058	43/18‘058	65.1 (35.9, 82.0)
	Subgroup[a]			
	Age 60-69 years	10/11‘305	25/11‘351	60.0 (13.8, 82.9)
	Age 70-79 years	4/5‘750	12/5‘742	Not conclusive[b]
	Age ≥80 years	1/995	6/981	Not conclusive[b]
	With ≥1 significant underlying condition	8/9‘377	22/9‘432	63.6 (15.2, 86.0)
	RSV subgroup A	3/18‘050	16/18‘074	81.3 (34.5, 96.5)
	RSV subgroup B	12/18‘050	26/18‘074	53.8 (5.2, 78.8)
First episode of RSV-associated lower respiratory tract illness with ≥3 symptoms	Total	2/18‘058	18/18‘076	88.9 (53.6, 98.7)
	Subgroup[a]			
	Age 60-69 years	2/11‘305	11/11‘351	81.8 (16.7, 98.0)
	Age 70-79 years	0/5‘750	4/5‘742	Not conclusive[b]
	Age ≥80 years	0/995	3/981	Not conclusive[b]
	With ≥1 significant underlying condition	2/9‘377	11/9‘432	81.8 (16.7, 98.0)
	RSV subgroup A	1/18‘050	5/18‘074	80.0 (-78.7, 99.6)
	RSV subgroup B	1/18‘050	12/18‘074	91.7 (43.7, 99.8)

CI = confidence interval; RSV = respiratory syncytial virus; VE = vaccine efficacy
[a] Exploratory analysis.
[b] Vaccine efficacy in this subgroup cannot be concluded due to the low number of total cases accrued.

The vaccine efficacy at the end of the second season and combined across the two RSV seasons with a median follow-up period of 16.4 months based on exploratory analysis is presented in Table 5.

Table 5 Analysis of vaccine efficacy of Abrysvo against RSV lower respiratory tract disease at the end of the second RSV season and combined across the two RSV seasons by subgroup (Study C3671013)

Efficacy endpoint		*Abrysvo Number of cases n/N*	*Placebo Number of cases n/N*	*VE (%) (95% CI)*
Second RSV season				

Efficacy endpoint		*Abrysvo Number of cases n/N*	*Placebo Number of cases n/N*	*VE (%) (95% CI)*
First episode of RSV-associated lower respiratory tract illness with ≥2 symptoms	Total	39/16‘164	88/16‘059	55.7 (34.7, 70.4)
	Subgroup			
	Age 60-69 years	24/10‘222	55/10‘196	56.4 (28.3, 74.2)
	Age 70-79 years	11/5‘111	28/5‘056	60.7 (18.6, 82.4)
	Age ≥80 years	4/831	5/807	Not conclusive[b]
	With ≥1 significant underlying condition	28/8‘415	49/8‘399	42.9 (7.3, 65.4)
	RSV subgroup A	24/16‘164	64/16‘059	62.5 (39.2, 77.6)
	RSV subgroup B	14/16‘164	26/16‘059	46.2 (-7.0, 74.0)[c]
First episode of RSV-associated lower respiratory tract illness with ≥3 symptoms	Total	8/16‘164	36/16‘059	77.8 (51.4, 91.1)
	Subgroup			
	Age 60-69 years	5/10‘222	27/10‘196	81.5 (51.2, 94.4)
	Age 70-79 years	3/5‘111	7/5‘056	Not conclusive[b]
	Age ≥80 years	0/831	2/807	Not conclusive[b]
	With ≥1 significant underlying condition	7/8‘415	23/8‘399	69.6 (26.7, 89.0)
	RSV subgroup A	5/16‘164	26/16‘059	80.8 (49.1, 94.2)
	RSV subgroup B	2/16‘164	10/16‘059	80.0 (6.1, 97.9)
Across 2 RSV seasons[a]				
First episode of RSV-associated lower respiratory tract illness with ≥2 symptoms	Total	54/18‘050	131/18‘074	58.8 (43.0, 70.6)
	Subgroup			
	Age 60-69 years	34/11‘305	80/11‘351	57.5 (35.8, 72.4)
	Age 70-79 years	15/5‘750	40/5‘742	62.5 (30.6, 80.8)
	Age ≥80 years	5/995	11/981	Not conclusive[b]
	With ≥1 significant underlying condition	36/9‘387	71/9‘448	49.3 (23.2, 67.0)
	RSV subgroup A	27/18‘050	80/18‘074	66.3 (47.2, 79.0)
	RSV subgroup B	26/18‘050	52/18‘074	50.0 (18.5, 70.0)
First episode of RSV-associated lower respiratory tract illness with ≥3 symptoms	Total	10/18‘050	54/18‘074	81.5 (63.3, 91.6)
	Subgroup			
	Age 60-69 years	7/11‘305	38/11‘351	81.6 (58.2, 93.1)
	Age 70-79 years	3/5‘750	11/5‘742	Not conclusive[b]
	Age ≥80 years	0/995	5/981	Not conclusive[b]
	With ≥1 significant underlying condition	9/9‘387	34/9‘448	73.5 (43.6, 88.8)
	RSV subgroup A	6/18‘050	31/18‘074	80.6 (52.9, 93.4)
	RSV subgroup B	3/18‘050	22/18‘074	86.4 (54.6, 97.4)

CI – confidence interval; RSV – respiratory syncytial virus; VE – vaccine efficacy

[a] RSV seasons 1 and 2 combined, with a median follow-up period of 16.4 months.

[b] Vaccine efficacy in this subgroup cannot be concluded due to the low number of total cases accrued.

Immunogenicity in individuals 18 through 59 years of age with increased risk of developing lower respiratory tract disease caused by RSV

Studies on the clinical efficacy of Abrysvo were conducted in individuals aged 60 years and older (see Study C3671013 above).

The effectiveness of Abrysvo in individuals 18-59 years of age at increased risk of developing lower respiratory tract disease caused by RSV can be inferred from a comparable immune response compared to a subgroup of individuals in study C3671013, in which the efficacy of the vaccine was demonstrated (Immunobridging).

C3671023 Substudy A was a phase 3, multicentre, randomised, double-blind, placebo-controlled study to assess the safety and immunogenicity of Abrysvo in individuals 18 through 59 years of age considered to be at increased risk of developing lower respiratory tract disease caused by RSV. The study enrolled individuals who had chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, haematologic or metabolic disorders (including diabetes mellitus and hyper/hypothyroidism). Immunocompromised individuals were excluded from the study. Participants were randomised (2:1) to receive a single dose of Abrysvo (n=437) or placebo (n=217).

Demographic characteristics in C3671023 Substudy A were generally similar with regard to age, race and ethnicity among participants who received Abrysvo and those who received placebo. Fifty-three percent (53%) were 18 to 49 years and 47% were 50 to 59 years. The vaccine and placebo groups were similar with regards to having at least one prespecified medical condition, which included 53% with ≥1 chronic pulmonary condition, 8% with ≥1 cardiovascular condition, 42% with diabetes and 31% ≥1 other disease (liver, renal, neurologic, haematologic or other metabolic disease).

The non-inferiority criteria were met for increased risk individuals 18 through 59 years of age compared to individuals ≥60 years of age for the ratio of RSV neutralising geometric mean titres (GMTs) by the lower bounds of the 2-sided 95% CIs >0.667 (1.5-fold non-inferiority margin), and for the difference in seroresponse rates by the lower bounds of the 2-sided 95% CIs >-10% for both RSV A and RSV B.

Table 6 Comparison of model adjusted RSV neutralising titre GMTs at 1 month after vaccination with Abrysvo, 18 through 59 years at increased risk (C3671023 Substudy A, SSA) versus 60 years and older (Study C3671013)

	Population group and ANCOVA adjusted GMTs				
	Study C3671023 SSA 18-59 years of age at increased risk		*Study C3671013 ≥60 years*		*ANCOVA comparison*
RSV subgroups	*n*	*Adjusted GMT (95% CI)*	*n*	*Adjusted GMT (95% CI)*	*Adjusted GMR (95% CI)*
A	435	41’097 (37’986, 44’463)	408	26’225 (24’143, 28’486)	1.57 (1.396, 1.759)
B	437	37’416 (34’278, 40’842)	408	24’680 (22’504, 27’065)	1.52 (1.333, 1.725)

ANCOVA – analysis of covariance; CI – confidence interval; GMR – geometric mean ratio; GMT – geometric mean titre

Table 7 Comparison of RSV neutralising titre GMTs seroresponse rates 1 month after vaccination with Abrysvo, 18 through 59 years at increased risk (C3671023 Substudy A, SSA) versus 60 years and older (Study C3671013)

	Population group				
	Study C3671023 SSA 18-59 years of age at increased risk		*Study C3671013 ≥60 years*		*Comparison*
RSV subgroups	*n/N (%)*	*95% CI*	*n/N (%)*	*95% CI*	*Difference (95% CI)*
A	405/435 (93)	90.3, 95.3	359/408 (88)	84.4, 91.0	5.1 (1.2, 9.2)
B	408/437 (93)	90.6, 95.5	347/408 (85)	81.2, 88.4	8.3 (4.2, 12.6)

CI – confidence interval; GMT – geometric mean titre

Immunogenicity in immunocompromised individuals 18 years of age and older

C3671023 Substudy B was a phase 3, single-arm, open-label, multicentre study to assess the safety and immunogenicity of Abrysvo in immunocompromised individuals ≥18 years of age (N = 203). Participants had history of a solid organ transplant (kidney, liver, lung or heart) at least 3 months prior to enrollment (n (%) = 75 (36.9%)); end stage renal disease and on haemodialysis (n (%) = 31 (15.3%)); autoimmune inflammatory disorders with active immunomodulator therapy (n (%) = 97 (47.8%)); or advanced non-small cell lung cancer and receiving active immunomodulator therapy (n (%) = 5 (2.5%)). Participants received 2 doses of Abrysvo with an interval of 1 month.

A single dose of Abrysvo elicited neutralising responses approximately 8- or 9-fold above baseline against RSV A and RSV B in participants ≥18 years of age with immunocompromising conditions (n=188). Responses did not further increase with a second dose of Abrysvo 1 month after the first dose.

Pharmacokinetics

Absorption

Not applicable.

Distribution

Not applicable.

Metabolism

Not applicable.

Elimination

Not applicable.

Preclinical data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity and toxicity to reproduction and development.

Other information

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf life

Do not use this medicine after the expiry date («EXP») stated on the pack.

The unopened vial is stable for 5 days when stored at temperatures from 8-30 °C. At the end of this period Abrysvo should be used or discarded. This information is used to guide healthcare professionals in case of temporary temperature excursions only.

Shelf life after opening

After reconstitution: Abrysvo should be administered immediately after reconstitution or within 4 hours if stored between 15-30 °C. Do not freeze.

Chemical and physical in-use stability has been demonstrated for 4 hours between 15-30 °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.

Special precautions for storage

Store in a refrigerator (2-8 ºC).

Do not freeze. Discard if the carton has been frozen.

Keep out of the reach of children.

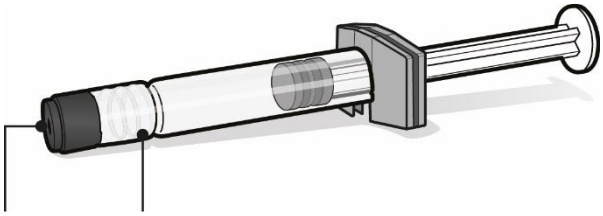
Instructions for handling

Abrysvo must be reconstituted prior to the administration by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder using the vial adaptor.

The vaccine must be reconstituted only with the solvent provided.

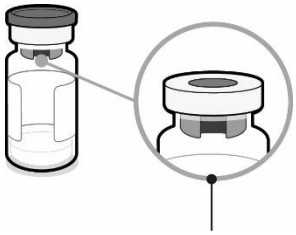
Preparation for administration

Pre-filled syringe containing solvent for Abrysvo



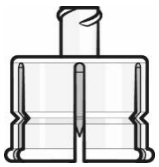
Syringe cap Luer lock adaptor

Vial containing antigens for Abrysvo (powder)



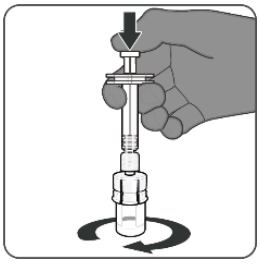
Vial stopper (with flip off cap removed)

Vial adaptor



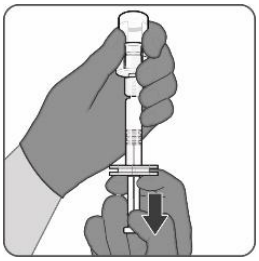
Step 1. Attach the vial adapter

- Peel off the top cover from the vial adapter packaging and remove the flip off cap from the vial.
- While keeping the vial adapter in its packaging, centre over the vial's stopper and connect with a straight downward push. Do not push the vial adapter in at an angle as it may result in leaking. Remove the packaging.



Step 2. Reconstitute lyophilised vaccine component to form Abrysvo

- For all syringe assembly steps, hold the syringe only by the Luer lock adapter. This will prevent the Luer lock adapter from detaching during use.
- Twist to remove the syringe cap, then twist to connect the syringe to the vial adapter. Stop turning when you feel resistance.
- Inject the entire contents of the syringe into the vial. Hold the plunger rod down and gently swirl the vial until the powder is completely dissolved (approximately 1-2 minutes). Do not shake.



Step 3. Withdraw the reconstituted vaccine

- Invert the vial completely and slowly withdraw the entire contents into the syringe to ensure a 0.5 ml dose of Abrysvo.
- Twist to disconnect the syringe from the vial adapter.
- Attach a sterile needle suitable for intramuscular injection.

The prepared vaccine is a clear and colourless solution. Visually inspect the vaccine for large particulate matter and discolouration prior to administration. Do not use if large particulate matter or discolouration is found.

Authorisation number

69691 (Swissmedic).

Packs

Pack containing 1 vial with powder, 1 pre-filled syringe with solvent, 1 vial adaptor and 1 needle. [B]

Pack containing 5 vials with powder, 5 pre-filled syringes with solvent, 5 vial adaptors and 5 needles. [B]

Pack containing 10 vials with powder, 10 pre-filled syringes with solvent, 10 vial adaptors and 10 needles. [B]

Marketing authorisation holder

Pfizer AG, Zürich.

Date of revision of the text

July 2025.