ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼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 adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Abrysvo powder and solvent for solution for injection

Respiratory syncytial virus vaccine (bivalent, recombinant)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

After reconstitution, one dose (0.5 mL) contains:

RSV subgroup A stabilised prefusion F antigen[1,2]	60 micrograms
RSV subgroup B stabilised prefusion F antigen[1,2]	60 micrograms

(RSV antigens)
[1]glycoprotein F stabilised in the prefusion conformation
[2]produced in Chinese Hamster Ovary cells by recombinant DNA technology.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

The powder is white.
The solvent is a clear, colourless liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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 maternal immunisation during pregnancy. See sections 4.2 and 5.1.

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

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

4.2 Posology and method of administration

Posology

Pregnant individuals
A single dose of 0.5 mL should be administered between weeks 24 and 36 of gestation (see sections 4.4 and 5.1).

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

Paediatric population
The safety and efficacy of Abrysvo in children (from birth to less than 18 years of age) have not yet been established. Limited data are available in pregnant adolescents and their infants (see section 5.1).

Method 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 section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

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.

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

The efficacy and safety of the vaccine have not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of Abrysvo may be lower in immunosuppressed individuals.

Individuals less than 24 weeks of gestation

Abrysvo has not been studied in pregnant individuals less than 24 weeks of gestation. Since protection of the infant against RSV depends on transfer of maternal antibodies across the placenta, Abrysvo should be administered between weeks 24 and 36 of gestation (see sections 4.2 and 5.1).

Limitations of vaccine effectiveness

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

Excipients

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Abrysvo contains polysorbate 80. Polysorbate 80 may cause hypersensitivity reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Abrysvo can be administered concomitantly with:

- seasonal influenza vaccines, either standard dose adjuvanted or high dose unadjuvanted
- COVID-19 mRNA vaccines, with or without high dose unadjuvanted influenza vaccine administered concomitantly.

A minimum interval of two weeks is recommended between administration of Abrysvo and administration of a tetanus, diphtheria and acellular pertussis vaccine (Tdap). There were no safety concerns when Abrysvo was co-administered with Tdap in healthy non-pregnant women. 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 and did not meet the criteria for non-inferiority. The clinical relevance of this finding is unknown.

4.6 Fertility, pregnancy and 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 section 5.3).

In a phase 3 study (Study 1), maternal adverse events reported within 1 month after vaccination were similar in the Abrysvo group (14%) and the placebo group (13%).

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 (37%) and the placebo group (35%). Major birth outcomes assessed in the Abrysvo group compared to placebo included premature birth (201 (6%) and 169 (5%), respectively), low birth weight (181 (5%) and 155 (4%), respectively) and congenital anomalies (174 (5%) and 203 (6%), respectively).

Breast-feeding

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 section 5.3).

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Summary of the safety profile

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 18 years of age and older
In individuals 18 years of age and older the most frequently reported adverse reactions were fatigue (23%), headache (20%), vaccination site pain (19%) and myalgia (16%). The majority of reactions were mild to moderate in severity and resolved within 1-2 days of onset.

Tabulated list of adverse reactions

The safety of administering a single dose of Abrysvo to pregnant women at 24-36 weeks of gestation (n=3 682) and to individuals 18 years of age and older (n=20 275) was evaluated in clinical trials.

Adverse reactions are listed according to the following frequency categories:
Very common (≥1/10);
Common (≥1/100 to <1/10);
Uncommon (≥1/1 000 to <1/100);
Rare (≥1/10 000 to <1/1 000);
Very rare (<1/10 000);
Not known (cannot be estimated from the available data).

Adverse reactions reported are listed per system organ class, in decreasing order of seriousness.

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		
Anaphylaxis		Very rare
Hypersensitivity reactions (includes rash, urticaria)	Rare	Rare
Nervous system disorders		
Headache	Very common	Very common
Guillain-Barré syndrome		Very rare
Musculoskeletal and connective tissue disorders		
Myalgia	Very common	Very common
Arthralgia		Common
General disorders and administration site conditions		
Fatigue		Very common
Vaccination site pain	Very common	Very common
Vaccination site redness	Common	Common
Vaccination site swelling	Common	Common
Pyrexia		Uncommon
Vaccination site pruritus		Rare
Vaccination site bruising		Rare
Vaccination site haematoma		Rare

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccines, other viral vaccines; 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 between weeks 24 and 36 of gestation, 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.

Clinical efficacy

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

Study 1 is 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. The need for revaccination with subsequent pregnancies has not been established.

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, 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, 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 this study, 3 695 pregnant individuals with uncomplicated, singleton pregnancies were randomised to the Abrysvo group and 3 697 to placebo.

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. 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.

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 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 – Study 1

Time period	Abrysvo Number of cases N=3 495	Placebo Number of cases N=3 480	VE % (CI)[a]
90 days	6	33	81.8 (40.6, 96.3)
120 days	12	46	73.9 (45.6, 88.8)
150 days	16	55	70.9 (44.5, 85.9)
180 days	19	62	69.4 (44.3, 84.1)

CI = confidence interval; VE = vaccine efficacy

[a] 99.5% CI at 90 days; 97.58% CI at later intervals

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 - Study 1

Time period	Abrysvo Number of cases N=3 495	Placebo Number of cases N=3 480	VE % (CI)[a]
90 days	24	56	57.1 (14.7, 79.8)
120 days	35	81	56.8 (31.2, 73.5)
150 days	47	99	52.5 (28.7, 68.9)
180 days	57	117	51.3 (29.4, 66.8)

CI = confidence interval; VE = vaccine efficacy

[a] 99.5% CI at 90 days; 97.58% CI at later intervals

A post-hoc analysis of VE by maternal gestational age was conducted. For severe medically attended lower respiratory tract illness occurring within 180 days, VE was 57.2% (95% CI 10.4, 80.9) for women vaccinated early in pregnancy (24 to <30 weeks) and 78.1% (95% CI 52.1, 91.2) for women vaccinated later in the pregnancy eligible window (30 to 36 weeks). For medically attended lower respiratory tract illness occurring within 180 days, VE was 30.9% (95% CI -14.4, 58.9) for women vaccinated early in pregnancy (24 to <30 weeks) and 62.4% (95% CI 41.6, 76.4) for women vaccinated later in the pregnancy eligible window (30 to 36 weeks).

Individuals 60 years of age and older

Study 2 is 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=18 488) or placebo (n=18 479). Enrollment was stratified by age 60-69 years (63%), 70-79 years (32%) and ≥80 years (5%). Subjects with stable chronic underlying conditions were eligible for this study and 52% of participants had at least 1 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.

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.

Of the participants who received Abrysvo, 51% were male and 80% were White, 12% were Black or African American and 41% were Hispanic/Latino. The median age of participants was 67 years (range 59-95 years).

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.

Vaccine efficacy information is presented in Table 4.

Table 4 Vaccine efficacy of Abrysvo against RSV disease - active immunisation of individuals 60 years of age and older – Study 2

Efficacy endpoint	Abrysvo Number of cases N=18 058	Placebo Number of cases N=18 076	VE (%) (95% CI)
First episode of RSV-associated lower respiratory tract illness with ≥2 symptoms[a]	15	43	65.1 (35.9, 82.0)
First episode of RSV-associated lower respiratory tract illness with ≥3 symptoms[b]	2	18	88.9 (53.6, 98.7)

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

[a] In an exploratory analysis in RSV subgroup A (Abrysvo n=3, placebo n=16) VE was 81.3% (CI 34.5, 96.5); and in RSV subgroup B (Abrysvo n=12, placebo n=26) VE was 53.8% (CI 5.2, 78.8).

[b] In an exploratory analysis in RSV subgroup A (Abrysvo n=1, placebo n=5) VE was 80.0% (CI -78.7, 99.6); and in RSV subgroup B (Abrysvo n=1, placebo n=12) VE was 91.7% (CI 43.7, 99.8).

Immunogenicity in individuals 18 through 59 years of age

Study 3 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 high risk of developing severe lower respiratory tract disease caused by RSV. Study 3 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). Participants were randomised (2:1) to receive a single dose of Abrysvo (n=437) or placebo (n=217).

Demographic characteristics in study 3 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).

Vaccine efficacy in individuals 18 through 59 years of age is inferred by immunobridging to study 2 where vaccine efficacy was demonstrated in individuals 60 years of age and older. The non-inferiority criteria were met for high risk individuals 18 through 59 years of age compared to a randomly selected immunogenicity subset (external control group) of individuals ≥60 years of age from study 2 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 5 Comparison of model adjusted RSV neutralising titre GMTs at 1 month after vaccination with Abrysvo, 18 through 59 years at high risk (Study 3) versus 60 years and older (Study 2)

	Study 3 18-59 years of age at high risk		Study 2 ≥60 years		ANCOVA comparison
RSV subgroups	**n**	**Adjusted GMT (95% CI)**	**n**	**Adjusted GMT (95% CI)**	**Adjusted GMR (95% CI)**
A	435	41097 (37986, 44463)	408	26225 (24143, 28486)	1.57 (1.396, 1.759)
B	437	37416 (34278, 40842)	408	24680 (22504, 27065)	1.52 (1.333, 1.725)

CI – confidence interval; GMR – geometric mean ratio; GMT – geometric mean titre

Table 6 Comparison of RSV neutralising titre seroresponse rates 1 month after vaccination with Abrysvo, 18 through 59 years at high risk (Study 3) versus 60 years and older (Study 2)

	Study 3 18-59 years of age at high risk		Study 2 ≥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

Paediatric population
The European Medicines Agency has deferred the obligation to submit the results of studies with Abrysvo in children from 2 to less than 18 years of age in prevention of lower respiratory tract disease caused by RSV (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder

Trometamol
Trometamol hydrochloride
Sucrose
Mannitol (E421)
Polysorbate 80 (E433)
Sodium chloride
Hydrochloric acid (for pH adjustment)

Solvent

Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

3 years

The unopened vial is stable for 5 days when stored at temperatures from 8°C to 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.

After reconstitution

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

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

6.4 Special precautions for storage

Store in a refrigerator (2ºC - 8ºC).

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

For storage conditions after reconstitution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Vial of antigens for Abrysvo (powder) and pre-filled syringe of solvent

Powder for 1 dose in a vial (type 1 glass or equivalent) with a stopper (synthetic bromobutyl rubber or synthetic chlorobutyl rubber) and a flip off cap

Solvent for 1 dose in a pre-filled syringe (type 1 glass) with a stopper (synthetic chlorobutyl rubber) and a tip cap (synthetic isoprene/bromobutyl blend rubber)

Vial adaptor

Vial of antigens for Abrysvo (powder) and vial of solvent

Powder for 1 dose in a vial (type 1 glass or equivalent) with a stopper (synthetic bromobutyl rubber or synthetic chlorobutyl rubber) and a flip off cap

Solvent for 1 dose in a vial (type 1 glass or equivalent) with a stopper (bromobutyl rubber) and a flip off cap

Pack sizes

Pack containing 1 vial of powder (antigens), 1 pre-filled syringe of solvent, 1 vial adaptor with 1 needle or without needles (1 dose pack).
Pack containing 5 vials of powder (antigens), 5 pre-filled syringes of solvent, 5 vial adaptors with 5 needles or without needles (5 dose pack).
Pack containing 10 vials of powder (antigens), 10 pre-filled syringes of solvent, 10 vial adaptors with 10 needles or without needles (10 dose pack).
Pack containing 5 vials of powder (antigens) and 5 vials of solvent (5 dose pack).
Pack containing 10 vials of powder (antigens) and 10 vials of solvent (10 dose pack).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

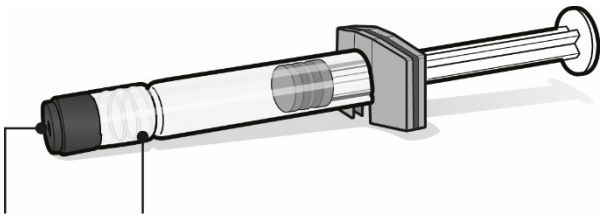
For use of vial of antigens for Abrysvo (powder), pre-filled syringe of solvent and vial adaptor

Abrysvo must be reconstituted prior to 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.

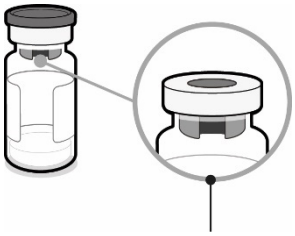
Preparation for administration

Pre-filled syringe containing solvent for Abrysvo



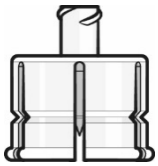
Syringe cap Luer lock adaptor

Vial containing antigens for Abrysvo (powder)



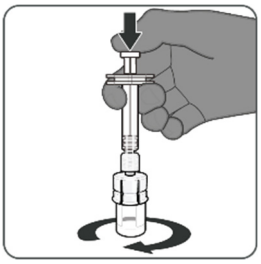
Vial stopper (with flip off cap removed)

Vial adaptor



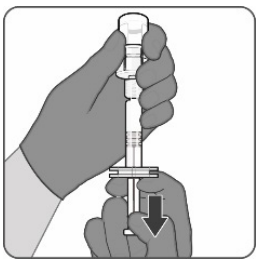
Step 1. Attach vial adaptor

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



Step 2. Reconstitute the powder component (antigens) to form Abrysvo

- For all syringe assembly steps, hold the syringe only by the Luer lock adaptor. This will prevent the Luer lock adaptor from detaching during use.
- Twist to remove the syringe cap, then twist to connect the syringe to the vial adaptor. 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. Do not shake.



Step 3. Withdraw 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 adaptor.
- 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.

For use of vial of antigens for Abrysvo (powder) and vial of solvent

The vial containing antigens for Abrysvo (powder) must be reconstituted only with the vial of solvent provided to form Abrysvo.

Preparation for administration

1. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the solvent and inject the entire contents of the syringe into the vial containing the powder.
2. Gently swirl the vial in a circular motion until the powder is completely dissolved. Do not shake.
3. Withdraw 0.5 mL from the vial containing the reconstituted vaccine.

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.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/23/1752/001 – 1 vial (antigens), 1 vial adaptor, 1 pre-filled syringe (solvent), 1 needle
EU/1/23/1752/002 – 1 vial (antigens), 1 vial adaptor, 1 pre-filled syringe (solvent)
EU/1/23/1752/003 – 5 vials (antigens), 5 vial adaptors, 5 pre-filled syringes (solvent), 5 needles
EU/1/23/1752/004 – 5 vials (antigens), 5 vial adaptors, 5 pre-filled syringes (solvent)
EU/1/23/1752/005 – 10 vials (antigens), 10 vial adaptors, 10 pre-filled syringes (solvent), 10 needles
EU/1/23/1752/006 – 10 vials (antigens), 10 vial adaptors, 10 pre-filled syringes (solvent)
EU/1/23/1752/007 – 5 vials (antigens), 5 vials (solvent)
EU/1/23/1752/008 – 10 vials (antigens), 10 vials (solvent)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 August 2023

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency https://www.ema.europa.eu.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substances

Wyeth BioPharma
Division of Wyeth Pharmaceuticals LLC
1 Burtt Rd
Andover, MA 01810
USA

Name and address of the manufacturers responsible for batch release

Pfizer Manufacturing Belgium NV
Rijksweg 12
2870 Puurs-Sint-Amands
Belgium

Pfizer Ireland Pharmaceuticals
Grange Castle Business Park
Clondalkin, Dublin 22
Ireland

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

- **Official batch release**

In accordance with Article 114 of Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING – OUTER CARTON

1 VIAL (POWDER) AND 1 PRE-FILLED SYRINGE (SOLVENT) WITH AND WITHOUT NEEDLE
5 VIALS (POWDER) AND 5 PRE-FILLED SYRINGES (SOLVENT) WITH AND WITHOUT NEEDLES
10 VIALS (POWDER) AND 10 PRE-FILLED SYRINGES (SOLVENT) WITH AND WITHOUT NEEDLES

1. NAME OF THE MEDICINAL PRODUCT

Abrysvo powder and solvent for solution for injection
Respiratory syncytial virus vaccine (bivalent, recombinant)

2. STATEMENT OF ACTIVE SUBSTANCES

After reconstitution, one dose (0.5 mL) contains:
RSV subgroup A stabilised prefusion F antigen 60 micrograms
RSV subgroup B stabilised prefusion F antigen 60 micrograms

3. LIST OF EXCIPIENTS

Trometamol, trometamol hydrochloride, sucrose, mannitol, polysorbate 80, sodium chloride, hydrochloric acid, water for injections. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Powder and solvent for solution for injection

1 vial with powder (antigens)
1 pre-filled syringe of solvent
1 vial adaptor
1 needle

1 vial with powder (antigens)
1 pre-filled syringe of solvent
1 vial adaptor

5 vials with powder (antigens)
5 pre-filled syringes of solvent
5 vial adaptors
5 needles

5 vials with powder (antigens)
5 pre-filled syringes of solvent
5 vial adaptors

10 vials with powder (antigens)
10 pre-filled syringes of solvent
10 vial adaptors
10 needles

10 vials with powder (antigens)
10 pre-filled syringes of solvent
10 vial adaptors

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use after reconstitution

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. Discard if the carton has been frozen.

After reconstitution, use immediately or within 4 hours if stored between 15°C and 30°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/23/1752/001 – 1 vial (antigens), 1 vial adaptor, 1 pre-filled syringe (solvent), 1 needle
EU/1/23/1752/002 – 1 vial (antigens), 1 vial adaptor, 1 pre-filled syringe (solvent)
EU/1/23/1752/003 – 5 vials (antigens), 5 vial adaptors, 5 pre-filled syringes (solvent), 5 needles
EU/1/23/1752/004 – 5 vials (antigens), 5 vial adaptors, 5 pre-filled syringes (solvent)
EU/1/23/1752/005 – 10 vials (antigens), 10 vial adaptors, 10 pre-filled syringes (solvent), 10 needles
EU/1/23/1752/006 – 10 vials (antigens), 10 vial adaptors, 10 pre-filled syringes (solvent)

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING – OUTER CARTON

5 VIALS (POWDER) AND 5 VIALS (SOLVENT)
10 VIALS (POWDER) AND 10 VIALS (SOLVENT)

1. NAME OF THE MEDICINAL PRODUCT

Abrysvo powder and solvent for solution for injection
Respiratory syncytial virus vaccine (bivalent, recombinant)

2. STATEMENT OF ACTIVE SUBSTANCES

After reconstitution, one dose (0.5 mL) contains:
RSV subgroup A stabilised prefusion F antigen 60 micrograms
RSV subgroup B stabilised prefusion F antigen 60 micrograms

3. LIST OF EXCIPIENTS

Trometamol, trometamol hydrochloride, sucrose, mannitol, polysorbate 80, sodium chloride, hydrochloric acid, water for injections. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Powder and solvent for solution for injection

5 vials with powder (antigens)
5 vials of solvent
10 vials with powder (antigens)
10 vials of solvent

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use after reconstitution

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. Discard if the carton has been frozen.

After reconstitution, use immediately or within 4 hours if stored between 15°C and 30°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/23/1752/007 – 5 vials (antigens), 5 vials (solvent)
EU/1/23/1752/008 – 10 vials (antigens), 10 vials (solvent)

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL (POWDER)

1. NAME OF THE MEDICINAL PRODUCT

Antigens for Abrysvo
IM

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENT BY WEIGHT, BY VOLUME OR BY UNIT

1 dose

6. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PRE-FILLED SYRINGE (SOLVENT)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Solvent for Abrysvo

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.5 mL

6. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL (SOLVENT)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Solvent for Abrysvo

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.5 mL

6. OTHER

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Abrysvo powder and solvent for solution for injection
Respiratory syncytial virus vaccine (bivalent, recombinant)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Abrysvo is and what it is used for

Abrysvo is a vaccine to prevent lung (respiratory tract) disease caused by a virus called respiratory syncytial virus (RSV). Abrysvo is given to:

- pregnant individuals to protect their infants from birth through 6 months of age

or

- individuals 18 years of age and older.

RSV is a common virus which, in most cases, causes mild, cold-like symptoms such as a sore throat, cough or a blocked nose. However, in young infants RSV can cause serious lung problems. In older adults and people with chronic medical conditions, RSV can worsen illnesses such as chronic obstructive pulmonary disease (COPD) and congestive heart failure (CHF). RSV can lead to hospitalisation in severe cases and in some cases it can be fatal.

How Abrysvo works
This vaccine helps the immune system (the body's natural defences) to make antibodies (substances in the blood that help the body fight infections) which protect against lung disease caused by RSV. In pregnant individuals who are vaccinated between weeks 24 and 36 of pregnancy, these antibodies are passed to the infant through the placenta before birth which protects infants when they are at most risk from RSV.

2. What you need to know before you receive Abrysvo

Abrysvo should not be given
- if you are allergic to the active substances or any of the other ingredients of this vaccine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given this vaccine

- if you have ever had a severe allergic reaction or breathing problems after you received any other vaccine injection or after you were given Abrysvo in the past.
- if you are feeling nervous about getting the vaccine or have ever fainted after any injection. Fainting can happen before or after any injection.
- if you have an infection with a high fever. If this is the case, then vaccination will be postponed. There is no need to delay vaccination for a minor infection, such as a cold, but talk to your doctor first.
- if you have a bleeding problem or bruise easily.
- if you have a weakened immune system which may prevent you from getting the full benefit from Abrysvo.
- if you are less than 24 weeks pregnant.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Abrysvo.

As with any vaccine, Abrysvo may not fully protect all those who receive it.

Children and adolescents
Abrysvo is not recommended in children and young people below 18 years of age except during pregnancy (see 'Pregnancy' section below).

Other medicines and Abrysvo
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Abrysvo may be given at the same time as a flu vaccine or a COVID-19 vaccine. A gap of at least two weeks is recommended between administration of Abrysvo and administration of a vaccine against tetanus, diphtheria and acellular pertussis (whooping cough).

Pregnancy and breast-feeding
Pregnant individuals can be given this vaccine in the late second or third trimester (weeks 24 to 36). Talk to your doctor or nurse for advice before getting this vaccine if you are breast-feeding.

Driving and using machines
Abrysvo is unlikely to affect your ability to drive or use machines.

Abrysvo contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Abrysvo contains polysorbate 80
One dose of Abrysvo contains 0.08 mg of polysorbate 80. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How Abrysvo is given

You will be given one injection of 0.5 mL into a muscle of your upper arm.

If you have any questions on the use of Abrysvo, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, this vaccine can cause side effects, although not everybody gets them.

Serious side effects

Very rare (may affect up to 1 in 10 000 people)
- severe allergic reactions - signs of a severe allergic reaction include swelling of the face, lips, tongue or throat, difficulty breathing or swallowing and dizziness. See also section 2.
- Guillain-Barré syndrome (a neurological disorder that usually starts with pins and needles and weakness of the limbs and may progress up to paralysis of part or all of the body).

Tell your doctor immediately if you notice signs of these serious side effects.

The following side effects were reported in pregnant individuals

Very common (may affect more than 1 in 10 people)
- pain where the injection is given
- headache
- muscle pain (myalgia).

Common (may affect up to 1 in 10 people)
- redness where the injection is given
- swelling where the injection is given.

Rare (may affect up to 1 in 1 000 people)
- allergic reactions such as rash or hives
- swollen glands (lymphadenopathy).

No side effects were reported in infants born to vaccinated mothers.

The following side effects were reported in individuals 18 years of age and older

Very common (may affect more than 1 in 10 people)
- tiredness (fatigue)
- headache
- pain where the injection is given
- muscle pain (myalgia).

Common (may affect up to 1 in 10 people)
- joint pain (arthralgia)
- redness where the injection is given
- swelling where the injection is given.

Uncommon (may affect up to 1 in 100 people)
- fever (pyrexia).

Rare (may affect up to 1 in 1 000 people)
- allergic reactions such as rash or hives
- swollen glands (lymphadenopathy)
- bruising where the injection is given (haematoma)
- itching where the injection is given (pruritus).

Very rare (may affect up to 1 in 10 000 people)
- severe allergic reactions (see Serious side effects, above)
- Guillain-Barré syndrome (see Serious side effects, above).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Abrysvo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2ºC - 8ºC).

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

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

6. Contents of the pack and other information

What Abrysvo contains

The active substances are:
RSV subgroup A stabilised prefusion F antigen[1,2] 60 micrograms
RSV subgroup B stabilised prefusion F antigen[1,2] 60 micrograms
(RSV antigens)
[1]glycoprotein F stabilised in the prefusion conformation
[2]produced in Chinese Hamster Ovary cells by recombinant DNA technology.

The other ingredients are:
Powder
- trometamol
- trometamol hydrochloride
- sucrose
- mannitol (E421)
- polysorbate 80 (E433)
- sodium chloride
- hydrochloric acid

Solvent
- water for injections

What Abrysvo looks like and contents of the pack

Abrysvo is provided as
- a white powder in a glass vial
- a solvent in a pre-filled syringe or a vial to dissolve the powder

After dissolving the powder in the solvent, the solution is clear and colourless.

Abrysvo is available in
- a carton containing 1 vial of powder, 1 pre-filled syringe of solvent, 1 vial adaptor, with 1 needle or without needles (1 dose pack).

- a carton containing 5 vials of powder, 5 pre-filled syringes of solvent, 5 vial adaptors, with 5 needles or without needles (5 dose pack).
- a carton containing 10 vials of powder, 10 pre-filled syringes of solvent, 10 vial adaptors, with 10 needles or without needles (10 dose pack).
- a carton containing 5 vials of powder and 5 vials of solvent (5 dose pack).
- a carton containing 10 vials of powder and 10 vials of solvent (10 dose pack).

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

Manufacturer
Pfizer Manufacturing Belgium NV
Rijksweg 12
2870 Puurs-Sint-Amands
Belgium

Pfizer Ireland Pharmaceuticals
Grange Castle Business Park
Clondalkin, Dublin 22
Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
Luxembourg/Luxemburg
Pfizer NV/SA
Tél/Tel: + 32 (0)2 554 62 11

България
Пфайзер Люксембург САРЛ,
Клон България
Тел: +359 2 970 4333

Česká republika
Pfizer, spol. s r.o.
Tel: +420 283 004 111

Danmark
Pfizer ApS
Tlf: + 45 44 20 11 00

Deutschland
PFIZER PHARMA GmbH
Tel: +49 (0)30 550055-51000

Eesti
Pfizer Luxembourg SARL Eesti filiaal
Tel: +372 666 7500

Lietuva
Pfizer Luxembourg SARL
filialas Lietuvoje
Tel: +370 5 251 4000

Magyarország
Pfizer Kft
Tel: + 36 1 488 37 00

Malta
Vivian Corporation Ltd.
Tel: + 356 21344610

Nederland
Pfizer bv
Tel: +31 (0)800 63 34 636

Norge
Pfizer AS
Tlf: +47 67 52 61 00

Österreich
Pfizer Corporation Austria
Ges.m.b.H
Tel: +43 (0)1 521 15-0

Ελλάδα
Pfizer Ελλάς A.E.
Τηλ.: +30 210 6785800

España
Pfizer, S.L.
Télf: +34 91 490 99 00

France
Pfizer
Tél +33 (0)1 58 07 34 40

Hrvatska
Pfizer Croatia d.o.o.
Tel: + 385 1 3908 777

Ireland
Pfizer Healthcare Ireland Unlimited Company
Tel: +1800 633 363 (toll free)
Tel: +44 (0)1304 616161

Ísland
Icepharma hf.
Simi: + 354 540 8000

Italia
Pfizer S.r.l.
Tel: +39 06 33 18 21

Κύπρος
Pfizer Ελλάς A.E. (Cyprus Branch)
Τηλ: +357 22817690

Latvija
Pfizer Luxembourg SARL filiāle Latvijā
Tel.: + 371 670 35 775

Polska
Pfizer Polska Sp. z o.o.
Tel.: +48 22 335 61 00

Portugal
Laboratórios Pfizer, Lda.
Tel: +351 21 423 5500

România
Pfizer Romania S.R.L
Tel: +40 (0) 21 207 28 00

Slovenija
Pfizer Luxembourg SARL
Pfizer, podružnica za svetovanje s področja farmacevtske dejavnosti, Ljubljana
Tel.: +386 (0)1 52 11 400

Slovenská republika
Pfizer Luxembourg SARL, organizačná zložka
Tel: + 421 2 3355 5500

Suomi/Finland
Pfizer Oy
Puh/Tel: +358 (0)9 430 040

Sverige
Pfizer AB
Tel: +46 (0)8 550 520 00

United Kingdom (Northern Ireland)
Pfizer Limited
Tel: + 44 (0) 1304 616161

This leaflet was last revised in

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: https://www.ema.europa.eu

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The following information is intended for healthcare professionals only:

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Administration

Abrysvo is for intramuscular use only.

The unopened vial is stable for 5 days when stored at temperatures from 8°C to 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.

Storage of reconstituted vaccine

Abrysvo should be used immediately after reconstitution or within 4 hours. Store the reconstituted vaccine between 15ºC and 30ºC. Do not freeze reconstituted vaccine.

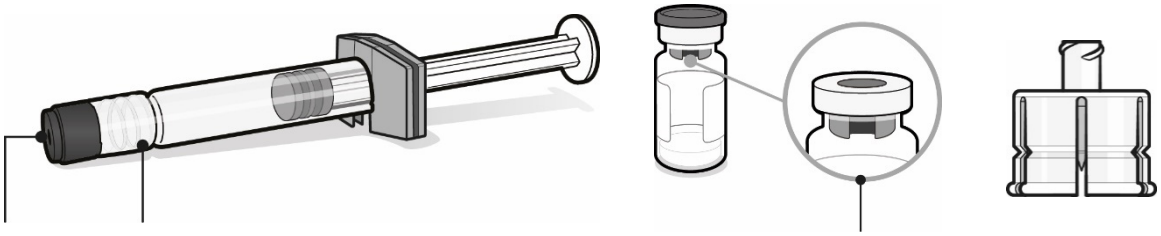
Chemical and physical in-use stability has been demonstrated for 4 hours between 15°C and 30°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Preparation for administration

For use of vial of antigens for Abrysvo (powder), pre-filled syringe of solvent and vial adaptor

The powder must be reconstituted only with the solvent provided in the pre-filled syringe using the vial adaptor.

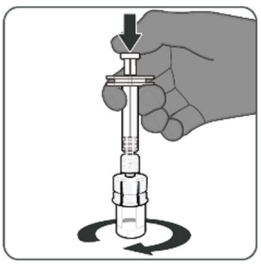
Pre-filled syringe containing solvent for Abrysvo | **Vial containing antigens for Abrysvo (powder)** | **Vial adaptor**



Syringe cap Luer lock adaptor Vial stopper (with flip off cap removed)

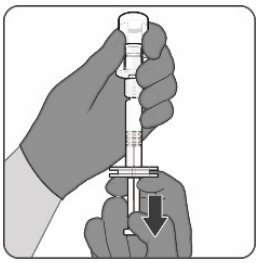
Step 1. Attach vial adaptor

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



Step 2. Reconstitute the powder component (antigens) to form Abrysvo

- For all syringe assembly steps, hold the syringe only by the Luer lock adaptor. This will prevent the Luer lock adaptor from detaching during use.
- Twist to remove the syringe cap, then twist to connect the syringe to the vial adaptor. 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. Do not shake.



Step 3. Withdraw 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 adaptor.
- 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.

For use of vial of antigens for Abrysvo (powder) and vial of solvent

The powder must be reconstituted only with the vial of solvent provided.

1. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the solvent and inject the entire contents of the syringe into the vial containing the powder.
2. Gently swirl the vial in a circular motion until the powder is completely dissolved. Do not shake.
3. Withdraw 0.5 mL from the vial containing the reconstituted vaccine.

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.

Disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

ANNEX IV

CONCLUSIONS ON THE REQUEST FOR ONE-YEAR MARKETING PROTECTION PRESENTED BY THE EUROPEAN MEDICINES AGENCY

Conclusions presented by the European Medicines Agency on:

- **one-year marketing protection**

The CHMP reviewed the data submitted by the marketing authorisation holder, taking into account the provisions of Article 14 (11) of Regulation (EC) No 726/2004, and considers that the new therapeutic indication brings significant clinical benefit in comparison with existing therapies as further explained in the European Public Assessment Report.