**Abrysvo** ™

Respiratory syncytial virus vaccine

120 mcg/0.5mL

powder and solvent for solution for injection

Reference market: EU

▼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 60 years of age and older for the prevention of lower respiratory tract disease caused by RSV.
- Active immunization for the prevention of LRTD caused by RSV in individuals 18 through 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.

### 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 60 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.

Excipient

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

## 4.5 Interaction with other medicinal products and other forms of interaction

Abrysvo can be administered concomitantly with seasonal influenza vaccine (QIV, surface antigen, inactivated, adjuvanted). In a randomised study in adults 65 years of age and older, 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 titres were observed when Abrysvo and inactivated adjuvanted seasonal influenza vaccine were co-administered than when they were administered separately. 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). 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 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 with chronic medical conditions, the most commonly reported (≥10%) adverse reactions and for which the rate for ABRYSVO exceeds the rate for placebo were pain at the injection site (35.3%), muscle pain (24.4%), joint pain (12.4%), and nausea (11.8%).

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 60 years of age and older (n=18 575) was evaluated in phase 3 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 ≥60 years |
|---|---|---|
| Immune system disorders | | |
| Hypersensitivity | | Very rare |
| Nervous system disorders | | |
| Headache | Very common | |
| Guillain-Barré syndrome | | Rare |
| Musculoskeletal and connective tissue disorders | | |
| Myalgia | Very common | |
| General disorders and administration site conditions | | |
| Vaccination site pain | Very common | Very common |
| Vaccination site redness | Common | Common |
| Vaccination site swelling | Common | Common |

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after marketing 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 according to their local country requirements.

### 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 60 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).

Active immunisation of 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).

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).

*Individuals 18 through 59 Years of Age Considered to be at Increased Risk of LRTD caused by RSV*

The safety of ABRYSVO was evaluated in Study 4 (NCT05842967) in which 453 participants received ABRYSVO and 225 received placebo (0.5 mL dose, containing the same buffer ingredients in the same quantities as in a single dose of ABRYSVO *[see Description (11)]*). Study 4 was a multicenter, randomized, 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 LRTD caused by RSV due to certain chronic medical conditions *[see Clinical Studies (14.3)]*. This study was conducted in the US. Demographic characteristics among individuals who received ABRYSVO and those who received placebo were generally similar with regard to age, race, and ethnicity; 43% and 32% of participants in the ABRYSVO and placebo groups, respectively, were male. Of the participants in the study, 68% were White, 24% were Black or African American, 5% were Asian, and 22% were Hispanic/Latino. Fifty-two percent (52%) were 18 to 49 years and 48% were 50 to 59 years. The median age of participants was 49 years. The vaccine and placebo groups were similar with regard to the prevalence of underlying medical conditions: one or more chronic pulmonary condition (52%), diabetes (43%), one or more other disease (liver, renal, neurologic, hematologic, or other metabolic disease) (31%), and one or more cardiovascular condition (8%).

Solicited local and systemic adverse reactions that occurred within 7 days following study vaccination were self-reported in electronic diaries or were reported to an investigator. Unsolicited adverse events were collected for 1 month after study vaccination; serious adverse events (SAEs) were collected for 6 months after study vaccination.

*Solicited Local and Systemic Reactions in Study 4*

Solicited local and systemic reactions reported within 7 days after vaccination in Study 4 are presented in Tables 6 and 7.

**Table 6 Percentage of Participants 18 through 59 Years of Age at Increased Risk of LRTD caused by RSV with Local Reactions Reported, by Maximum Severity, within 7 Days after Vaccination – Study 4[a]**

| Local Reactions | ABRYSVO N=451[b] % | PLACEBO N=225[b] % |
|---|---|---|
| Injection site pain[c] | | |
| Any[d] | 35.3 | 10.7 |
| Mild | 29.7 | 10.2 |
| Moderate | 5.5 | 0.4 |
| Severe | 0 | 0 |
| Redness[e] | | |
| Any[d] | 6.0 | 0.4 |
| Mild | 3.8 | 0 |
| Moderate | 2.2 | 0.4 |
| Severe | 0 | 0 |
| Swelling[e] | | |
| Any[d] | 7.1 | 0.9 |
| Mild | 4.0 | 0.4 |
| Moderate | 2.9 | 0.4 |
| Severe | 0.2 | 0 |

[a] NCT05842967

[b] N = number of participants reporting at least one response in the e-diary.

[c] Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity.

[d] Any includes all participants who reported a reaction as mild, moderate, or severe during Day 1 to Day 7 after vaccination.

[e] Mild: >2 cm to 5 cm; moderate: >5 cm to 10 cm; severe: >10 cm (for data reported from e-diaries).

**Table 7 Percentage of Participants 18 through 59 Years of Age at Increased Risk of LRTD caused by RSV with Systemic Reactions Reported, by Maximum Severity, within 7 Days after Vaccination – Study 4[a]**

| Systemic Reactions | ABRYSVO N=451[b] % | PLACEBO N=225[b] % |
|---|---|---|
| Fever (≥38.0°C) | | |
| ≥38.0°C | 1.6 | 1.3 |
| ≥38.0°C to 38.4°C | 0.4 | 0.4 |
| >38.4°C to 38.9°C | 1.1 | 0.9 |
| >38.9°C to 40.0°C | 0 | 0 |
| Fatigue[c] | | |
| Any[d] | 37.3 | 38.2 |
| Mild | 18.2 | 22.2 |
| Moderate | 18.2 | 15.6 |
| Severe | 0.9 | 0.4 |
| Headache[c] | | |
| Any[d] | 28.4 | 30.2 |
| Mild | 20.8 | 18.7 |

| Systemic Reactions | ABRYSVO N=451[b] % | PLACEBO N=225[b] % |
|---|---|---|
| Moderate | 7.3 | 11.6 |
| Severe | 0.2 | 0 |
| Muscle pain[c] | | |
| Any[d] | 24.4 | 16.0 |
| Mild | 15.7 | 9.8 |
| Moderate | 8.6 | 6.2 |
| Severe | 0 | 0 |
| Joint pain[c] | | |
| Any[d] | 12.4 | 10.2 |
| Mild | 7.1 | 4.0 |
| Moderate | 5.1 | 6.2 |
| Severe | 0.2 | 0 |
| Nausea[c] | | |
| Any[d] | 11.8 | 10.2 |
| Mild | 9.3 | 8.9 |
| Moderate | 2.4 | 0.9 |
| Severe | 0 | 0.4 |
| Vomiting[e] | | |
| Any[d] | 2.0 | 1.3 |
| Mild | 1.6 | 0.4 |
| Moderate | 0.4 | 0.9 |
| Severe | 0 | 0 |
| Diarrhea[f] | | |
| Any[d] | 14.9 | 16.9 |
| Mild | 11.1 | 12.4 |
| Moderate | 3.1 | 3.6 |
| Severe | 0.7 | 0.9 |

[a] NCT05842967

[b] N = number of participants reporting at least one response in the e-diary.

[c] Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily routine activity.

[d] Any includes all participants who reported a reaction as mild, moderate, or severe during Day 1 to Day 7 after vaccination.

[e] Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration.

[f] Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours.

Solicited local and systemic reactions had a median duration of 1-2 days.

*Unsolicited Adverse Events in Study 4*

Unsolicited adverse events occurring within 1 month after vaccination were reported in 7.1% and 7.6% of participants who received ABRYSVO and placebo, respectively. One case of urticaria occurred on the same day as vaccine administration and was considered related to ABRYSVO.

*Serious Adverse Events in Study 4*

In Study 4, SAEs were reported by 1.1% of participants in the ABRYSVO group and 3.1% in the placebo group. No SAEs were assessed as related to study vaccination.

### 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
Polysorbate 80
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

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.

Do not use **Abrysvo** after the expiry date which is stated on the carton /Vial label after EXP:. The expiry date refers to the last day of that month

## 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

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

Solvent
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
Sterile vial adaptor

Pack size
Pack containing 1 vial of powder, 1 pre-filled syringe of solvent, 1 vial adaptor with 1 needle or without needles.
Pack containing 5 vials of powder, 5 pre-filled syringes of solvent, 5 vial adaptors with 5 needles or without needles.
Pack containing 10 vials of powder, 10 pre-filled syringes of solvent, 10 vial adaptors with 10 needles or without needles.

Not all pack sizes may be marketed.

## 6.6 Special precautions for disposal and other 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.

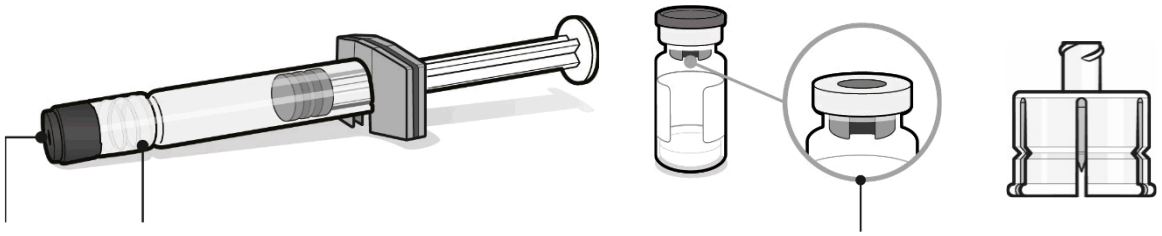
The vaccine must be reconstituted only with the solvent provided.

Preparation for administration

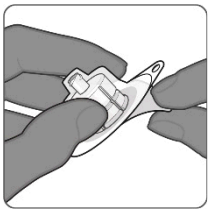
**Pre-filled syringe containing solvent for Abrysvo**

**Vial containing antigens for Abrysvo (powder)**

**Vial adaptor**

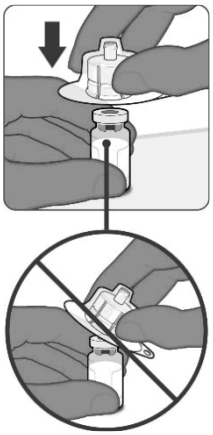


Syringe cap  Luer lock adaptor  Vial stopper (with flip off cap removed)



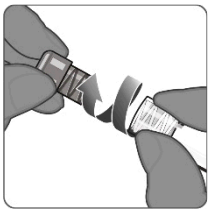
**Step 1. Prepare vial adaptor**

- Remove plastic flip off cap from vial and wipe the rubber stopper.
- Open the packaging containing the vial adaptor by peeling the top cover off.
- Do not remove the vial adaptor from its package.



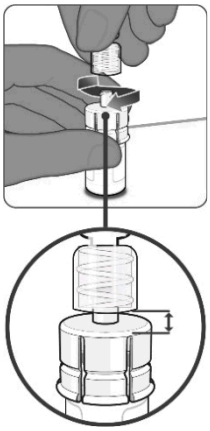
**Step 2. Attach the vial adaptor to the vial containing antigens for Abrysvo**

- Hold the base of the vial on a flat surface.
- Keep the vial adaptor in the packaging and orient it vertically over the centre of the vial so that the adaptor spike aligns with the centre of the vial's rubber stopper.
- Connect the vial adaptor to the vial with a straight downward push. The vial adaptor will lock into place.
- Do not push vial adaptor in at an angle as this may result in leaking during use.
- Remove the vial adaptor packaging.



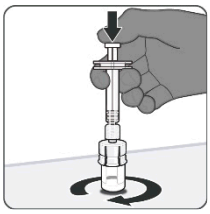
**Step 3. Remove syringe cap**

- For all syringe assembly steps, hold the syringe only by the Luer lock adaptor located at the tip of the syringe. This will prevent the Luer lock adaptor from detaching during use.
- Remove the syringe cap by slowly turning the cap anti-clockwise while holding the Luer lock adaptor.



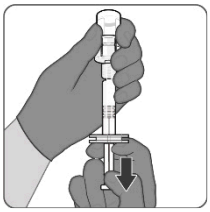
**Step 4. Connect syringe to the vial adaptor**

- Hold the syringe's Luer lock adaptor and connect it to the vial adaptor by turning clockwise.
- Stop turning when you feel resistance, overtightening the syringe may result in leaking during use.
- Once the syringe is securely attached to the vial adaptor, there will be a small space between the top of the vial adaptor and the Luer lock adaptor of the syringe.



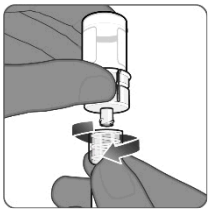
**Step 5. Inject solvent and gently swirl**

- Inject the entire contents of the syringe containing the solvent into the vial.
- Do not remove the empty syringe.
- While holding the plunger rod down, gently swirl the vial in a circular motion until the powder is completely dissolved (approximately 1-2 minutes).
- Do not shake.



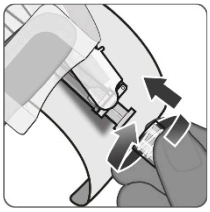
**Step 6. Withdraw the contents**

- Invert the vial completely with the vial adaptor and syringe still attached.
- Slowly withdraw the entire contents into the syringe.
- Drawing up all obtainable content ensures a complete 0.5 mL dose for administration.
- Do not pull the plunger rod out.



**Step 7. Disconnect syringe**

- Hold the Luer lock adaptor of the syringe and disconnect the syringe from the vial adaptor by turning anti-clockwise.



**Step 8. Attach needle**

- Attach a sterile needle suitable for intramuscular injection to the pre-filled syringe by turning clockwise.
- Do not overtighten the needle as this may result in leaking during use.

**Step 9. Visual inspection**

- 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.

Keep out of the sight and reach of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 7. FURTHER INFORMATION

**MARKETING AUTHORISATION HOLDER**
Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium

**Manufacturer, Primary & Secondary packager and batch releaser**
Pfizer Manufacturing Belgium NV
Rijksweg 12
2870 Puurs-Sint-Amands
Belgium.

## 8. DATE OF REVISION OF THE TEXT:

**October 2024**

**THIS IS A MEDICAMENT**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

**Keep all medicaments out of reach and sight of children**

**Council of Arab Health Ministers**
**Union of Arabic Pharmacists**