Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Abrysvo®

Powder and solvent for solution for injection

Each vial contains:
RSV stabilised prefusion F antigen (subgroup B) 60 mcg
RSV stabilised prefusion F antigen (subgroup A) 60 mcg

Each dose (0.5 ml) contains:
RSV subgroup B stabilised prefusion F antigen 60 mcg[1,2]
RSV subgroup A stabilised prefusion F antigen 60 mcg[1,2]
(RSV antigens)
[1]glycoprotein F stabilised in the prefusion conformation.
[2]produced in Chinese Hamster Ovary cells by recombinant DNA technology.

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

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

Therapeutic group: Viral vaccines.

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 does Abrysvo work?
Abrysvo is a vaccine administered to prevent lung (respiratory tract) disease caused by a virus called respiratory syncytial virus (RSV).

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 women who are vaccinated between weeks 24 and 36

of pregnancy, these antibodies pass through the placenta to the infant before birth, protecting infants when they are at most risk from RSV.

2. BEFORE USING THIS MEDICINE

Do not use this Abrysvo if:

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine (listed in section 6).

Special warnings regarding use of Abrysvo
Before you are given this vaccine, tell your doctor or nurse if:

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

If one or more of the above issues 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 vaccination may not fully protect all those who receive it.

Children and adolescents
Efficacy and safety have not been established in children below 18 years of age. There is limited information regarding pregnant adolescents.

Other medicines and Abrysvo
If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, or if you have recently received another vaccine, tell your doctor, pharmacist or nurse.

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

Pregnancy and breast-feeding
Data on pregnant women 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.
No side effects were reported in infants born to vaccinated mothers.
It is unknown whether Abrysvo is excreted in human milk. No side effects of Abrysvo have been observed in breast-fed newborns of vaccinated mothers.
Consult your doctor or nurse before getting this vaccine if you are breast-feeding.

Driving and using machines
Abrysvo has no or negligible influence on your ability to drive or use machines.

Important information about some of this medicine's ingredients
Abrysvo contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
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 TO USE THIS MEDICINE?

Always use this vaccine according to your doctor's instructions.
Check with your doctor or pharmacist if you are uncertain about the dosage and method of administration of the vaccine.
The dosage and method of administration of the vaccine will be determined by your doctor only.

The recommended dosage is usually one injection of 0.5 ml into the muscle of your upper arm.
The recommended dosage for pregnant women is one injection of 0.5 ml between weeks 24 and 36 of pregnancy.

Do not exceed the recommended dose.

If you received an overdose, it is unlikely that you will receive an overdose with Abrysvo, because you will receive one injection.
There is no specific treatment for an overdose with Abrysvo. In the event of an overdose, you should be monitored medically and provided with symptomatic treatment as appropriate.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Abrysvo may cause side effects in some users. Do not be alarmed by this list of side effects; You may not experience any of them.

Contact your doctor immediately if a serious side effect appears:

Very rare side effects (may occur in 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 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).

Contact your doctor immediately if one of these serious side effects occurs.

Additional side effects

The following side effects were reported in pregnant women

Very common side effects (may occur in more than 1 in 10 people):
- pain where the injection is given
- headache
- muscle pain

Common side effects (may occur in up to 1 in 10 people):
- redness where the injection is given
- swelling where the injection is given

Rare side effects (may occur in up to 1 in 1,000 people):
- allergic reactions such as rash or hives
- swollen glands (lymphadenopathy)

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

Very common side effects (may occur in more than 1 in 10 people):
- tiredness
- headache
- pain where the injection is given
- muscle pain

Common side effects (may occur in up to 1 in 10 people):
- joint pain
- redness where the injection is given
- swelling where the injection is given

Uncommon side effects (may occur in up to 1 in 100 people):
- fever

Rare side effects (may occur in up to 1 in 1,000 people):
- allergic reactions such as rash or hives
- swollen glands (lymphadenopathy)
- bruising where the injection is given
- itching where the injection is given

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

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link ‘Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C-8°C). See also the instructions below that are intended for healthcare professionals.
- Do not freeze. Discard if the carton has been frozen.
- After reconstitution Abrysvo should be used immediately or within 4 hours if stored between 15°C-30°C. Do not freeze. See also the instructions below that are intended for healthcare professionals.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

In the powder:
- mannitol
- sucrose
- sodium chloride
- tris (hydroxymethyl) aminomethane hydrochloride (Tris-HCl)
- tromethamine (Tris base)
- polysorbate 80

In the solvent:
- water for injections

What the medicine looks like and contents of the pack:
Abrysvo is marketed as a white powder in a glass vial and a solvent in a pre-filled syringe to dissolve the powder.
After dissolving the powder in the solvent, the solution is clear and colourless.

Abrysvo is marketed in a carton containing:
- 1 vial of powder, 1 pre-filled syringe, and 1 vial adaptor, with or without a needle (1 dose pack).
- 5 vials of powder, 5 pre-filled syringes, and 5 vial adaptors, with or without needles (5 dose pack).
- 10 vials of powder, 10 pre-filled syringes, and 10 vial adaptors, with or without needles (10 dose pack).

Not all pack sizes may be marketed.

Registration holder and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 177-81-37958

Revised in 10/2025.

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.

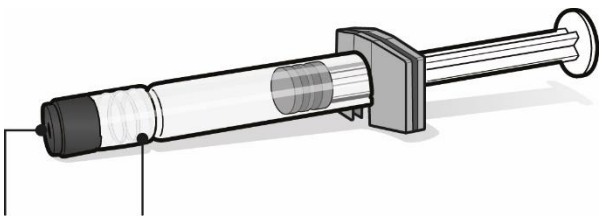
Chemical and physical in-use stability has been demonstrated for 4 hours between 15°C and 30°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

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.

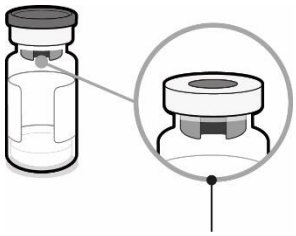
Pre-filled syringe containing solvent for Abrysvo



Syringe cap

Luer lock adaptor

Vial containing antigens for Abrysvo (powder)

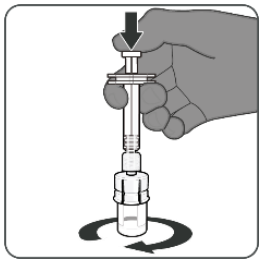


Vial stopper (with flip off cap removed)

Vial adaptor

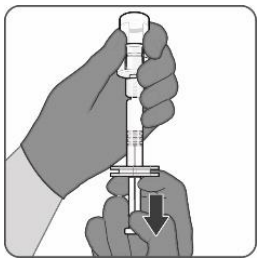
Step 1. Attach vial adaptor

- 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.

Disposal

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