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 60 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 28 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 28 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. 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 third trimester (weeks 28 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'.

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

Rare (may affect up to 1 in 1 000 people)

- 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).

Very rare (may affect up to 1 in 10 000 people)
- allergic reactions – signs of an allergic reaction include swelling of the face, lips, tongue or throat, hives, difficulty breathing or swallowing and dizziness. See also section 2.

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.

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

The following side effects were reported in individuals 60 years of age and older

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

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)
- Guillain-Barré syndrome (see Serious side effects, above).

Very rare (may affect up to 1 in 10 000 people)
- allergic reactions (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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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).

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
United Kingdom

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:
Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.
Telephone 01304 616161

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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.

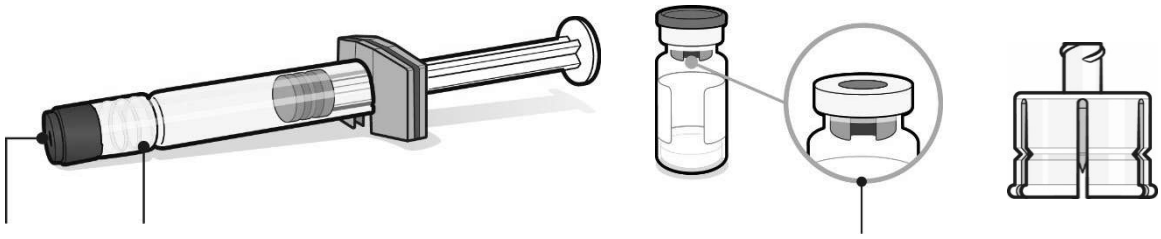
Chemical and physical in-use stability has been demonstrated for 4 hours between 15°C and 30°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

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**



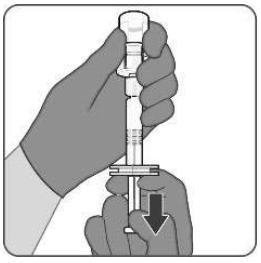
Syringe cap Luer lock adaptor Vial stopper (with flip-off cap removed)

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 (approximately 1-2 minutes). 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.