PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ABRYSVO 120 µg powder and solvent for solution for injection

Respiratory syncytial virus vaccine (bivalent, recombinant)

Each vial contains 11,3 mg sucrose and 22,5 mg mannitol

Read all of this leaflet carefully before you start using ABRYSVO

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What ABRYSVO is and what it is used for
2. What you need to know before you use ABRYSVO
3. How to use ABRYSVO
4. Possible side effects
5. How to store ABRYSVO
6. Contents of the pack and other information

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 use ABRYSVO

Do not use ABRYSVO

if you are allergic to the RSV antigens or any of the other ingredients of ABRYSVO (listed in section 6).

Warnings and precautions

Tell your doctor or health care provider before you are given ABRYSVO:

- 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 postponed.
- 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

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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 breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

Pregnant individuals can be given this vaccine in the late second or third trimester (weeks 28 to 36). Talk to your doctor or nurse for advice before getting this vaccine if you are breastfeeding.

Driving and using machines

It is not always possible to predict to what extent ABRYSVO may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ABRYSVO affects them.

ABRYSVO is unlikely to affect your ability to drive and 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

Do not share medicines prescribed for you with any other person.

Your doctor will tell you how long your treatment with ABRYSVO will last. If you have the impression that the effect of ABRYSVO is too strong or too weak, tell your doctor or pharmacist.

How ABRYSVO is given

You will be given one injection of 0,5 mL into a muscle of your upper arm.

If you receive more ABRYSVO than you should

Since a health care provider will administer ABRYSVO he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive the ABRYSVO vaccine

Since a health care provider will administer ABRYSVO, it is unlikely that the dose will be missed

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

4. Possible side effects

ABRYSVO can have side effects.

Not all side effects reported for ABRYSVO are included in this leaflet. Should your general health worsen or if you experience any untoward effects during or after receipt of ABRYSVO, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Side effects reported following administration of ABRYSVO in pregnant individuals < 49 years:

Frequent side effects:

- headache
- muscle pain (myalgia)

- pain at the injection site
- redness and swelling at the injection site (injection site reactions)

Side effects reported following administration of ABRYSVO in individuals > 60 years:

Frequent side effects:

- pain at the injection site
- redness and swelling at the injection site (injection site reactions)

Less frequent side effects:

- 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).
- 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.)

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ABRYSVO.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com.

5. How to store ABRYSVO

Store all medicines out of reach of children.

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

Store in a refrigerator (2 ºC – 8 ºC).

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 substance 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
- polysorbate 80
- 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 clear, colourless glass vial
- 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 available in:

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

Holder of Certificate of Registration

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