

## **Consumer Medicine Information (CMI) summary**

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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▼ This vaccine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

## **1. Why am I being given ABRYSVO?**

ABRYSVO is a vaccine given to prevent disease of the respiratory tract (airways and lungs) 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 or older.

ABRYSVO contains the active ingredient recombinant respiratory syncytial virus pre-fusion F protein.

For more information, see Section [1. Why am I being given ABRYSVO?](#) in the full CMI.

## **2. What should I know before I am given ABRYSSVO?**

You should not be given ABRYSSVO if you have ever had an allergic reaction to ABRYSSVO or any of the ingredients listed at the end of the CMI. Tell your healthcare professional if you have or have had an allergic reaction after being given any other vaccine in the past, bleeding problems, have an infection with a high fever, anxiety or fainting following any needle injections or a weakened immune system.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given ABRYSSVO?](#) in the full CMI.

## **3. What if I am taking other medicines?**

Tell your healthcare professional if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your healthcare professional if you have recently been given or plan to be given any other vaccine.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

## 4. How is ABRYSVO given?

- ABRYSVO will be given as a single dose injection into the muscle of your upper arm by a doctor, nurse or other trained healthcare professional.

More instructions can be found in Section [4. How is ABRYSVO given?](#) in the full CMI.

## 5. What should I know after being given ABRYSVO?

|                                    |  |
|------------------------------------|--|
| <b>Things you should do</b>        | <ul style="list-style-type: none"><li>• Check with your healthcare professional before you receive any other vaccines or take other medicines.</li></ul>   |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"><li>• ABRYSVO is unlikely to affect your ability to drive or use machines.</li></ul>   |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"><li>• ABRYSVO will normally be stored at the doctor's surgery or in the pharmacy.</li><li>• If you need to store ABRYSVO, store the carton in a refrigerator (2°C to 8°C) in the original package.</li></ul> |

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|--|---|
|  | <ul style="list-style-type: none"><li>• Do not freeze. Discard if the carton has been frozen.</li></ul> |
|--|---|

For more information, see Section [5. What should I know after being given ABRYSSVO?](#) in the full CMI.

## **6. Are there any side effects?**

Side effects of ABRYSSVO include: pain, swelling or redness in the area where the vaccine was given, muscle pain and headaches. Serious side effects include allergic reactions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This vaccine 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. You can report side effects to your doctor, or directly at [www.tga.gov.au/safety/reporting-problems](http://www.tga.gov.au/safety/reporting-problems).

## ABRYSVO®

**Active ingredient(s):** *recombinant respiratory syncytial virus pre-fusion F protein*

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using ABRYSVO. **You should also speak to your healthcare professional if you would like further information or if you have any concerns or questions about using ABRYSVO.**

**Where to find information in this leaflet:**

- [1. Why am I being given ABRYSVO?](#)
- [2. What should I know before I am given ABRYSVO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is ABRYSVO given?](#)
- [5. What should I know after being given ABRYSVO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I being given ABRYSSVO?**

**ABRYSSVO is a vaccine, which is a type of medicine that helps to protect (immunise) people from certain infectious diseases. It does this by preparing the body's defences to fight the infection before you catch the bacteria or virus.**

**ABRYSSVO is used to prevent disease of the respiratory tract (lungs) caused by a virus called respiratory syncytial virus (RSV).**

**ABRYSSVO contains a protein (antigen) from each of the two subgroups (A and B) of RSV.**

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, some individuals are at higher risk of respiratory disease caused by RSV. This includes young infants, older adults and those with chronic medical conditions such as heart or lung disease. In infants RSV can cause serious lung problems such as bronchiolitis and pneumonia. In older adults it can make existing conditions such as chronic obstructive pulmonary disease (COPD) and congestive heart failure (CHF) worse. It can lead to hospitalisation in severe cases, and in some cases it can be fatal.

ABRYSSVO is given to:

- pregnant individuals to protect their infants from birth through 6 months of age, or
- individuals 60 years of age or older.

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

## **2. What should I know before I am given ABRYSVO?**

### **Warnings**

#### **Do not use ABRYSVO if:**

- you are allergic to ABRYSVO or any of the ingredients listed at the end of this leaflet

#### **Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition
- 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.

- have any bleeding problems or disorders, or bruise easily
- are feeling nervous about the vaccination process or have ever fainted following any needle injection
- have a weakened immune system which may prevent you from getting the full benefit from ABRYSVO
- are less than 24 weeks pregnant
- are less than 18 years of age

During vaccination, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this vaccine.

Pregnant individuals can be given this vaccine in the late second or third trimester (weeks 24 to 36).

It is unknown whether ABRYSV0 is excreted into breast milk.

## **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your healthcare professional if you have recently been given or plan to be given any other vaccine.

## **4. How is ABRYSV0 given?**

### **How many injections will be given**

**For the vaccination of pregnant individuals to protect their infants**



- One single dose is given in the late second or third trimester of pregnancy (24 - 36 weeks).

### **For the vaccination of adults aged 60 years or over**

- One single dose is given.

## **Multiple vaccinations**

If ABRYSVO is given at the same time as another vaccine, a different injection site will be used for each injection.

## **If you are given too much ABRYSVO**

Overdose is unlikely as ABRYSVO is available in a single dose presentation and will be given by a trained healthcare professional.

## **5. What should I know after being given ABRYSVO?**

### **Things you should do**

Check with your healthcare professional before you receive any other vaccines or take other medicines.

### **Driving or using machines**

ABRYSVO is unlikely to affect your ability to drive or use machines.

## **Looking after your medicine**

- ABRYSVO will normally be stored at the doctor's surgery or in the pharmacy.
- If you need to store ABRYSVO, store the carton in a refrigerator (2°C to 8°C) in the original package.
- Do not freeze. Discard if the carton has been frozen.

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

Your healthcare professional will dispose of any unused vaccine.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your healthcare professional if you have any further questions about side effects.

## Side effects

| Side effects   | What to do   |
|--|--|
| <p><b>Injection site reactions:</b></p> <ul style="list-style-type: none"> <li>• Pain, redness or swelling around the area where the injection was given.</li> </ul> <p><b>Effects on the body:</b></p> <ul style="list-style-type: none"> <li>• Muscle pain</li> <li>• Headaches</li> <li>• Mild tingling in the toes or fingers that doesn't seem to spread or get worse.</li> <li>• Lumps or bumps under the skin, particularly in the neck, armpits or groin (where your upper thighs meet your abdomen), which may be symptoms of swollen lymph nodes.</li> </ul> | <p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>                             |
| <p><b>Allergic reactions:</b></p> <ul style="list-style-type: none"> <li>• Allergic reaction such as rash, itching or hives on the skin, swelling of the face, lips, tongue or</li> </ul>  | <p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</b></p> |

| Side effects   | What to do  |
|--|---|
| <p>other parts of the body, shortness of breath or trouble breathing</p> <p><b>Effects on the body:</b></p> <ul style="list-style-type: none"> <li>• Tingling or weakness, usually starting in the legs then spreading up your body</li> <li>• Difficulty walking or climbing stairs</li> <li>• Difficulty with facial movements, including speaking, chewing or swallowing; choking on saliva</li> <li>• Double vision or inability to move the eyes</li> <li>• Severe pain that may feel like aches, shooting pain or cramps that may be worse at night</li> <li>• Difficulty breathing or shortness of breath when lying flat</li> <li>• Lumps or bumps under the skin that are painful, particularly in the neck, armpits or groin,</li> </ul> | <p><b>notice any of these serious side effects.</b></p> |

| Side effects  | What to do |
|---|------------|
| <p>together with fever, sore throat or weight loss</p> <p><b>Effects on the heart:</b></p> <ul style="list-style-type: none"> <li>• Rapid heart rate</li> <li>• Low or high blood pressure</li> </ul> |            |

**Tell your healthcare professional if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/safety/reporting-problems](http://www.tga.gov.au/safety/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is only available with a doctor's prescription.

### What ABRYSVO contains

|                           |                |
|---------------------------|----------------|
| <b>Active ingredients</b> | <b>Powder:</b> |
|---------------------------|----------------|

|   |   |
|---|---|
| <b>(main ingredients)</b>                           | RSV subgroup A stabilised<br>pre-fusion F protein<br><br>RSV subgroup B stabilised<br>pre-fusion F protein  |
| <b>Other ingredients<br/>(inactive ingredients)</b> | <b>Powder:</b><br>trometamol<br>trometamol hydrochloride<br>sucrose<br>mannitol<br>polysorbate 80<br>sodium chloride<br><b>Diluent:</b><br>water for injections |
| <b>Potential allergens</b>                          | n/a   |

**Do not use this medicine if you are allergic to any of these ingredients.**

ABRYSVO does not contain lactose, gluten, tartrazine or any other azo dyes.

## **What ABRYSVO looks like**

ABRYSVO is supplied as:

- a white powder in a glass vial, plus
- a diluent in a pre-filled syringe to dissolve the powder

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

ABRYSVO is supplied in cartons containing:

- 1 vial of powder for injection, 1 pre-filled syringe of diluent and 1 vial adapter
- 10 vials of powder for injection, 10 pre-filled syringes of diluent and 10 vial adapters

(AUST R 406624)

## **Who distributes ABRYSVO**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

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