PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ABRYSVO®

(Respiratory Syncytial Virus Stabilized Prefusion F Subunit Vaccine)

Lyophilized powder for solution for Intramuscular Injection

Read this carefully before you receive **Abrysvo**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Abrysvo**.

What is Abrysvo used for?

Abrysvo is a vaccine to prevent disease of the respiratory tract (lung) caused by a virus called respiratory syncytial virus (RSV). Abrysvo is given to:

- pregnant individuals (32 – 36 week gestation) to protect their infants from birth through 6 months of age;
- individuals 60 years of age and older;
- individuals 18-59 years of age who are at increased risk for LRTD caused by RSV.

How does Abrysvo work?

The vaccine works by helping the body to make antibodies (substances your body uses to fight an infection) which protect against this disease. In pregnant individuals, these antibodies are passed to the infant through the placenta before birth which protects infants after birth when they are at most risk from RSV.

What are the ingredients in Abrysvo?

Medicinal ingredients: One dose (0.5 mL) contains the following active substances:

- RSV subgroup A stabilized prefusion F protein: 60 micrograms
- RSV subgroup B stabilized prefusion F protein: 60 micrograms

Non-medicinal ingredients: Mannitol, polysorbate 80, sodium chloride, sucrose, tromethamine, trometamol hydrochloride, sterile water for injection.

Abrysvo comes in the following dosage forms:

White powder for solution.

Do not use Abrysvo if:

- you are allergic (hypersensitive) to the active substances or to any of the other ingredients in this vaccine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive Abrysvo. Talk about any health conditions or problems you may have, including if you:

- have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given Abrysvo in the past.

- have a bleeding problem or bruise easily.
- 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.
- 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 32 weeks pregnant. Pregnant individuals can be given this vaccine in the third trimester (from 32 through 36 weeks gestation). Abrysvo is not recommended in children and adolescents below 18 years, except in pregnancy.

Other warnings you should know about:

As with any vaccine, Abrysvo will not protect all persons who are vaccinated.

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

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Tell your healthcare professional if you have recently received any other vaccine.

How Abrysvo is given:

A healthcare professional will inject the recommended dose (0.5 mL) of the vaccine into your arm.

If you have any further questions on the use of Abrysvo, ask your healthcare professional.

Usual dose:

Individuals 18 years of age and older:

You should receive one injection (0.5 mL dose) of the vaccine.

Pregnant individuals:

You should receive one injection (0.5 mL dose) of the vaccine in the third trimester of pregnancy (from 32 through 36 weeks gestation).

Overdose:

Overdose with Abrysvo is unlikely as it is administered as a single-dose presentation.

If you think you, or a person you are caring for, have received too much Abrysvo, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using Abrysvo?

Fainting, feeling faint, or other stress-related reactions can occur as a response to any needle injection.

Like all vaccines, Abrysvo can cause side effects, although not everybody gets them.

The following side effects include those reported for Abrysvo in pregnant individuals:

Very common: may affect more than 1 in 10 people

- pain where the injection is given

- headache
- muscle pain.

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.

These are not all the possible side effects you may have when receiving Abrysvo. If you experience any side effects not listed here, tell your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY RARE			
Allergic reactions: swelling of the face, lips, tongue or throat, hives, difficulty breathing or swallowing, dizziness which are signs and symptoms of hypersensitivity reactions.		X	
Guillain-Barré syndrome, a neurological disorder that usually has weakness of the limbs and may progress up to paralysis of part or all of the body.		X	

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Pfizer Canada ULC cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php) and send it to your local Health Unit.

Storage:

Store the unreconstituted vaccine in a refrigerator (2°C to 8°C). Abrysvo should be used as soon as possible after being removed from refrigeration.

Do not freeze. Discard if carton has been frozen.

The unopened vial of vaccine 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 (within 4 hours) after reconstitution. Store the reconstituted vaccine between 15°C and 30°C.

Do not freeze. Discard if vaccine has been frozen.

Keep out of reach and sight of children.

Do not use this vaccine 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.

If you want more information about Abrysvo:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.pfizer.ca, or by calling 1-800-463-6001.

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