

For the 2mL ampule Ventavis is supplied in cartons of 30 clear glass single-use ampules (20 mcg iloprost per 2mL ampule):

30 single-use ampule cartons: NDC 10148-101-30

For the 1 mL ampule Ventavis is supplied in cartons of 30 clear glass single-use ampules (10 mcg iloprost per 1mL ampule):

30 single-use ampule cartons: NDC 66215-302-30

STORAGE

Store at 20 – 25°C (68 – 77°F)

Excursions permitted to 15 – 30°C (59 – 86°F)

[See USP Controlled Room Temperature]

Distributed by:

Actelion Pharmaceuticals US, Inc.
5000 Shoreline Court, Ste. 101

South San Francisco, CA 94080

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PATIENT INFORMATION

Ventavis® (ven TAY vis) Inhalation Solution (iloprost)

Read the Patient Information that comes with Ventavis before you start using it and each time you get a refill. There may be new information. The leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT VENTAVIS?

Ventavis may cause dizziness, lightheadedness, and fainting (syncope) because it lowers your blood pressure. These are also common symptoms of pulmonary arterial

hypertension (PAH).

- To reduce your chances of fainting, stand up slowly when you get out of chairs or bed.
- Use Ventavis before increased physical exertion.
- Tell your doctor if fainting gets worse with Ventavis. Your doctor may need to adjust your dose or change your treatment.

Do not drive a car or operate any tools or machines if dizziness or fainting from low blood pressure is a problem for you.

WHAT IS VENTAVIS?

Ventavis is a prescription medicine for adults with certain kinds of severe PAH. It is used to improve exercise ability and symptoms for a short time. PAH is a condition where blood pressure is too high in the blood vessels between the heart and the lungs.

Ventavis has not been studied in children under the age of 18.

HOW DOES VENTAVIS WORK?

Ventavis lowers blood pressure within the pulmonary arteries by opening up the blood vessels in the lungs.

WHAT SHOULD I TELL MY DOCTOR BEFORE STARTING VENTAVIS?

Tell your doctor about all of your medical conditions including if you:

- **have liver or kidney problems.** Your doctor may need to give you a lower dose of Ventavis.
- **are pregnant, or planning to become pregnant.** It is not known if Ventavis can harm your unborn baby. Ventavis should be used during pregnancy only if clearly needed. Women who can get pregnant should use effective birth control during treatment with Ventavis. Talk to your doctor about effective birth control methods.
- **are breast-feeding. It is not known if Ventavis passes into your milk.** Talk to your doctor about the best way to feed your baby while using Ventavis.

Tell your doctor about all the medicines you are taking including prescription and nonprescription medicines, vitamins, and herbal supplements. Ventavis and certain other medicines may affect each other in the way they work in your body. Be sure to tell your doctor if you take:

- medicines used to treat high blood pressure or heart disease
- medicines that decrease blood clotting

Keep a list of all the medicines you take. Show this list to your doctor and pharmacist each time you get a new medicine.

HOW SHOULD I TAKE VENTAVIS?

See the end of this leaflet for instructions for using Ventavis with the Prodose[®] AAD[®] System or I-neb[™] AAD[®] System.

- **Take Ventavis exactly as prescribed by your doctor.** Ventavis is usually used 6 to 9 times a day during waking hours. Your doctor will tell you how to space your doses. You should take Ventavis when you wake up and also before any physical activity, but not more frequently than every 2 hours. Do not change your dose without talking to your doctor.
- Ventavis is breathed (inhaled) into your lungs with the help of the Prodose[®] AAD[®] System or I-neb[™] AAD[®] System. One treatment session will usually last about 4 to 10 minutes.
- **Do not drink Ventavis.**
- **Do not let Ventavis solution come into contact with your skin or eyes.** If it does, rinse the skin or your eyes right away with water.
- If you take too much Ventavis, you may get a severe headache, chest pain, reddening of the face, jaw pain, dizziness, nausea, vomiting and diarrhea. If this happens stop taking Ventavis. If symptoms persist, call your doctor.
- Do not allow other people to be exposed to Ventavis while you are breathing it, especially babies and pregnant women.

WHAT ARE THE SIDE EFFECTS WITH VENTAVIS?

Ventavis may cause dizziness, lightheadness, and fainting (syncope) because it lowers your blood pressure. See “What is the most important information I should know about Ventavis?”

The most common side effects with Ventavis include reddening of the face caused by dilation of blood vessels (flushing), increased cough, low blood pressure (hypotension), headaches, nausea, spasm of the jaw muscles that causes trouble opening your mouth, and fainting (syncope).

Talk to your doctor about any side effect that bothers you or that does not go away.

These are not all of the side effects with Ventavis. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA 1088.

HOW SHOULD I STORE VENTAVIS?

- Store Ventavis ampules at **68 to 77°F (20 to 25°C)**.
- Safely dispose of Ventavis that is out of date or no longer needed.
- **Keep Ventavis and all medicines out of the reach of children.**

GENERAL INFORMATION ABOUT VENTAVIS

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use Ventavis for a condition for which it was not prescribed. Do not give Ventavis to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about Ventavis. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Ventavis that was written for healthcare professionals. Additional information can be found at **www.4VENTAVIS.com** or by calling 1-877-4VENTAVIS (1-877-483-6828).

WHAT ARE THE INGREDIENTS IN VENTAVIS?

Active ingredient: iloprost. Each ampule contains 10 micrograms per mL of iloprost. 2 mL ampules contain 20 micrograms of iloprost and 1 mL ampules contain 10 micrograms of iloprost.

Inactive ingredients: tromethamine, ethanol, sodium chloride, hydrochloric acid for pH adjustment, and water for injection.

INSTRUCTIONS FOR USING VENTAVIS WITH THE PRODOSE[®] AAD[®] SYSTEM OR THE I-NEB[™] AAD[®] SYSTEM

Do not use Ventavis until your doctor or other healthcare provider has trained you on how to use the Prodose[®] AAD[®] System or the I-neb[™] AAD[®] System. Make sure you understand all the instructions or ask questions until you do.

Ventavis should only be taken using the Prodose[®] AAD[®] System or the I-neb[™] AAD[®] System. The Prodose[®] AAD[®] System or the I-neb[™] AAD[®] System has been made to deliver the right dose of Ventavis. Using other devices is not recommended and other devices may not deliver the prescribed amount of Ventavis.

If you are using the Prodose[®] AAD[®] System, your doctor will give you 2 dosing discs for your Prodose[®] AAD[®] System. These dosing discs will control the amount of Ventavis you use. **Do not change the dosing disc in your Prodose[®] AAD[®] System without talking to your doctor. Always use the entire contents of a 2 mL ampule when using your Prodose[®] AAD[®] System.** Using less than the 2 mL of liquid may not

provide you with enough medication.

If you are using the I-neb™ AAD® System, your doctor will give you two medication chambers (one with a red latch and one with a purple latch) and two color matching control discs. The medication chamber controls the amount of Ventavis you use. The medication chamber with the red latch delivers the 2.5 microgram dose and the medication chamber with the purple latch delivers the 5.0 microgram dose. The matching control disc operates the I-neb™ AAD® System. The red control disc should be used with the red- latched medication chamber, and the purple control disc should be used with the purple-latched medication chamber. **Do not change the medication chamber and control disc in your I-neb™ AAD® System without talking to your doctor.**

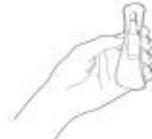
Do not put any medicines other than Ventavis in your Prodose® AAD® System or I-neb™ AAD® System.

TO USE VENTAVIS:

1. Open the small glass bottle (ampule) of Ventavis by:
 - holding the ampule with the blue dot facing away from your body



- wrapping the included rubber pad around the ampule to protect from getting cut



- using your thumbs to break open the neck of the ampule by snapping the top towards you



2. Using the small tube (pipette) that comes with Ventavis, draw-up the entire amount of one ampule of Ventavis and empty it into the center of the Prodose® AAD® System or the I-neb™ AAD® System medicine chamber. The amount of Ventavis you receive will be controlled by either the dosing disc or the medication chamber that has been prescribed for you.



3. Safely dispose of the open ampule and pipette as instructed by your healthcare practitioner. Keep both out of the reach of children.



4. Follow the instructions that come with your Prodose[®] AAD[®] System or I-neb[™] AAD[®] System for using it to breathe in your dose of Ventavis. Each treatment session with Ventavis lasts about 4 to 10 minutes. The Prodose[®] AAD[®] System or I-neb[™] AAD[®] System allows you to interrupt your treatment for up to ten minutes with no effect on the final dose you receive. If your treatment is interrupted for more than ten minutes, the Prodose[®] AAD[®] System or I-neb[™] AAD[®] System will reset itself. In such cases, **you should discard the remaining solution in the chamber and wait at least two hours before taking your next dose. Taking a second dose immediately could result in receiving too much medication.**
5. After each treatment dispose of any Ventavis that is left in the Prodose[®] AAD[®] System or the I-neb[™] AAD[®] System medicine chamber. Use of the remainder of Ventavis will not give you the right dose.
6. Follow the instructions that come with the Prodose[®] AAD[®] System or the I-neb[™] AAD[®] System for cleaning it after each treatment.
7. Make sure you have a back-up Prodose[®] AAD[®] System or I-neb[™] AAD[®] System to use for Ventavis treatments. This is especially important if your original Prodose[®] AAD[®] System or I-neb[™] AAD[®] System does not work for some reason.

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