Iloprost (Ventavis®)

Issued by PHA's Scientific Leadership Council
Information is based on the United States Food and Drug Administration drug labeling
Last Updated November 2013

WHAT IS ILOPROST?

Iloprost is an inhaled medication approved for the treatment of pulmonary arterial hypertension (PAH) in World Health Organization (WHO) Group 1 patients. Iloprost is a synthetic analogue of prostacyclin, a naturally occurring substance in the body, which has effects on dilating blood vessels. Iloprost is administered through a special device called the I-neb Delivery (AAD) System. Iloprost was approved for PAH by the United States Food and Drug Administration (FDA) in 2004.

HOW DOES ILOPROST WORK?

Iloprost works by direct dilation of narrowed blood vessels (arteries) in the lungs. Relaxing and widening of the blood vessels in the lungs decreases the pulmonary blood pressure to the heart and improves its function. This reduces blood pressure in the lungs which generally results in the ability to be more active.

HOW IS ILOPROST GIVEN?

Iloprost is inhaled through the mouth through a special device: the I-neb® AAD® System (a device which delivers medication to your lungs). The device is compact, portable and lightweight.

The I-neb AAD System is small—about 6 inches by 2 inches—and it has an internal rechargeable battery so the medication can be taken almost anywhere at any time. Iloprost should be inhaled as prescribed by a physician, usually 6-9 times a day, but not more often than every 2 hours. If a treatment session is missed or interrupted, therapy should be resumed as soon as possible at the usual dose.

HOW IS ILOPROST SUPPLIED?

Iloprost comes in 1 mL small vials that can be stored at room temperature.

There are 2 concentrations: 10 mcg/mL and 20 mcg/mL.

The delivered dose varies as in the table below.

	Lower Concentration	Higher Concentration
Nebulizer	10 mcg/mL	20 mcg/mL
I-neb® AAD®	2.5 mcg or 5.0 mcg from 1 ampule	5.0 mcg from 1 ampule

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For each inhalation session, the entire contents of each opened ampule should be transferred into the I-neb® AAD® System medication chamber immediately before use.

The 20 mcg/mL solution may be inhaled in half the time that it takes to inhale the 10 mcg/ml concentration. Patient's physicians will decide which dose is right for them.

HOW CAN A PATIENT OBTAIN ILOPROST?

Iloprost is a limited distribution medication which means it cannot be purchased at a local pharmacy. It must be prescribed by a physician and insurance approval must be obtained prior to starting therapy. Once approved by insurance, iloprost is then sent directly to patients by either of two specialty pharmacies: Accredo Health Inc. or CVS Caremark.

A specialty pharmacy works with the patient to train them on the I-neb AAD—the device used to take iloprost.

WILL INSURANCE PAY FOR ILOPROST?

It is expected that most health insurance plans will pay part of the cost of this medication. However, some plans still leave patients with a high out-of-pocket responsibility.

Depending on your insurance type, you may be eligible for assistance from the company that manufactures your therapy or from a non-profit charitable assistance organization. For more information visit www.PHAssociation.org/Help or call 301-565-3004.

WHAT ARE FREQUENT SIDE EFFECTS OF ILOPROST?

The most common side effects of iloprost include:

- Flushing of the skin
- Increased cough
- Low blood pressure
- Headaches
- Nausea
- Jaw pain
- Passing out

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Iloprost may cause side effects including feeling dizzy, lightheaded and passing out. If you have any of these side effects, you should stand up slowly when you get out of chairs or bed. Tell your doctor if your passing out gets worse during treatment with iloprost. Your doctor may need to change your dose or treatment.

Do not drive a car or operate any tools or machines if dizziness or passing out from low blood pressure is a problem for you. You may have trouble breathing after taking iloprost, because it may cause the muscles around your airway to tighten (bronchospasm). Get emergency help right away if you have trouble breathing.

HOW ARE SIDE EFFECTS OF ILOPROST MONITORED?

Vital signs should be monitored while initiating iloprost. Iloprost should generally be avoided if the systemic systolic blood pressure is below 85 mmHg.

Iloprost has not been evaluated in pregnant women or women who are breastfeeding. It should be used in pregnant or nursing mothers only if the potential benefit justifies the risk to the fetus or infant.

Safety and efficacy in pediatric patients has not been established, and this drug should not be used in patients under 18 years of age.

Clinical studies did not include a sufficient number of patients over age 65 to determine either safety or efficacy.

Iloprost has not been evaluated in patients with impaired liver function; however, consideration should be given to increasing the dosing interval (e.g. 3 – 4 hours between doses) in patients with moderate to severe liver impairment.

Iloprost has not been evaluated in patients with impaired kidney function. Likewise, the effect of dialysis is unknown.

COULD A PATIENT BE ALLERGIC TO ILOPROST?

This is possible, but unlikely.

WHAT ARE IMPORTANT DRUG INTERACTIONS WITH ILOPROST? (PLEASE SEE PACKAGE INSERT FOR FULL DETAILS)

There is potential risk when iloprost is used with medicines used to treat systemic high blood pressure or heart problems of low systemic blood pressure and passing out. Iloprost has the potential to increase risk of bleeding, particularly in patients maintained on blood thinners (e.g. heparin, warfarin, clopidogrel, dabigantran). Patients should discuss with the medications (including over the counter and herbal preparations) they are currently taking with their physician so that any potential or known drug to drug interactions can be avoided.