Treprostinil Inhaled (Tyvaso®)

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 INHALED TREPROSTINIL?

Inhaled treprostinil is an inhaled medication approved for the treatment of pulmonary arterial hypertension in World Health Organization (WHO) Group 1 patients. Inhaled treprostinil is a synthetic analogue of prostacyclin, a naturally occurring substance in the body, which has effects on dilating blood vessels.

Inhaled treprostenil was approved for PAH by the United States Food and Drug Administration (FDA) in 2009.

HOW DOES INHALED TREPROSTINIL WORK?

Inhaled treprostinil works by direct dilation of narrowed blood vessels (arteries) in the lungs. It may also inhibit platelets from aggregating (clumping together). 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 INHALED TREPROSTINIL GIVEN?

The medication is inhaled using the Tyvaso Inhalation System which consists of the Optineb-ir Model ON-100/7 (an ultrasonic, pulsed delivery device that delivers medication to your lungs).

Inhaled treprostinil is dosed in 4 separate, equally-spaced treatment sessions during the day (i.e. during waking hours). The treatment sessions should be approximately 4 hours apart.

Therapy should begin with 3 breaths of inhaled treprostinil per treatment session. Dosing is increased by an additional 3 breaths generally at 1 – 2 week intervals until a target (maximum) dose of 9 breaths per session is reached. If a treatment session is missed or interrupted, therapy should be resumed as soon as possible at the usual dose.

HOW IS INHALED TREPROSTINIL SUPPLIED?

Inhaled treprostinil comes in small vials containing 1.74 mg treprostinil (0.6 mg per mL). Inhaled treprostinil system starter and refill kits contain 28 vials packaged as 7 foil pouches each containing four 2.9 mL vials.

Vials of inhaled treprostinil are stable when stored in the unopened foil pouch at room temperature. Once the foil pouch has been opened, the vial should be used within 7 days.

Treprostenil Inhaled (Tyvaso®)

Continued

HOW CAN A PATIENT OBTAIN INHALED TREPROSTINIL?

Inhaled treprostinil 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, inhaled treprostinil is then sent directly to patients by one of the following specialty pharmacies: Accredo Health Group, Inc., Curascript, or CVS Caremark.

WILL INSURANCE PAY FOR INHALED TREPROSTINIL?

It is expected that most insurance plans will pay for inhaled treprostinil prescriptions; however, plans with a set co-payment may result in additional cost to the patient.

Medicaid and most state-run insurance plans will pay for inhaled treprostinil. Medicare will also cover inhaled treprostinil in most cases under Part D.

There are a number of patient assistance program options to cover either partial or full drug costs for any patient providing evidence of adequate financial need. To find the most appropriate program, United Therapeutics® has created ASSIST (877-864-8437). Caring Voice Coalition (888-267-1440), an organization that provides grants to assist with drug cost for patients with chronic illnesses, may also provide coverage if the patient proves a need for such assistance.

WHAT ARE THE SIDE EFFECTS OF INHALED TREPROSTINIL?

The most common side effects include:

- Increased cough and throat irritation
- Headache
- Gastrointestinal effects (e.g. nausea)
- Muscle, jaw or bone pain
- Flushing of the skin
- Passing out.

Other side effects may include:

- Decreased systemic blood pressure
- Nosebleed
- Coughing up blood
- Wheezing

Inhaled treprostinil solution can also irritate the eyes and skin. If inhaled treprostinil comes in contact with the skin or eyes, rinse immediately with water.

Treprostenil Inhaled (Tyvaso®)

Continued

HOW ARE SIDE EFFECTS OF INHALED TREPROSTINIL MONITORED?

Blood pressure should be monitored frequently due to the blood-pressure-lowering effect of the drug.

WHAT ARE CONSIDERATIONS FOR USE OF INHALED TREPROSTINIL IN SPECIAL POPULATIONS?

There are no adequate, well-controlled studies of the potential effect of inhaled treprostinil in either pregnant humans or animals. In pregnant rabbits, studies of continuous subcutaneous infusions (under the skin) of treprostinil sodium, using doses higher than normally used in humans, has been shown to cause damage to the fetus.

It is not known whether inhaled treprostinil is excreted in breast milk of nursing mothers.

Inhaled treprostinil 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.

Inhaled treprostinil has not been evaluated in patients with impaired liver function; however, plasma clearance of treprostinil when administered by subcutaneous infusion is reduced by up to 80 percent in patients with mild-to-moderate liver impairment.

Inhaled treprostinil has not been evaluated in patients with impaired kidney function. Since treprostinil is mainly excreted through the kidney, reduced drug clearance may potentially increase dose-related adverse effects.

COULD A PATIENT BE ALLERGIC TO INHALED TREPROSTINIL?

This is possible, but unlikely.

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

There is potential risk when inhaled treprostinil is used with medicines used to treat systemic high blood pressure or heart problems of low systemic blood pressure and passing out.

Inhaled treprostinil has the potential to increase risk of bleeding, particularly in patients maintained on blood thinners (e.g. heparin, warfarin, clopidogrel, dabigatran).

No pharmacokinetic interactions have been observed in human studies of co-administration of treprostinil with either bosentan or sildenafil.

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.