

PATIENT INFORMATION

Tyvaso (Tī-vāsō) (treprostinil) inhalation solution

What is Tyvaso?

Tyvaso is a prescription medicine used in adults to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs.

Tyvaso can improve the ability to exercise. Your ability to exercise decreases 4 hours after treatment with Tyvaso.

It is not known if Tyvaso is safe and effective in children under 18 years of age.

Before taking Tyvaso, tell your healthcare provider about all of your medical conditions, including if you:

- have lung disease, such as asthma or chronic obstructive pulmonary disease (COPD)
- have a lung infection
- have liver problems or kidney problems
- have low blood pressure
- have bleeding problems
- are pregnant or plan to become pregnant. It is not known if Tyvaso will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Tyvaso passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with Tyvaso.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tyvaso and other medicines may affect each other.

Especially tell your healthcare provider if you take:

- medicines used to treat high blood pressure or heart disease
- medicines that decrease blood clotting (anticoagulants)
- water pills (diuretics)
- gemfibrozil (Lopid)
- rifampin (Rimactane, Rifadin, Rifamate, Rifater)

Know the medicines you take. Keep a list of them and show it to your healthcare provider and specialty pharmacist when you get a new medicine.

How should I take Tyvaso?

- **See the detailed “Instructions for Use Manual” that comes with your Tyvaso Inhalation System for instructions on how to take Tyvaso the right way.**
- Tyvaso must be used only with the Tyvaso Inhalation System.
- Do not mix Tyvaso with other medicines in the Tyvaso Inhalation System.
- Take Tyvaso exactly as your healthcare provider tells you to. Your healthcare provider may change your dose if needed.
- Do not swallow Tyvaso inhalation solution.
- Tyvaso is breathed in (inhaled) through your mouth into your lungs. Tyvaso is taken in 4 separate treatment sessions every day during waking hours. The sessions should be at about 4 hours apart.
- Each treatment session will take 2 to 3 minutes.
- Avoid getting Tyvaso solution in your eyes or onto your skin. If you get Tyvaso in your eyes or on your skin, rinse your skin or eyes right away with water.
- If you miss a dose of Tyvaso, take your usual dose as soon as possible.
- If you take too much Tyvaso, call your healthcare provider or go to the nearest hospital emergency room right away.
- To avoid a possible delay in your Tyvaso treatment, you should always have access to a back-up Tyvaso Inhalation System device.

What are the possible side effects of Tyvaso?**Tyvaso can cause serious side effects, including:**

- **Low blood pressure (symptomatic hypotension).** If you have low blood pressure, Tyvaso may lower your blood pressure more.
- **Bleeding problems.** Tyvaso may increase the risk of bleeding in people who take blood thinners (anticoagulants).

The most common side effects of Tyvaso include:

- cough
- headache
- nausea
- reddening of your face and neck (flushing)
- dizziness
- diarrhea
- throat irritation and pain
- fainting or loss of consciousness

These are not all the possible side effects of Tyvaso.

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

How should I store Tyvaso?

- Store at 25°C (77°F), with excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
- Store Tyvaso ampules in the unopened foil pouch and out of the light until you are ready to use them.
- If unopened and stored in the foil pouch, Tyvaso ampules can be used until the expiration date printed on the pouch. Do not use Tyvaso ampules past the expiration date printed on the pouch.
- Tyvaso ampules should be used within 7 days after opening the foil pouch.
- Tyvaso can be kept in the Tyvaso Inhalation System medicine cup for no more than 1 day. Throw away any remaining Tyvaso that is left in the medicine cup at the end of the day.

Keep Tyvaso and all medicines out of the reach of children.**General information about the safe and effective use of Tyvaso.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Tyvaso for a condition for which it was not prescribed. Do not give Tyvaso to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or specialty pharmacist for information about Tyvaso that is written for health professionals.

What are the ingredients in Tyvaso?

Active ingredient: treprostinil

Inactive ingredients: sodium chloride, sodium citrate, sodium hydroxide, hydrochloric acid, and water for injection

Manufactured by: United Therapeutics Corp., Research Triangle Park, NC 27709 USA

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For more information, go to www.tyvaso.com or call 1-877-864-8437.