



Tyvaso Starter Guide

For the treatment of pulmonary arterial hypertension (WHO Group 1). Tyvaso can improve the ability to exercise in people who also take bosentan (an ERA) or sildenafil (a PDE-5 inhibitor).

Please see Important Safety Information on pages 15-16.

Refer to the Full Prescribing Information in pocket, and see Patient Package Insert and the Tyvaso Inhalation System Instructions for Use manual at tyvaso.com.

TYVASO®
(treprostinil) INHALATION
SOLUTION

INDICATION

Tyvaso (treprostinil) is a prescription medicine used in adults to treat pulmonary arterial hypertension (PAH) (WHO Group 1), which is high blood pressure in the arteries of your lungs. Tyvaso can improve exercise ability in people who also take bosentan (an endothelin receptor antagonist, (ERA)) or sildenafil (a phosphodiesterase-5 (PDE-5) inhibitor). Your ability to do exercise decreases 4 hours after taking Tyvaso.

The effects of Tyvaso are unknown in patients under 18 years of age.

Please see complete Important Safety Information on pages 15-16.

Your guide to Tyvaso

Starting a new treatment can be overwhelming. With the right support, Tyvaso treatments don't have to be. Use this guide to learn more about Tyvaso and how it can help treat your pulmonary arterial hypertension (PAH).

What's inside?

Learning about Tyvaso _____	3
Taking Tyvaso _____	5
Using the Tyvaso Inhalation System _____	7
Medication side effects _____	13
Important Safety Information _____	15
Keeping track of your treatment sessions _____	18
Connecting with someone who's been there _____	19



TYVASO®
(treprostinil) INHALATION
SOLUTION

Learning about Tyvaso® (treprostinil) Inhalation Solution

What is Tyvaso?

Tyvaso is a synthetic (man-made) form of prostacyclin called a prostacyclin analogue. Prostacyclin is a natural substance found in the body. It helps keep arteries in the lungs open and working properly. If you have PAH, your body may not produce enough prostacyclin.

Tyvaso mimics the effects of the natural prostacyclin that your body lacks, making it easier for your heart to pump blood through your lungs.

Tyvaso has been shown to help improve exercise ability as measured by 6-minute walk distance (6MWD). For some patients, this could mean improvement in your ability to walk to the mailbox, take a short stroll in the neighborhood, or walk your kids to the bus stop.

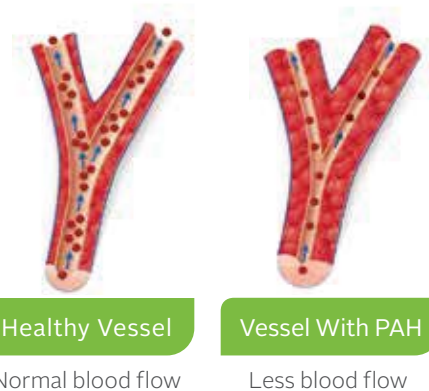
The Tyvaso Difference

- Tyvaso is the only inhalable PAH treatment studied solely as an add-on therapy to be used with oral medications such as bosentan (an endothelin receptor antagonist [ERA]) or sildenafil (a phosphodiesterase type 5 [PDE-5] inhibitor)
- Tyvaso is an inhaled medicine, delivered directly to the lungs
- In the clinical trial, patients who added Tyvaso to their oral therapy were able to increase their exercise ability by an average of 20 meters, as shown by their 6MWD

SELECTED IMPORTANT SAFETY INFORMATION

- Tyvaso is breathed in (inhalable) through your mouth into your lungs. Tyvaso should only be used with the Tyvaso Inhalation System.

Please see complete Important Safety Information on pages 15-16.



Taking Tyvaso® (treprostinil) Inhalation Solution

Tyvaso is breathed in through your mouth directly into your lungs using the Tyvaso Inhalation System.

- Tyvaso is inhaled during 4 treatment sessions each day
- The recommended starting dose is 3 breaths per treatment session
- Your doctor may increase or decrease the number of breaths per treatment session depending on how you tolerate the medicine — the target dose is 9 breaths
- Each treatment session can be completed in as little as 2-3 minutes
- Treatment sessions should be about 4 hours apart during normal waking hours
- Take your first Tyvaso treatment session as soon as possible in the morning. Take your last Tyvaso treatment before bedtime

**Tyvaso is taken
4x/day, for example:**



Breakfast



Lunch



Dinner



Bedtime

The recommended target dose of Tyvaso is 9 breaths per treatment session. Treatments should be about 4 hours apart during normal waking hours, 4 times daily.

SELECTED IMPORTANT SAFETY INFORMATION

- Talk to your healthcare provider if you have a lung disease (such as asthma or chronic obstructive pulmonary disease (COPD)) or a lung infection, the effects of Tyvaso are unknown.
- Talk to your healthcare provider if you have liver or kidney problems, as your ability to tolerate Tyvaso may be affected.

Please see complete Important Safety Information on pages 15-16.



Using the Tyvaso Inhalation System

The Tyvaso Inhalation System is a handheld, portable device that allows you to inhale Tyvaso Inhalation Solution directly through your mouth into your lungs. The lightweight device comes with plastic accessories for inhaling Tyvaso, one rechargeable battery, a carrying case, and other components. The system is designed for quick assembly and only needs to be cleaned once a day.

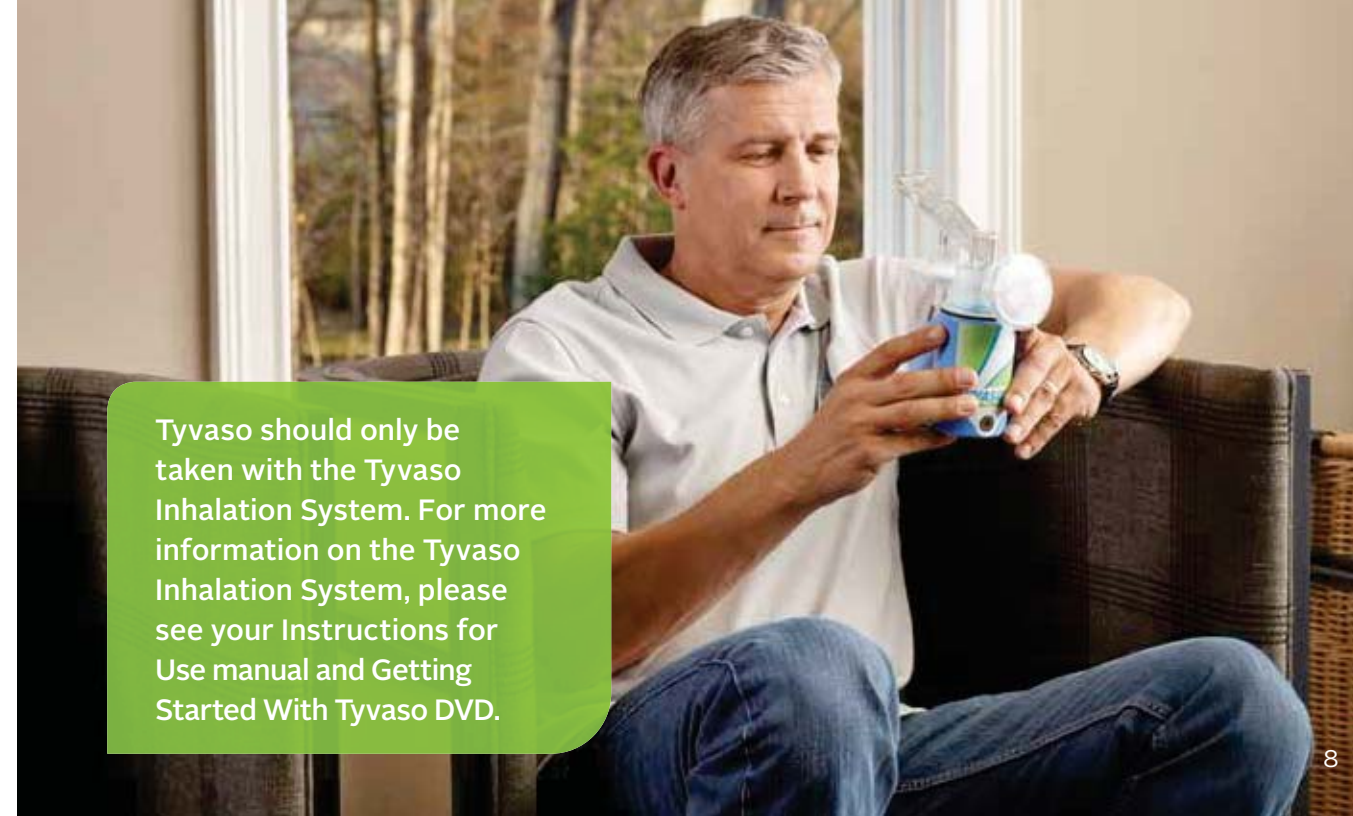


SELECTED IMPORTANT SAFETY INFORMATION

- Talk to your healthcare provider if you have low blood pressure, as Tyvaso may cause symptomatic hypotension (low blood pressure).
- Talk to your healthcare provider if you are pregnant or plan to become pregnant. It is not known if Tyvaso will harm your unborn baby. Women who can become pregnant should use effective birth control while taking Tyvaso.

7 **Please see complete Important Safety Information on pages 15-16.**

Tyvaso should only be taken with the Tyvaso Inhalation System. For more information on the Tyvaso Inhalation System, please see your Instructions for Use manual and Getting Started With Tyvaso DVD.



Getting started

Your doctor, nurse, or Specialty Pharmacy Service (SPS) provider will train you on how to use the Tyvaso Inhalation System. Make sure you understand all directions and practice putting the device together. Do not start treatment until you have completed your training.

SELECTED IMPORTANT SAFETY INFORMATION

- Talk to your healthcare provider if you are breast-feeding or plan to breast-feed. It is not known if Tyvaso passes into your breast milk.
- It is important to tell your healthcare provider about all the medicines you may be taking, including prescription and non-prescription medicines, vitamins, and herbal supplements, as they may affect your use of Tyvaso by increasing the risk of side effects or decreasing effectiveness.

Please see complete Important Safety Information on pages 15-16.

Your Tyvaso Inhalation System Starter Kit includes:

- Two inhalation devices and accessories
- 28-day supply of Tyvaso® (treprostinil) Inhalation Solution (7 foil pouches, each containing 4 plastic ampules)
- Carrying case
- Instructions for Use manual
- Three options for power supply

Every four weeks you will receive a refill shipment that contains:

- 28-day supply of Tyvaso
- Device accessories
- New Tyvaso Treatment Tracker

Each month your specialty pharmacy will contact you to assess your needs prior to sending your refill shipment.



To learn more about taking Tyvaso or using the inhalation system, go to tyvaso.com.

Setting up the device

Setting up your inhalation system takes about 5 minutes each morning, and only needs to be done once per day.

- The parts fit together only one way, and they should fit easily
- Do not force the parts together

Discard any Tyvaso® (treprostinil) Inhalation Solution left in the medicine cup at the end of each day. Always start each day with a new Tyvaso ampule.

For more information on device setup, please see the Tyvaso Inhalation System Instructions for Use manual.



For best results, charge the battery pack 40 hours before first use.



The Tyvaso Inhalation System

One plastic ampule per day

Provides a full day's supply of medication

Lightweight and portable

System weighs less than a pound (under 14 oz) and comes with a rechargeable battery and carrying case

Maintenance

Accessories require once-daily cleaning with warm, soapy water

Device preparation takes about 5 minutes a day

SELECTED IMPORTANT SAFETY INFORMATION

- It is important to tell your healthcare provider if you are taking medicines that decrease blood clotting such as warfarin or heparin, as Tyvaso reduces the ability of your blood to clot (coagulate), and increases your risk for bleeding if you are taking blood thinners (anticoagulants).
- It is important to tell your healthcare provider if you are taking diuretics (water pills), antihypertensives (medications used to treat high blood pressure or heart disease), or other vasodilators (medications that lower blood pressure), as Tyvaso may increase your risk for hypotension (low blood pressure).

Please see complete Important Safety Information on pages 15-16.

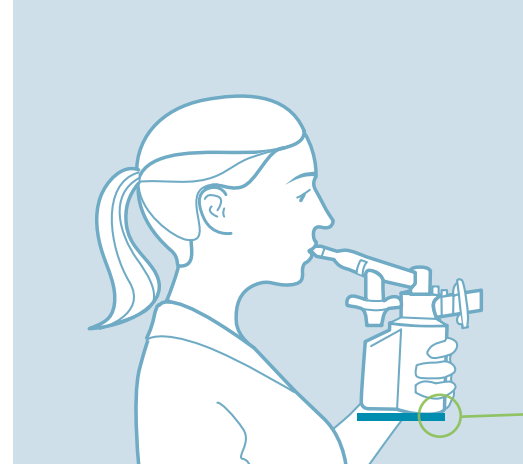
Medication side effects

If you are experiencing side effects, talk to your doctor and make sure you are using the Tyvaso Inhalation System properly.

The most common side effects of Tyvaso® (treprostinil) Inhalation Solution are coughing, headache, throat irritation and pain, nausea, reddening of the face and neck (flushing), and fainting or loss of consciousness.

If you experience cough and/or throat irritation, you can try

- Placing the mouthpiece further into your mouth
- Using the pause button to take time between breaths
- Drinking cold or hot water before and after treatment (for example, hot tea with honey)
- Taking a full normal breath rather than a deep breath



If you experience nausea, you can try

- Eating a small meal before treatment
- Swishing with water before and after treatment
- Rinsing and spitting with salt water after treatment

To ensure proper use, please keep Tyvaso Inhalation System level.

Call your healthcare provider for medical advice about side effects. You are encouraged to report negative side effects to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

SELECTED IMPORTANT SAFETY INFORMATION (CONTINUED FROM PAGE 12)

- It is important to tell your healthcare provider if you are taking gemfibrozil such as Lopid (for high cholesterol) or rifampin such as Rimactane, Rifadin, Rifamate or Rifater (for infection), as your Tyvaso dosage may need adjustment.

Please see complete Important Safety Information on pages 15-16.

Important Safety Information

- Tyvaso (treprostinil) is breathed in (inhalable) through your mouth into your lungs. Tyvaso should only be used with the Tyvaso Inhalation System.

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

- Have a lung disease (such as asthma or chronic obstructive pulmonary disease (COPD)).
- Have a lung infection.
- Have liver or kidney problems, as your ability to tolerate Tyvaso may be affected.
- Have low blood pressure, as Tyvaso may cause symptomatic hypotension (low blood pressure).
- Are pregnant or plan to become pregnant. It is not known if Tyvaso will harm your unborn baby. Women who can become pregnant should use effective birth control while taking Tyvaso.

- Are breast-feeding or plan to breast-feed. It is not known if Tyvaso passes into your breast milk.

It is important to tell your healthcare provider about all the medicines you may be taking, including prescription and non-prescription medicines, vitamins, and herbal supplements, as they may affect your use of Tyvaso by increasing the risk of side effects or decreasing effectiveness. Especially tell your healthcare provider if you take any of these medicines:

- Medicines that decrease blood clotting such as warfarin or heparin, as Tyvaso reduces the ability of your blood to clot (coagulate), and increases your risk for bleeding if you are taking blood thinners (anticoagulants).

- Diuretics (water pills), antihypertensives (medications used to treat high blood pressure or heart disease), or other vasodilators (medications that lower blood pressure), as Tyvaso may increase your risk for hypotension (low blood pressure).
- Gemfibrozil such as Lopid (for high cholesterol) or rifampin such as Rimactane, Rifadin, Rifamate or Rifater (for infection), as your Tyvaso dosage may need adjustment.

The most common side effects of Tyvaso are coughing, headache, throat irritation and pain, nausea, reddening of the face and neck (flushing), and fainting or loss of consciousness. These are not all the possible side effects of Tyvaso. Tell your healthcare provider about any side effects that bother you or do not go away. Your healthcare provider may be able to help you manage the side effects.

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Please see the Full Prescribing Information, Patient Package Insert, and the Tyvaso Inhalation System Instructions for Use manual in pocket.

For additional information about Tyvaso, visit www.tyvaso.com or call 1-877-UNITHER (1-877-864-8437).

This information is provided for an informational purpose and is not intended as treatment advice. Patients should consult a healthcare professional for treatment advice.

Getting the support you need

Specialty pharmacies provide individualized training and follow-up by a specialized team of pharmacists, nurses, and administrative coordinators. This support is designed to help every step of the way and offers these services to you at no cost:

- Within 1st month:**
- One-on-one training on the Tyvaso Inhalation System
 - Guidance, support, and review of Tyvaso and the Inhalation System
- 1 to 6 months:**
- Phone consultations
 - Assessment of condition, goals, treatment, and side effects
- After 6 months:**
- Specialty pharmacy clinical team reviews your progress and treatment goals with your doctor
 - Ongoing calls to monitor your needs

Keeping track of your treatment sessions

Tyvaso Treatment Trackers are included in your starter kit and with each additional shipment of Tyvaso. These diaries can help you keep track of the number of breaths you're taking during your 4 treatment sessions per day. Please use the Treatment Tracker instructions to help you keep track of your breaths and treatment sessions, and share this information with your healthcare providers.

SELECTED IMPORTANT SAFETY INFORMATION

The most common side effects of Tyvaso are coughing, headache, throat irritation and pain, nausea, reddening of the face and neck (flushing), and fainting or loss of consciousness. These are not all the possible side effects of Tyvaso. Tell your healthcare provider about any side effects that bother you or do not go away. Your healthcare provider may be able to help you manage the side effects.

Please see complete Important Safety Information on pages 15-16.

Connecting with someone who's been there



The PEER Network connects you with a patient on Tyvaso® (treprostinil) Inhalation Solution or a caregiver who can share personal experiences, practical tips, and emotional support. For more information on this no-cost service, call 1-866-505-PEER (7337) or visit peernetwork.net.

Interactions are completely confidential and can be conducted by phone or by e-mail.

Practical advice and emotional support:

- Tips for integrating treatment into everyday life
- Insights from someone who's on the same therapy
- Encouragement to help address fears and concerns



Tyvaso is available only through the following specialty pharmacy providers:

accredo®

♥ **CVS** specialty™

Glossary of key terms

- **Ampule** – A sealed, lightweight clear plastic vial (containing a 1-day supply of Tyvaso)
- **Heritable** – Capable of being passed from one generation to the next
- **Idiopathic** – A disease that has no known cause
- **Prostacyclin** – A naturally occurring substance that helps to keep blood vessels dilated (open) and working properly. Levels may be low in patients with PAH
- **Prostacyclin Analogue** – Helps replace some of the activity of prostacyclin in the body. Available in 3 forms: oral (pill), inhaled (breathed into the lungs), and infused (injected into a vein or under the skin)
- **Pulmonary Arterial Hypertension (PAH)** – High blood pressure in the arteries of the lungs. In PAH, high blood pressure occurs in the pulmonary arteries that lead from the heart to the lungs
- **WHO Group** – System used by the World Health Organization (WHO) to classify PH based on its cause. The 5 classifications of PH are
 - Group 1: PAH
 - Group 2: PH with left heart disease
 - Group 3: PH with other lung diseases
 - Group 4: PH due to blood clots
 - Group 5: Miscellaneous



Please see Important Safety Information
for Tyvaso on pages 15-16.



This educational material provided by United Therapeutics Corporation.

For more information on Tyvaso or the Tyvaso Inhalation System, please see your Instructions for Use manual and Getting Started With Tyvaso DVD.

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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.

TYVASO[®] ***INHALATION SYSTEM*** Instructions for Use

TYVASO[®]
(treprostinil) INHALATION
SOLUTION



Table of Contents

General Instructions.....	2
Introduction.....	3
Preparing for Treatment With TYVASO.....	3
Preparing the Use Environment.....	3
Markings, Indicators, and Symbols.....	4
Gathering Supplies.....	6
Setting Up Your TYVASO Inhalation System.....	8
Filling the Inhalation Device Chamber and Medicine Cup.....	8
Assembling the Inhalation Device.....	10
Turning On the Inhalation Device.....	13
Setting the Number of Breaths in a Treatment Session.....	14
Inhaling Your Medicine (TYVASO).....	16
Storing the TYVASO Inhalation System Between Treatment Sessions.....	20
Cleaning and Maintenance of the TYVASO Inhalation System.....	24
End of Day Cleaning of the Accessories.....	24
Weekly Cleaning.....	27
Monthly Refill Kit.....	27
Device Replacement.....	27
Charging Your TYVASO Inhalation System.....	28
Rechargeable Battery.....	28
Troubleshooting the TYVASO Inhalation System.....	30
Specifications.....	36
Glossary.....	38
Warranty Information.....	40

General Instructions

The TYVASO Inhalation System should be handled with care. Follow these important instructions to ensure proper use:

- Always unplug the device after each use.
- Do not immerse the device in water or other liquids.
- Do not place the device in a microwave or regular oven.
- Do not place the device or use the device in the presence of strong electric or magnetic fields (eg, microwave oven, magnetic imaging equipment).
- Do not leave the device alone with a small child.
- Do not use the device near flammable liquids and materials or heated surfaces.
- Read the instructions carefully and completely to prevent damage to your TYVASO Inhalation System and help you get the best results.
- This device should only be used on the order of your doctor or licensed healthcare practitioner.
- Ensure the breath counter is correctly programmed prior to beginning a treatment (see page 14).
- Do not peel or remove the labels from device.
- Do not drop the device.

Introduction

Your doctor has prescribed TYVASO® (treprostinil) Inhalation Solution. Please see the accompanying Patient Package Insert for important safety information on TYVASO.

TYVASO is breathed in (inhaled) using the TYVASO Inhalation System, which consists of the inhalation device and its accessories.

These Instructions for Use (IFU) for the TYVASO Inhalation System provide important safety information. It is important that you read these instructions and the TYVASO Patient Package Insert (PPI) before setting up and using the TYVASO Inhalation System. If you have any questions, talk to your doctor or specialty pharmacy provider.

Before beginning treatment with TYVASO, you will receive either a Patient Starter Kit containing a 28-day supply of TYVASO or an Institutional Starter Kit containing a 4-day supply of medication. Both kits include two (2) complete inhalation devices (all accessories and supplies included). When you refill your prescription for TYVASO each month, you will receive a Refill Kit that contains a 28-day supply of TYVASO and new accessories. You will receive a replacement device every two (2) years.

IMPORTANT

- **Do not start treatment with TYVASO until you have been trained to use the TYVASO Inhalation System. Make sure you understand all of the directions. Always ask your doctor or specialty pharmacy provider if you have any questions or are unsure of anything you are taught.**
- **TYVASO is for use only with the TYVASO Inhalation System.**

Preparing for Treatment With TYVASO Preparing the Use Environment for Treatment

Follow these important instructions before setting up your treatment:

- Use the device in a quiet, distraction-free area.
- Try to use the device at times when your treatment will not be interrupted. If you encounter any distractions during treatment, you can pause your treatment (see page 19).
- Use the device in a comfortable space where you can stand or sit in an upright position that allows you to take deep breaths.
- Use the device in an area that provides enough space for the TYVASO Inhalation System and its accessories.
- Gather all necessary supplies before starting to prepare for treatment (see pages 6 and 7).
- The TYVASO Inhalation System is recommended for use indoors. Be sure to use and store the inhalation device in environments that match the specified temperature and humidity ranges (see Specifications on page 36).

Markings, Indicators, and Symbols

Inhalation device

The device is equipped with a multifunctional status light and a separate control light for inhalation.



Control light for inhalation

- Green light on - Inhale
- Green light off - Exhale, then breathe normally

Status light

- Yellow - ready for operation
- Green - device in operation
- Red - device error indication

Device Display Messages

09

Displays the number of breaths in an active cycle.

PA

(PA) Pause - Displayed if user pauses a treatment session.

En

(En) End - Displayed when a treatment session is complete.

LH

(LH) Low Hydrogen (ie, Low Water) - Displayed if device detects wrong or missing contact fluid in chamber.

LB

(LB) Low Battery - Displayed if device battery does not have enough power to start a treatment.

START
STOP

"START/STOP"
Treatment Button -
Begins or pauses
treatment.

ON
OFF

"ON/OFF" Button -
Switches between
fully on and fully off
power states.

Device markings



The TYVASO Inhalation System complies with the requirements of Protection Class II. Class II equipment provides additional precautions, over and above basic insulation, to provide protection against electric shock.



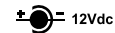
Please read the accompanying instructions and labels for important information regarding the TYVASO Inhalation System.



The TYVASO Inhalation System has a Type B Applied part. Type B Applied parts comply with specific requirements to provide protection against shock and are not suitable for direct cardiac applications.

! Rx Only

The TYVASO Inhalation System should only be used on the order of your doctor or licensed healthcare provider.



The TYVASO Inhalation System requires a 12V DC power supply.

Gathering Supplies

Gather the following supplies before starting treatment. Use only the parts and accessories that are provided with your starter kit or in the monthly refill kit. Note: supplies are not shown to scale.

1. Inhalation device



2. Water Level Cup with 45 mL of distilled water



Use only distilled water to fill your inhalation device once per day.

3. Pack of TYVASO ampules



Use one (1) ampule per day.

4. One of the provided power sources



AC wall plug (2)



Rechargeable battery



12V DC adapter

5. Accessories



Medicine cups*



Dome assembly with baffle plate inside*



Inhalation piece*



Mouthpiece*



Two (2) Filter shells*



Filter membranes (use two (2) per day)*



Plugs*



Treatment Tracker*



Carrying case



Distilled water carrier (optional)

Note: Supplies are not shown to scale.

*These accessories are replaced every month. Replacement accessories are included in the Monthly Refill Kit.

Setting Up Your TYVASO Inhalation System

Filling the Inhalation Device Chamber and Medicine Cup

Before using the TYVASO Inhalation System, you should:

- Wash your hands



- Make sure the device is **NOT** connected to a power source
- Make sure the device is resting on a stable, flat surface during assembly

ONLY USE DISTILLED WATER in the device. Distilled water is highly purified water that can be purchased at most grocery stores and pharmacies. It is necessary for the device to function properly. If you use another type of water (such as bottled or tap water), the device may not function properly.

- 1** Fill the white chamber inside the device with approximately 45 mL of distilled water (about 1.5 ounces), using the water level cup provided. Fill the cup until water level is between the two arrow markings.

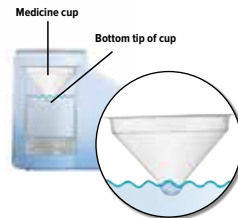


There is a silver sensor on the inside wall of the chamber. The water level should be above the silver sensor and below the blue ring in the device chamber. **DO NOT OVERFILL** the chamber, or the medicine cup will not fit correctly. Check the water level after filling the chamber.



- 2** Obtain one (1) medicine cup and inspect it for any damage, holes, cracks, or dents. Do not use the medicine cup if it is damaged.

Insert the empty medicine cup into the chamber of the device, making sure that the cup's bottom tip is in the distilled water. The cup will sit on the blue ring.



CAUTION

Make sure you insert only one (1) medicine cup. Inserting multiple cups will prevent the flow of medicine.

- 3** Carefully cut open the top of the foil pouch, making sure not to cut the ampules. Each pouch contains four (4) ampules.

Remove one (1) ampule of TYVASO. Keep unused ampules in the foil pouch because the TYVASO medicine is sensitive to light.

One (1) ampule contains enough medicine for one (1) day of treatment no matter how many breaths your doctor has prescribed.

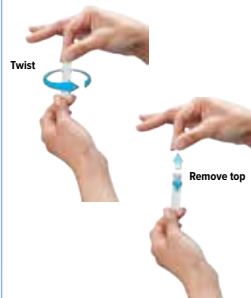


CAUTION

Ampules must be used within seven (7) days of opening foil pouch.

Open only (1) pouch at a time. Discard any unused ampules after seven (7) days.

- 4** Gently hold the ampule in the upright (top-up) position and twist off its top.



CAUTION

If any medicine from the ampule spills on your hands, wash your hands immediately.

Medicine contact with the skin can cause irritation.

- 5** Point the ampule straight down toward the medicine cup's center to avoid spills.

Gently squeeze the medicine out of the ampule into the medicine cup. Squeeze until it is empty. Check to see that all of the medicine is in the medicine cup.



Assembling the Inhalation Device

The TYVASO Inhalation System is designed so the parts only fit together properly one way.

When the device is assembled correctly, the parts should fit together easily.

Do not force the parts together.



1

Visually check to make sure the blue plastic baffle plate and black ring are correctly placed in the dome assembly. They should appear as they do in the images below.

In the unlikely event that the baffle plate is loose or disconnected, use a new dome assembly. If you need to order a new dome assembly, contact your specialty pharmacy provider.



2

Align the raised circle on the side of the dome assembly with the circle on the side of the device. Push down and screw the dome assembly onto the device clockwise (right) until you hear a click, indicating the dome assembly is fully connected to the medicine cup. When the dome assembly is properly aligned, the filter shell port will point to the back of the device.



IMPORTANT

The dome assembly "clicks" only the first time it connects to the medicine cup. If you then realign the dome assembly you will not hear another click.

3

Insert the inhalation piece into the upper opening of the dome assembly and rotate toward the front of the device. Gently push down the inhalation piece to make sure it is securely inserted in the dome assembly.



4

Insert the mouthpiece into the inhalation piece.



5

Each day you will need to use a new filter membrane in each filter shell.

To install a new filter membrane:

- Open the filter shell by unscrewing the two (2) halves.
- Place a new filter membrane in one (1) of the filter shell halves.
- Close the filter shell by screwing the two (2) halves together until you can twist no further.

Note: New filter shells come with fresh filter membranes already installed.

Open



Close



Assembling the Inhalation Device (continued)

6

Insert one (1) of the filter shells into the filter shell port on the side of the dome assembly and insert the other filter shell into the port on the bottom of the inhalation piece. The two (2) filter shells are identical and can be used in either opening.

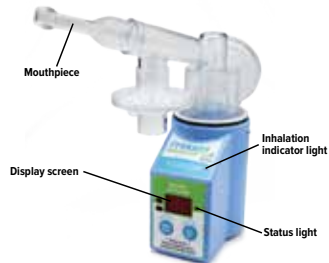
Make sure to insert the filter shells straight into their ports, rather than at an angle. If necessary, rotate the inhalation piece so you can best see the indicator lights and display screen, which provide important prompts during your treatment.



7

When the device is fully assembled, it should appear as it does in the photo below.

For convenience, rotate the inhalation piece so you can best see the indicator lights and display screen, which provide important prompts during your treatment.



Turning On the Inhalation Device

1

Connect your device to one (1) of the power source options by plugging one end of the power cord into the back of the inhalation device and the other end into the power source.

If using the AC wall plug, make sure to plug the output cable into the device before plugging adapter into the power source.

If using the rechargeable battery, make sure it is not also plugged into the AC wall plug.



2

To turn on the device, press and hold the ON/OFF button for approximately three (3) seconds. When you hear a short beep and the yellow status light is illuminated, release the ON/OFF button. Remember to press the center of the ON/OFF button when powering the device on or off.

When the power is on, the display screen will show the last number of breaths programmed and a yellow light will appear next to the screen.

Make sure the number matches the prescribed number of breaths for that treatment session. If it does not match, see the next page for instructions on setting the number of breaths in a treatment session.



Setting the Number of Breaths in a Treatment Session

You will inhale TYVASO during four (4) treatment sessions each day. During each treatment session, you will take a series of breaths through the mouthpiece of the TYVASO Inhalation System.

Your doctor will prescribe the number of breaths you should inhale in each treatment session.

You should record the number of breaths in your Treatment Tracker.

Monday I'm taking 6 breaths per treatment session.

DATE: 1 / 9 / 2012

1 TIME: 8:15 am

2 TIME: _____

3 TIME: _____

4 TIME: _____

BREATHS									
1	2	3	4	5	6	7	8	9	10

(example of Treatment Tracker)

1

Make sure the device is powered off. To power off the device, press and hold the ON/OFF button for three (3) seconds. When you hear a short beep and the display screen turns off, release the ON/OFF button.

To set the number of breaths, press and hold both the START/STOP and ON/OFF buttons at the same time until the display flashes and the device emits three (3) short beeps.

The flashing display indicates the inhalation device is in breath programming mode. You cannot begin a treatment while the display is flashing.

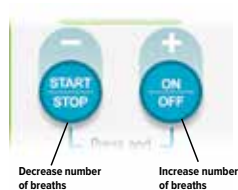


2

To increase the number of breaths press the + (ON/OFF) button.

To decrease the number of breaths press the — (START/STOP) button.

Remember to press in the center of the buttons.



3

Once you have entered your prescribed number of breaths, remove your hands from the device and wait approximately 15 seconds.

After approximately 15 seconds, the display will stop flashing and the device will emit three (3) short beeps, indicating that it has saved the new number of breaths. The new number of breaths will appear on the display.

Make sure the number of breaths on the display matches the number of breaths in your prescription. If the numbers do not match, repeat steps 1-3.



Inhaling Your Medicine, TYVASO® (treprostinil) Inhalation Solution

You will inhale TYVASO during four (4) treatment sessions each day. During each treatment session, you will take a series of breaths through the mouthpiece of the TYVASO Inhalation System.

IMPORTANT

Before inhaling your medicine, check the number on the display screen to make sure it matches the prescribed number of breaths for that treatment session. Record this value in your Treatment Tracker.



If the number of breaths on the display does not match the number of breaths in your prescription go to page 14 “Setting the Number of Breaths in a Treatment Session” and repeat steps 1-3.

Inhalation Tips

Technique:

When breathing each TYVASO treatment, be sure to keep the device level, directing the flow of medicine into the throat and not toward the roof of the mouth.

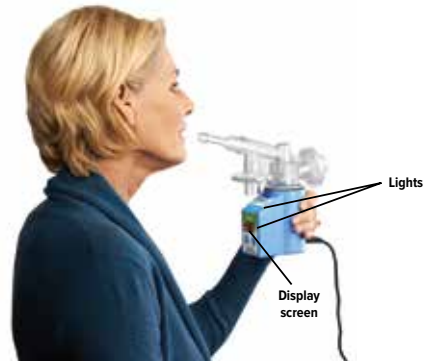
Seal your lips around the mouthpiece to ensure that you can inhale the full amount of TYVASO after it is produced by the device.

Inhalation:

Each breath should last approximately three (3) seconds, breathing “normal full breaths.” Do not hold your breath. Exhale normally and prepare for the next breath.

1

Hold the device upright as shown below. Make sure you can see the display screen and lights clearly and that your hands do not cover the display screen or lights while holding device. If the inhalation piece or mouthpiece block your view of the display screen or lights, move the inhalation piece so you can best see them.



Inhaling Your Medicine, TYVASO® (treprostinil) Inhalation Solution (continued)

2

Perform steps A-G to complete one (1) treatment session.
Follow the instructions exactly to make sure you receive the correct medication dose.

A



Press the START/STOP button to begin treatment.

B



The status light turns green and the device emits two (2) short beeps.

C



While the device emits one (1) long beep, exhale completely.

D

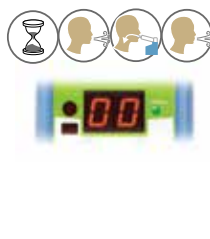


After the device emits a short beep and while the inhalation indicator light is flashing green, place your lips securely around the mouthpiece and inhale slowly for the duration of the beep (at least three (3) seconds). Exhale normally, mark a circle in the Treatment Tracker and prepare for the next breath.

CAUTION

If medicine does not appear to be flowing properly, the system might be set up incorrectly. See Troubleshooting section, pages 30-35, for details.

E



Repeat steps B through D for the number of prescribed breaths and until the display counts down to "00".

F



After the final breath, the display screen will show "00" then "En," indicating the treatment session is complete.

Check the number of breaths you inhaled on the Treatment Tracker.

G



To turn off the device, press and hold the ON/OFF button for three (3) seconds and then release.

If the device is left in "En" mode for more than 60 seconds, it will turn off automatically.

3

To pause the treatment between breaths, press the START/STOP button. The display screen will show "PA."



To resume treatment, press START/STOP again. "PA" will disappear and the display screen will show the number of breaths remaining.

If the device is disconnected from its power source for any reason (for example, a power failure), reconnect the device to a power source. Follow the instructions on page 13 to turn on the device. The display will show how many breaths are left in that treatment session. Press the START/STOP button to continue your treatment session.

Storing the TYVASO Inhalation System Between Treatment Sessions

If you have more treatment sessions left in the day, perform the following steps.

If you have completed your last treatment session of the day, skip to *Cleaning and Maintenance of the TYVASO Inhalation System* (see page 24).

Be sure to pack all parts, including a backup power supply, in the carry case whenever transporting your device.

1

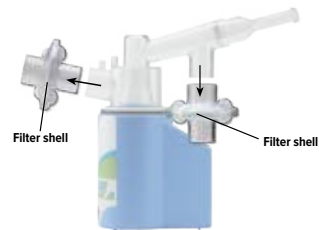
Disconnect the device from its power source.



2

Remove both filter shells.

Do NOT remove the filter membranes from filter shells until after the last treatment session of the day.



IMPORTANT

When removing accessories between treatment sessions, hold the device by its base to avoid spilling the medicine.

3

Remove the mouthpiece.



Storing the TYVASO Inhalation System Between Treatment Sessions (continued)

4

Remove the inhalation piece.



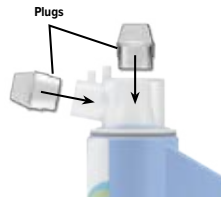
5

Leave the dome assembly and medicine cup (with the medicine still in it) connected to the device.



6

Insert a plug into each of the open holes on the dome assembly to prevent the medicine from spilling out.



IMPORTANT

If the plugs are not in place, the medicine may spill. If you spill any medicine, start over with a new ampule.

7

The inhalation device with the plugged dome assembly and all the accessories can be stored in the carrying case between treatment sessions.



IMPORTANT

Store the inhalation device in an upright position until the next treatment session. See page 36 for additional storage and transport information.

Cleaning and Maintenance of the TYVASO Inhalation System

End of Day Cleaning of the Accessories

1

Disconnect the device from the power source.



2

Remove both filter shells.



3

Open the filter shells by twisting in opposite directions.

Remove and discard the used filter membranes.



4

Remove the mouthpiece.



5

Remove the inhalation piece.



6

Remove the dome assembly by turning it counter-clockwise (to the left). The medicine cup should stay attached to the dome assembly.



⚠ CAUTION

If any medicine from the medicine cup spills on your hands, wash your hands immediately. Medicine contact with the skin can cause irritation.

End of Day Cleaning of the Accessories (continued)

7

Remove the medicine cup by gently squeezing on the sides where it is attached to the dome assembly. Empty the medicine cup into a sink or waste basket, then discard the medicine cup.

Be careful not to spill the medicine when removing or discarding the medicine cup.



IMPORTANT

Discard the remaining TYVASO® (treprostinil) Inhalation Solution in an appropriate waste receptacle. Throw away the plastic medicine cup. Do not reuse the medicine cup. Do not recycle the medicine cup.

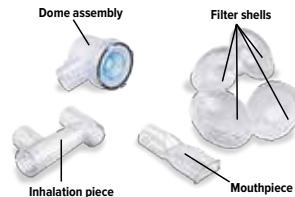
8

Empty the distilled water from the chamber and let the inhalation device air dry upside down. You can wipe the chamber with a soft cloth or paper towel to collect water.



9

Clean the accessories (pictured below) by hand in mild, soapy, warm water, then rinse them thoroughly with water. Allow accessories to air dry.



IMPORTANT

Do not place the inhalation device in water or in a dishwasher.
Do not place the inhalation device or its accessories in a microwave or conventional oven.

10

Once all the items are dry, the filter shells, inhalation piece, mouthpiece, dome assembly, and inhalation device can be stored in the carrying case until the next day's treatment sessions.



Weekly Cleaning

- Once a week, use a clean cloth to wipe the interior of the inhalation device chamber, be sure to wipe the disc in the bottom of the device. You may wipe the exterior of the device with a damp cloth if the lights or buttons become difficult to see. Proper cleaning will help to avoid corrosion and leaks and keep your device working properly.

Monthly Refill Kit

- Once a month, you will receive a refill kit that will come with a new set of accessories from your specialty pharmacy provider. Inspect the shipment to be sure all parts are included (see page 7). Once the new kit has arrived, discard the used dome assembly, inhalation piece, mouthpiece, and two (2) filter shells. Do not recycle the used accessories.

Device Replacement

- The inhalation device should be replaced every two (2) years from your first day of use. Replacement inhalation devices will be supplied by your specialty pharmacy provider.

IMPORTANT

All service of the TYVASO Inhalation System must be performed by the manufacturer. Attempting to alter the device in any way voids the warranty and may cause a malfunction.

Charging Your TYVASO Inhalation System Rechargeable Battery

The rechargeable battery is supplied with its own instructions for use. Refer to these instructions for more information.

- Your TYVASO Inhalation System is supplied with a portable, rechargeable battery. Do **NOT** use other batteries.

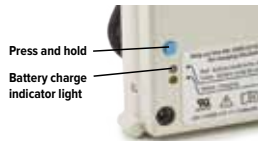


- Your battery can only be charged by using one (1) of the AC wall plugs that comes with your inhalation device.



- To check the battery's voltage level, press and hold the blue button on the front of the battery. You can only check the battery's voltage level when the battery is not plugged into a power source.

The light below the button will turn on and indicate the battery's voltage level. A red light indicates the battery needs to be charged. A green light indicates the battery is ready to operate the device.



IMPORTANT

A new battery might not be fully charged when you receive it. Always charge a new battery before you first use it.

- To charge the battery, connect the AC wall plug to the battery pack and plug the AC wall plug into an outlet.

A yellow light on the front of the battery will turn on, indicating that the battery is charging.

- Your battery may take up to 40 hours to fully charge. It is not possible to use the TYVASO Inhalation System with the battery while it is recharging.

A fully charged battery will typically last up to 200 inhalations. A battery charged for one (1) night (about 10 hours) will typically last up to one (1) day of therapy (about 40 inhalations).



IMPORTANT

Make sure the battery is not connected to the inhalation device while the battery is charging. The battery will charge more slowly and require a longer time to fully charge if plugged into the inhalation device.

- You should connect the charged battery to the TYVASO Inhalation System only for your treatment. When using the battery pack to power the device, make sure the battery is not plugged into a power source.
- After your treatment session is complete, remove the power plug of the battery from the device.
- Charge the battery whenever you are not using it to power the inhalation device.
- Always have your AC wall plug or 12V DC adapter available for backup, in case the battery is not charged.



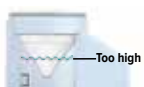
Troubleshooting the TYVASO Inhalation System

Problem	Possible causes	Corrective actions
Low battery (LB) 	Low battery	- Unplug the battery from the device. Charge the battery by attaching it to the AC wall plug and outlet. - Use an alternative power source, such as the AC wall plug or 12V DC adapter, for treatment.
	Defective adapter (AC wall plug or 12V DC adapter)	Ensure that the plug is properly connected to an outlet.
	AC wall plug is still plugged into battery and battery is connected to device.	- Turn off device (see page 14). - Disconnect AC wall plug from battery. - Check battery status, following instructions on page 28.
		If device is properly powered and still does not function, contact your specialty pharmacy provider for a replacement.

Problem	Possible causes	Corrective actions
Low hydrogen (LH) 	Device chamber is empty or distilled water level in the device chamber is too low.	Unplug the device from its power source. Remove the dome assembly carefully, making sure not to spill its medicine. Empty the device chamber then refill it with distilled water (see page 8) and reconnect the dome assembly (see page 10).
		
	The distilled water you are using is too purified	Empty device chamber. Add one (1) teaspoon of tap water to the water fill cup. Fill cup with distilled water up to level between the two arrow markings on cup (see page 8). Pour cup's contents into device chamber.
	The sensor has a thin layer of build-up	Clean sensor and interior surfaces of water chamber with a clean cloth.
		If device is properly powered and still does not function, contact your specialty pharmacy provider for a replacement.

Troubleshooting the TYVASO Inhalation System (continued)

Problem	Possible causes	Corrective actions
No medicine comes out of the device during a treatment session	No TYVASO® (treprostinil) Inhalation Solution in the medicine cup	Unplug the device from its power source. Fill medicine cup with one (1) ampule of TYVASO.
	Damaged medicine cup	Unplug the device from its power source. Replace the medicine cup.
	Distilled water level in the device chamber is too high	Unplug the device from its power source. Empty the device chamber then refill it with 45 mL of distilled water.
	Multiple medicine cups attached to the dome assembly	Unplug the device from its power source. Remove and dispose of all medicine cups in the device. Insert a single, new medicine cup into device chamber and fill with one (1) ampule of TYVASO.



Problem	Possible causes	Corrective actions
Difficult to breathe in medicine through the mouthpiece	Filter membrane is clogged	Unplug the device from its power source. Replace filter membrane (see page 11).



Troubleshooting the TYVASO Inhalation System (continued)

Problem	Possible causes	Corrective actions
No “click” was heard when attaching the dome assembly	• No medicine cup in the chamber of the device	• Insert an empty medicine cup into the chamber of the device and fill it with one (1) ampule of TYVASO.
	• Multiple medicine cups attached to the dome assembly	• Unplug the device from its power source. Remove and dispose of all medicine cups in the device. Insert a single, new medicine cup into device chamber and fill with one (1) ampule of TYVASO.
	• Dome assembly is not securely in place	• Unplug the device from its power source. Align the circle on the side of the dome assembly with the circle on the side of the device. Push down and screw the dome assembly onto the device clockwise (right) until you hear a click, indicating the dome assembly is fully connected to the medicine cup.



Problem	Possible causes	Corrective actions
Loss of power during treatment	• Device is disconnected from its power source	• Reconnect the device to a power source and press the ON/OFF button to turn on the device. The display will show how many breaths are left in that treatment session. Press the START/STOP button to continue your treatment session.
	• Power source is temporarily disrupted (for example, electricity interruption due to a storm)	• Reconnect the device to a power source and turn on the device (see page 13). The display will show how many breaths are left in that treatment session. Press the START/STOP button to continue your treatment session.

Specifications

Inhalation Device

Model	TD-100/A
Size	98 x 66 x 105 mm
Weight, inhalation device	280 g (9.9 ounces)
Types of power supply	AC wall plug 12V DC adapter Rechargeable battery
Power input	12V DC, 1.5A maximum
Operating power consumption	18 Watt maximum
Ultrasonic frequency	2.4 MHz (nominal)
Nebulization rate	0.50 - 0.55 mg/min (0.9% Saline)
Medicine cup capacity	6 mL, nominal
Contact fluid chamber capacity	45 mL, nominal
Electric protection class	II Type B
Storage temperature/humidity	-5 to 40°C/20-80% relative humidity
Operating temperature/humidity	15 to 25°C/40-75% relative humidity

Packaging Dimensions (Approximate Length x Width x Height)

Patient Starter Kit (PSK)	12.2" x 14.3" x 16.0"
Monthly Refill Kit (MRK)	9.9" x 6.1" x 16.1"
Institutional Starter Kit (ISK)	12.2" x 14.3" x 16.0"

TYVASO Mass and Particle Specifications for 9 breaths

Mass Median Aerosol Diameter (MMAD)*	mean = 2.0 µm SD = 0.3
Total Emitted Dose per Breath**	mean = 6.0 µg SD = 0.4
Total Aerosol Mass*	mean = 58 µg SD = 5.9
Total Respirable Dose*	mean = 44.6 µg SD = 3.5
Respirable Fraction*	mean = 73% SD = 5%
Geometric Standard Deviation (GSD)*	mean = 2.6 µm SD = 0.4

*n=108 data points from r=3 inhalation devices. Each data point was 9 breaths.

**n=216 data points from r=6 inhalation devices. Each data point was 1 breath.

Accessories

ON-110HPA	Rechargeable battery
ON-100Z	12V DC adapter
ON-100N-US	AC wall plug
ON-102/1/C	Medicine cup, Quantity-16
ON-109	Filter membranes
ON-120/C	Plugs
ON-101/C	Filter shell
TD-103/C	Dome assembly with baffle plate
ON-104/C	Inhalation piece
ON-105/C	Mouthpiece
TD-118	Water level cup
TD-153	Carrying case
TD-155	Distilled water carrier

Note: Part number subject to change.

Glossary

Accessories: Parts of the TYVASO Inhalation System. See pages 6 and 7.

Ampule: A sealed, lightweight clear plastic vial containing a 1-day supply of TYVASO® (treprostinil) Inhalation Solution.

Control light for inhalation: A green LED on the top surface of the inhalation device that signals when you should inhale.

Baffle plate: A blue plastic piece that is inside the dome assembly. The baffle plate helps turn TYVASO into particles that are the correct size to inhale.

Black ring: A round seal that fits on the bottom of the dome assembly. The seal helps ensure that TYVASO does not mix with the distilled water in the device chamber.

Display screen: A small area on the inhalation device that displays number and letter prompts to guide you through your treatment sessions.

Distilled water: Water that is highly purified so that it contains only essential elements.

Dome assembly: The plastic accessory that contains the baffle plate and connects the mouthpiece, inhalation piece, and filter shells to the base of the inhalation device.

Filter membrane: The white pad that goes into the filter shells.

Filter shells: Plastic accessories that hold the filter membranes.

Inhalation piece: The plastic accessory that connects the mouthpiece with the dome assembly.

Inhalation device: The base of the TYVASO Inhalation System to which the accessories connect. The inhalation device contains the display screen and lights.

Inhale: How you will breathe in TYVASO with the TYVASO Inhalation System.

Medicine cup: The disposable plastic cone-shaped cup into which TYVASO is poured. The medicine cup fits inside the inhalation device chamber.

Mouthpiece: The plastic part that you will breathe through (using your mouth) to inhale TYVASO.

ON/OFF button: A manually activated control on the front of the device that switches between fully on and fully off power states.

Plugs: Plastic accessories that are inserted into the openings of the dome assembly between treatment sessions. Plugs help keep TYVASO from spilling if the inhalation device tips over.

Prompts: The audio and visual signals that help guide you through the treatment sessions.

Sensor: The silver object on the inside wall of the device chamber. The sensor must be covered with distilled water for the TYVASO Inhalation System to function properly.

Status light: A multicolored LED on the front of the inhalation device that indicates the device's operational status.

Start/Stop treatment button: A manually activated control on the front of the device that begins or pauses treatment.

Specialty pharmacy provider: A pharmacy that carries only specialized medicines and medical devices. Your specialty pharmacy provider is a good source of information about TYVASO and the TYVASO Inhalation System.

Treatment session: One (1) of four (4) daily sessions during which you will take TYVASO with a specific number of inhalations.

TYVASO: The prescription medicine that you will use with the TYVASO Inhalation System.

Water chamber: The white hollow portion in the center of the inhalation device into which distilled water and the medicine cup are placed.

Warranty Information

Your TYVASO Inhalation System is granted a full replacement or repair warranty good for two (2) years from your date of receipt of the TYVASO Inhalation System Starter Kit or five (5) years from the date of manufacture, whichever comes first. This warranty applies to the TYVASO Inhalation System device only. Accessory components are not covered under warranty.

Circumstances that may void your warranty include:

- Modification or disassembly of the TYVASO Inhalation System device by anyone other than a factory-authorized technician
- Failure to comply with the written *Instructions for Use* manual when operating the TYVASO Inhalation System
- Unapproved use of the TYVASO Inhalation System

For all inquiries relating to service or warranty for your TYVASO Inhalation System, contact your specialty pharmacy provider. You should have the following information available:

- Device serial number (located on bottom of TYVASO Inhalation System)
- Date TYVASO Inhalation System was acquired
- Nature of the problem and any steps taken to fix it

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TYVASO[®]
(treprostinil) INHALATION
SOLUTION



TYVASO[®] **INHALATION SYSTEM**

Instructions for Use

TYVASO Inhalation Solution is for prescription use only.

TYVASO is a registered trademark of United Therapeutics Corporation.

Literature issued August, 2014

For further questions and information, or to report an adverse reaction, please call 1-877-UNITHER (1-877-864-8437).

Emergency contact information

Clinician: _____

Nurse educator: _____

Specialty pharmacist: _____

United Therapeutics: _____



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RTP 3098A Rev. 00

TYVASO[®]
(treprostinil) **INHALATION SOLUTION**