

SANDOZ[®] TREPROSTINIL INJECTION

FOR PULMONARY ARTERIAL HYPERTENSION

(WHO GROUP 1)



Indication

Treprostinil injection is a prescription medication used in adults with pulmonary arterial hypertension (PAH), World Health Organization (WHO) Group 1, to reduce symptoms associated with exercise. PAH is high blood pressure in the arteries of your lungs. Treprostinil was studied mainly in patients with New York Heart Association (NYHA) Functional Class II-IV symptoms.

In people with PAH who need to switch from epoprostenol sodium, Treprostinil injection is approved to slow the worsening of symptoms. The risks and benefits of each drug should be carefully considered before switching.

Selected Important Safety Information

WARNINGS AND PRECAUTIONS (continued on page 3)

- Treprostinil injection can be delivered using a tube placed in a big blood vessel (vein) within the chest. This type of delivery is associated with the risk of bloodstream infections and sepsis, which may be fatal. Therefore, continuous subcutaneous infusion delivered just beneath the skin is the preferred method of delivery.
- You should not stop or change your Treprostinil injection dose without consulting your doctor first, as this may cause your PAH symptoms to worsen.

Please see complete Important Safety Information on pages 10-11 and accompanying Brief Summary of full Prescribing Information. Please click [here](#) for full Prescribing Information.

Treprostinil
INJECTION™

Understanding PAH

Regardless of how much time has passed since you received a diagnosis of pulmonary arterial hypertension (PAH), you may have questions.

In this brochure, we'll help you find answers. We'll go through some important basics that may help you better understand PAH and an available treatment option for adults with PAH (World Health Organization Group 1).

First things first: What is PAH?

A straightforward definition of pulmonary arterial hypertension (PAH) is high blood pressure in the lungs. But living with PAH can feel anything but straightforward. PAH is a complex, serious condition that can make everyday tasks feel more difficult.

Our lungs receive blood from the right side of the heart. As blood is pumped through the blood vessels inside the lungs, it receives oxygen to deliver throughout the body.

For some people, these blood vessels become narrow, so that means that there's less space for the blood to flow. As a result, the heart has to work harder. This raises the blood pressure inside the blood vessels, and ultimately, inside the heart. This increased blood pressure is called pulmonary arterial hypertension, or PAH.

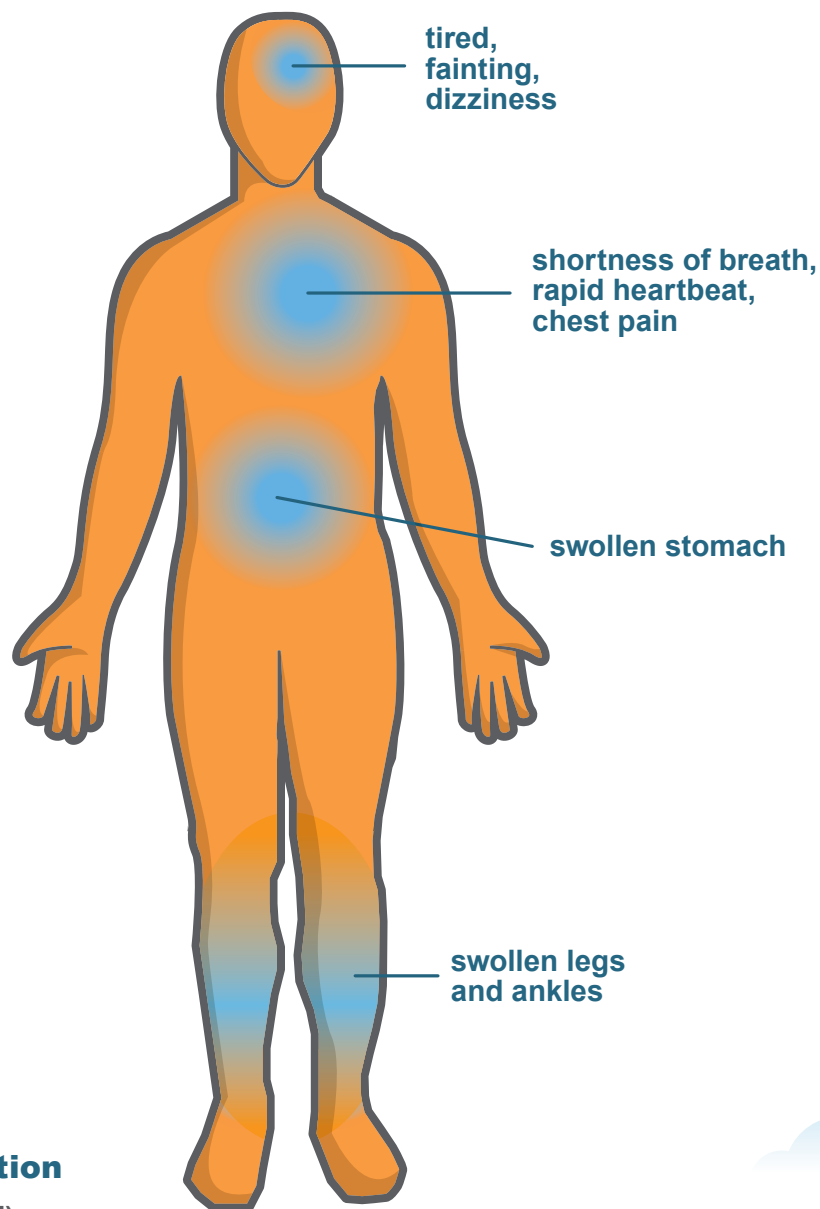


How does PAH feel?

Everyone's experience with PAH is a little different. People with PAH may experience symptoms such as:

- Tiredness
- Fainting
- Dizziness
- Shortness of breath
- Rapid heartbeat
- Chest pain
- Swollen stomach
- Swollen legs and ankles

How often you feel symptoms, and how severe they are, may change over time.



Selected Important Safety Information

WARNINGS AND PRECAUTIONS (continued)

- Treprostinil injection acts by lowering your blood pressure. In some cases, your blood pressure may become too low and cause other side effects. If you also take other drugs that lower your blood pressure, the risk is increased. You should discuss all of your symptoms with your doctor, including those associated with low blood pressure.
- If you have liver problems, your ability to tolerate Treprostinil injection may be affected.
- Because Treprostinil injection can reduce the blood's ability to clot, it may increase your risk of bleeding, especially if you are taking anticoagulants (blood thinners).
- Other medical conditions and medicines may affect your use of Treprostinil injection by increasing the risk of side effects or decreasing the drug's effectiveness. It is important to tell your doctor about your medical conditions and any medicines you may be taking.

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What type of PAH do I have?

The World Health Organization (WHO) has identified different causes for high blood pressure inside the heart and lungs and has created groups based on those causes. Treprostinil Injection is indicated for people in one of these groups, WHO Group 1, which includes PAH that has no known cause, PAH that's inherited, and PAH caused by certain drugs and conditions, such as connective tissue disease.

Treprostinil Injection is indicated only for use in adults with PAH (WHO Group 1).

How is the severity of PAH determined?

There are 4 functional classes to help assess how someone is affected by PAH day to day. These classes help your healthcare provider determine how you are doing. Your functional class may change over time.

Treprostinil Injection was studied in NYHA* Functional Classes II, III, and IV.

NYHA Functional Class I	No limitation on physical activity for the patient. Ordinary physical activity doesn't cause shortness of breath, fatigue, chest pain, or near fainting.
NYHA Functional Class II	Some limitation on physical activity. Patient may feel comfortable when resting, but ordinary activity causes shortness of breath, fatigue, chest pain, or near fainting.
NYHA Functional Class III	Clear limitation on physical activity. Patient may still feel comfortable at rest, but even less than ordinary activity causes shortness of breath, fatigue, chest pain, or near fainting.
NYHA Functional Class IV	Any level of physical activity is uncomfortable. Patient may already have signs of heart failure, and shortness of breath and/or fatigue may be present, even when resting.

*New York Heart Association.

Selected Important Safety Information

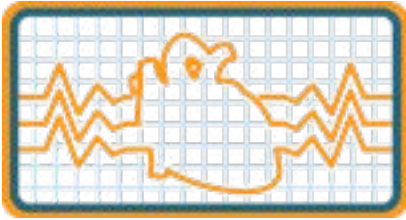
ADVERSE REACTIONS

During clinical trials with SC infusion of treprostinil, infusion site pain and infusion site reaction (e.g., redness of the skin, hardness of the skin, or rash) were the most common adverse events and occurred in the majority of those treated with treprostinil. Infusion site reactions were sometimes severe and led to discontinuation of treatment. Rash and low blood pressure (14% and 4% respectively) were also commonly reported with SC infusion of treprostinil. Other common adverse events ($\geq 3\%$ more than placebo) with either SC or IV treprostinil included headache, diarrhea, jaw pain, edema (swelling), vasodilatation (widening of the blood vessels), and nausea. The adverse reactions with treprostinil IV included bloodstream infections, arm swelling, tingling or prickling sensation, bruising, and pain.

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How does my healthcare provider diagnose and monitor PAH?

Your healthcare team may perform several tests to see what's happening inside your body.



Electrocardiogram (EKG):
Measures the electrical activity of your heart



Pulmonary function test:
Determines how well your lungs are working



6-minute walk test:
Measures the distance you can walk on a flat, hard surface in 6 minutes



Echocardiogram:
Checks the size and function of your heart using ultrasound



Chest x-ray and ventilation perfusion scan:
Provides images of your heart, lungs, and blood vessels



Cardiac catheterization:
Measures the pressure inside your heart and the blood vessels in your lungs

What's next?

Now that we've covered the basics of PAH, it's time to take the next step. In the following pages, you'll learn more about Treprostinil Injection, a treatment for adults with PAH (WHO Group 1) that has been studied in people with NYHA Functional Class II, III, or IV symptoms.

Treprostinil Injection is approved only for a treatment for people with PAH (WHO Group 1).

What is Sandoz® Treprostinil Injection?

Treprostinil Injection is a medicine that is given through a tube inserted under your skin or into a vein. Treprostinil Injection opens up blood vessels and may help relieve some of the common symptoms associated with PAH (WHO Group 1), such as shortness of breath with exercise.

Treprostinil Injection is a generic medicine.

Treprostinil Injection is a generic for the brand name medicine, Remodulin® (treprostinil) Injection, that is used to treat PAH (WHO Group 1). Treprostinil Injection is therapeutically equivalent to the brand name medicine.

Treprostinil Injection is available at generic pricing. Financial assistance for Treprostinil Injection may be available (see page 9).



What are potential side effects of Treprostinil Injection?

With Treprostinil Injection, you may experience side effects, including

- Headaches
- Diarrhea
- Nausea
- Jaw pain
- Reddening of your skin
- Dizziness
- Swelling
- Itching
- Muscle or joint pain
- Low blood pressure

When you have an IV infusion, your blood can become infected if bacteria or other germs get into the bloodstream. Your healthcare team will teach you how to set up your medicine, discuss ways to help you prevent infection, and manage potential side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call **1-800-FDA-1088** or contact Sandoz Inc. at **1-800-525-8747**.

Selected Important Safety Information

DRUG INTERACTIONS

If you are taking gemfibrozil (for high cholesterol), rifampin (for infection), or other drugs that affect liver enzymes, your doctor may need to adjust your Treprostinil injection dosage.

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How do I receive Sandoz® Treprostinil Injection?

Treprostinil Injection is provided by a specialty pharmacy that has pharmacists and nurses with specific training for PAH. Your specialty pharmacy has years of experience supporting people with PAH and medicines like Treprostinil Injection.

Your specialty pharmacy can provide:

- Specialized education from pharmacists and nurses
- Support understanding options to help address side effects*
- In-home or office visits to help you learn how to use Treprostinil Injection at home
- Answers to your questions 24/7
- Help understanding your insurance and financial assistance options

*Contact your healthcare provider for medical advice about managing side effects.

The specialty pharmacy may call from a phone number that you don't recognize. Be sure to answer the phone and return phone calls.

Delays may occur if the specialty pharmacy has trouble reaching you.

**Treprostinil Injection
is available at**

Accredo Health Group, Inc.
Phone **1-866-344-4874**

Is financial assistance available?

Treprostinil Injection co-payment assistance may be available for people who qualify.* If you are eligible, you may pay as little as \$0 per prescription filled for Treprostinil Injection, with up to \$8,000 annually in assistance available.

For information about how to receive co-payment assistance, visit TrepInjection.com or call the Treprostinil Injection Savings Program toll-free at **1-877-251-4947**.



*Treprostinil Injection Savings Program Eligibility

The Treprostinil Injection Savings Program provides up to \$8,000 in annual support for patient cost-sharing for prescriptions filled with Sandoz Treprostinil Injection. For commercially insured patients, you may pay a co-pay as low as \$0 out-of-pocket per Treprostinil Injection prescription filled. Sandoz will pay the balance of your cost-sharing up to \$8,000 per year. This program is not health insurance. This program is for commercially insured patients only; uninsured cash-paying patients are not eligible. Patients are not eligible if prescriptions are paid, in whole or in part, by any state or federally funded programs, including but not limited to Medicare (including Part D, even in the coverage gap) or Medicaid, Medigap, VA, DOD, or TriCare, or private indemnity, or HMO insurance plans that reimburse you for the entire cost of your prescription drugs, or where prohibited by law. Card may not be combined with any other rebate, coupon, or offer. Card has no cash value. Sandoz reserves the right to rescind, revoke, or amend this offer without further notice.

Selected Important Safety Information

USE IN SPECIFIC POPULATIONS

If you are pregnant, planning to become pregnant, or breast-feeding, talk with your doctor about whether you should use Treprostinil injection.

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Indication

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In people with PAH who need to switch from epoprostenol sodium, Treprostinil injection is approved to slow the worsening of symptoms. The risks and benefits of each drug should be carefully considered before switching.

Important Safety Information

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

- Treprostinil injection can be delivered using a tube placed in a big blood vessel (vein) within the chest. This type of delivery is associated with the risk of bloodstream infections and sepsis, which may be fatal. Therefore, continuous subcutaneous infusion delivered just beneath the skin is the preferred method of delivery.
- You should not stop or change your Treprostinil injection dose without consulting your doctor first, as this may cause your PAH symptoms to worsen.
- Treprostinil injection acts by lowering your blood pressure. In some cases, your blood pressure may become too low and cause other side effects. If you also take other drugs that lower your blood pressure, the risk is increased. You should discuss all of your symptoms with your doctor, including those associated with low blood pressure.
- If you have liver problems, your ability to tolerate Treprostinil injection may be affected.
- Because Treprostinil injection can reduce the blood's ability to clot, it may increase your risk of bleeding, especially if you are taking anticoagulants (blood thinners).
- Other medical conditions and medicines may affect your use of Treprostinil injection by increasing the risk of side effects or decreasing the drug's effectiveness. It is important to tell your doctor about your medical conditions and any medicines you may be taking.

ADVERSE REACTIONS

During clinical trials with SC infusion of treprostinil, infusion site pain and infusion site reaction (e.g., redness of the skin, hardness of the skin, or rash) were the most common adverse events and occurred in the majority of those treated with treprostinil. Infusion site reactions were sometimes severe and led to discontinuation of treatment. Rash and low blood pressure (14% and 4%, respectively) were also commonly reported with SC infusion of treprostinil. Other common adverse events ($\geq 3\%$ more than placebo) with either SC or IV treprostinil included headache, diarrhea, jaw pain, edema (swelling), vasodilatation (widening of the blood vessels), and nausea. The adverse reactions with treprostinil IV included bloodstream infections, arm swelling, tingling or prickling sensation, bruising, and pain.

DRUG INTERACTIONS

If you are taking gemfibrozil (for high cholesterol), rifampin (for infection), or other drugs that affect liver enzymes, your doctor may need to adjust your Treprostinil injection dosage.

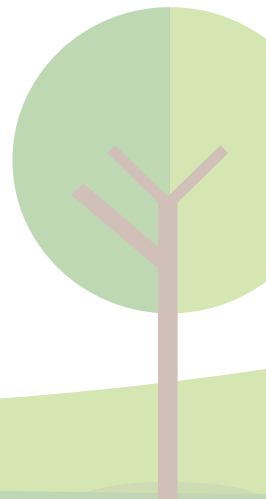
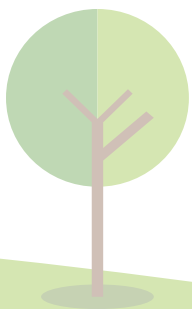
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Treprostinil INJECTION™



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BRIEF SUMMARY OF INFORMATION ABOUT TREPROSTINIL INJECTION

The risk information provided here is not comprehensive. To learn more, talk to your healthcare provider or pharmacist about Treprostinil Injection. The FDA-approved product labeling can be found at www.TreplInjection.com or by calling 1-800-525-8747.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088, or contact Sandoz Inc. at 1-800-525-8747.

What is Treprostinil injection?

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In people with PAH who need to switch from epoprostenol sodium, Treprostinil injection is approved to slow the worsening of symptoms. The risks and benefits of each drug should be carefully considered before switching.

What Warnings should I know about Treprostinil injection?

- Treprostinil injection can be delivered using an intravenous (IV) tube placed in a big blood vessel (vein) within the chest. This type of delivery is associated with the risk of bloodstream infections and sepsis, which may be fatal. Therefore, continuous subcutaneous (SC) infusion delivered just beneath the skin is the preferred method of delivery.
- You should not stop or change your Treprostinil Injection dose without consulting your doctor first, as this may cause your PAH symptoms to worsen.
- Treprostinil injection acts by lowering your blood pressure. In some cases, your blood pressure may become too low and cause other side effects. If you also take other drugs that lower your blood pressure, the risk is increased. You should discuss all of your symptoms with your doctor, including those associated with low blood pressure.
- If you have liver problems, your ability to tolerate Treprostinil injection may be affected.
- Because Treprostinil injection can reduce the blood's ability to clot, it may increase your risk of bleeding, especially if you are taking anticoagulants (blood thinners).

What should I tell my healthcare provider before using Treprostinil injection?

- Other medical conditions and medicines may affect your use of Treprostinil injection by increasing the risk of side effects or decreasing the drug's effectiveness. It is important to tell your doctor about your medical conditions and any medicines you may be taking.
- If you are pregnant, planning to become pregnant, or breast-feeding, talk with your doctor about whether you should use Treprostinil injection.

What are the side effects of Treprostinil injection?

- During clinical trials with SC infusion of treprostinil, infusion site pain and infusion site reaction (e.g., redness of the skin, hardness of the skin, or rash) were the most common adverse events and occurred in the majority of those treated with treprostinil. Infusion site reactions were sometimes severe and led to discontinuation of treatment.
- Rash and low blood pressure (14% and 4%, respectively) were also commonly reported with SC infusion of treprostinil.
- Other common adverse events ($\geq 3\%$ more than placebo) with either SC or IV treprostinil included headache, diarrhea, jaw pain, edema (swelling), vasodilatation (widening of the blood vessels), and nausea.
- The adverse reactions with treprostinil IV included bloodstream infections, arm swelling, tingling or prickling sensation, bruising, and pain.
- In another clinical trial with Treprostinil injection, additional adverse events were reported, including anorexia, vomiting, asthenia (weakness), and abdominal pain.
- Since FDA approval of Treprostinil Injection, the following events have been reported: blood clot that blocked one or more veins associated with peripheral IV infusion, low blood platelet count, bone pain, itching of the skin, dizziness, joint pain, muscle pain/muscle spasm, and pain in extremity. In addition, generalized rashes, sometimes consisting of spots or bumps, and bacterial infection of the skin have been infrequently reported.

What other medications might interact with Treprostinil injection?

If you are taking gemfibrozil (for high cholesterol), rifampin (for infection), or other drugs that affect liver enzymes, your doctor may need to adjust your Treprostinil injection dosage.

What other information should I know about Treprostinil injection?

- Safety and effectiveness of Treprostinil Injection in pediatric patients have not been established. It is not known if pediatric patients respond differently than adults.
- It is unknown if elderly patients respond differently than younger patients. In general, dose selection for elderly patients should be done with caution.
- Seek medical attention if you suspect a pump malfunction or if you experience signs or symptoms of treprostinil overdose, such as flushing, headache, low blood pressure, nausea, vomiting, and diarrhea.

Manufactured in Canada by
Sandoz Canada Inc. for
Sandoz Inc., Princeton, NJ 08540

For more information, go to www.TreplInjection.com or call 1-800-525-8747.
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