

getting started WITH ORENITRAM

IMPORTANT SAFETY INFORMATION for Orenitram

Who should not take Orenitram?

Do not take Orenitram if you have severe liver problems.





You're ready to do more with Orenitram

Together with your healthcare provider, you have made the important decision to add Orenitram to your current treatment plan. **That's a big step!** Orenitram is proven to delay the progression of PAH and may help improve symptoms to help you do more and help control your PAH.

You may have questions about how Orenitram could help you and what to expect. This guide was created to answer some of these questions and provide you with information that you can use over the course of your treatment:

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How could treatment with Orenitram help me?	6
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For your convenience, we've included some emergency contact cards that you can easily keep in a wallet or pocket. You'll find these cards on page 18.

What is Orenitram?

Orenitram is a prescription medicine used to treat pulmonary arterial hypertension (PAH) which is high blood pressure in the arteries of your lungs. Orenitram can help slow down the progression of your disease and improve your ability to exercise. It is not known if Orenitram is safe and effective in children.

PAH=pulmonary arterial hypertension.

BB With Orenitram, I feel like
I can do more things that
I want to do, like cooking
or baking—things that are
important to me personally.

- Angelie, an Orenitram patient

IMPORTANT SAFETY INFORMATION for Orenitram

What should I tell my healthcare provider before taking Orenitram?

Tell your healthcare provider:

If you have liver problems or diverticulosis.





What is Orenitram?

Orenitram is an oral prostacyclin medicine that works differently from other oral medicines you may already be taking for PAH.

PAH symptoms can occur when the blood vessels inside your lungs become narrow, making it harder for blood to flow. These changes are thought to be caused by imbalances of natural substances in 3 pathways in your body. There are medicines that treat each of those 3 pathways:

O ENDOTHELIN O PROSTACYCLIN

Depending on which pathway you are treating, there may be more you can do. Your healthcare provider has added Orenitram to help make sure you don't miss out on treating the prostacyclin pathway.

IMPORTANT SAFETY INFORMATION for Orenitram

What should I tell my healthcare provider before taking Orenitram? (cont)

Tell your healthcare provider:

• If you are pregnant, breastfeeding, and/or plan to become pregnant or breastfeed. It is not known if Orenitram will harm your unborn baby or if Orenitram passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with Orenitram.

EXTENDED-RELEASE TABLETS

How does Orenitram work?





When you have PAH, your body may not produce enough prostacyclin, a natural substance that keeps your blood vessels open and working properly.

Orenitram mimics the effects of natural prostacyclin, helping to open up blood vessels so it's easier for your heart to pump blood through your lungs.

Orenitram helps to replace the natural prostacyclin you may be missing.

IMPORTANT SAFETY INFORMATION for Orenitram

What should I tell my healthcare provider before taking Orenitram? (cont)

Tell your healthcare provider:

About all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Orenitram and other medicines may affect each other causing side effects. Do not start any new medicine until you check with your healthcare provider. Especially tell your healthcare provider if you take another medicine that contains treprostinil, such as Remodulin® or Tyvaso®.



How could treatment with Orenitram help me?

Orenitram is proven to delay the progression of PAH and may help reduce symptoms. Orenitram is the tablet form of the same proven and trusted type of medicine that has been available as a pump therapy for more than 18 years.

Proven to delay disease progression

In a clinical study, patients who added Orenitram were...

61% LESS LIKELY

TO HAVE THEIR PAH PROGRESS OVER TIME COMPARED WITH THOSE NOT TAKING ORENITRAM*

Before I was taking Orenitram, I was so short of breath and had trouble doing everyday things. I feel like it really does help.

- Angelie, an Orenitram patient

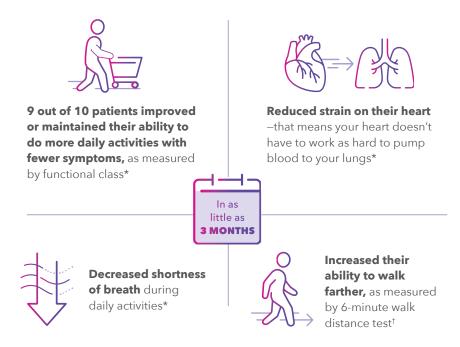
IMPORTANT SAFETY INFORMATION for Orenitram

How should I take Orenitram?

- Do not change your dose or suddenly stop taking Orenitram without first talking to your healthcare provider.
- Orenitram is usually taken 3 times a day (about every 8 hours) or 2 times a day (about every 12 hours). Your healthcare provider will tell you how often you should take Orenitram. If you have side effects, your healthcare provider may tell you to change your dose or when you take Orenitram. Take Orenitram with food.

Orenitram may help you do more and help control your PAH

In clinical studies, adding Orenitram helped patients improve in several ways:



^{*}In a clinical study that included 690 patients who were all taking a single oral PAH medicine (PDE-5i, sGCS, or ERA). At the beginning of the study, these patients added either Orenitram or placebo to their treatment.

IMPORTANT SAFETY INFORMATION for Orenitram

How should I take Orenitram? (cont)

 Swallow Orenitram tablets whole. Do not split, chew, crush, or break your Orenitram tablets. Do not take Orenitram tablets that are damaged or broken. If Orenitram tablets are not taken whole, they may release too much medicine at one time. This can lead to side effects.

Please see complete Important Safety Information throughout and Full Prescribing Information and Patient Information for Orenitram at www.orenitram.com.

ERA=endothelin receptor antagonist; PDE-5i=phosphodiesterase type 5 inhibitor; sGCS=soluble guanylate cyclase stimulator.



[†]In a clinical study that included 349 patients not taking any PAH therapy. At the beginning of the study, these patients began taking either Orenitram or placebo.

Orenitram may help improve your risk status*



Patients taking Orenitram either improved or maintained their risk status—and improvement was seen as early as 3 months. In fact, more than 30% of patients improved and were able to maintain improvement through week 60.

What is risk status and why is it important?

Your healthcare provider may use risk status to make decisions about your treatment. It helps them determine how you're doing today and predict how you will be doing in the future. It is based on a combination of factors such as your 6-minute walk distance test, functional class, and strain on the heart, as measured by NT-proBNP.

Want advice and tips to keep you motivated and on track with Orenitram? Orenitram Connect can provide you with information and resources through a series of emails and mailings. To join, please fill out and return the reply card included in this kit.



*In a clinical study that included 690 patients who were all taking a single oral PAH medicine (PDE-5i, sGCS, or ERA). At the beginning of the study, these patients added either Orenitram or placebo to their treatment.

IMPORTANT SAFETY INFORMATION for Orenitram

How should I take Orenitram? (cont)

- If you miss your dose of Orenitram, take the missed dose as soon as possible with food.
- If you miss 2 or more doses of Orenitram, call your healthcare provider to see if you need to change your dose.

NT-proBNP=N-terminal pro-B-type natriuretic peptide.



Your personalized dosing plan

Your healthcare provider will slowly increase or adjust your dose of Orenitram to help find the most effective dose for you.

Since PAH is a progressive disease, your treatment needs may change over time.

With Orenitram, you may not have to start a new medication. Your healthcare provider can continue to increase or change your dose to meet your needs so you may be able to stay with Orenitram for the long term to help control your PAH.† It's important that you continue working with your healthcare provider to find the right dose for you.











Orenitram is available in 5 tablet strengths, making it easier for your healthcare provider to adjust your dose.

Not shown at actual size.

IMPORTANT SAFETY INFORMATION for Orenitram

How should I take Orenitram? (cont)

• If you take too much Orenitram, call your healthcare provider or go to the nearest hospital emergency room right away.



[†]There is no maximum dose for Orenitram, so your healthcare provider can continue to increase your dose as long as you are able to tolerate the medication.

GG Orenitram helps me every day.

Just getting up from the bed,

walking, going to the kitchen—

the simple things.

- Angelie, an Orenitram patient

How can higher doses help me reach my treatment goals?

In a clinical study, patients who achieved a dose of Orenitram of at least 3 mg, 3 times per day, were able to walk farther and had less shortness of breath after 24 weeks. That's why it's important to work with your healthcare provider to achieve a dose of Orenitram that will help you reach your treatment goals.

Do not stop taking Orenitram without consulting your healthcare provider.

IMPORTANT SAFETY INFORMATION for Orenitram

How should I take Orenitram? (cont)

 You may see the tablet shell in your stools (bowel movements). This is usually normal.
 The tablet shell is not digested. If you have diverticulosis, the tablet shell may get stuck in a blind pouch or diverticulum in your intestine.



SUPPORT

How will I take Orenitram?

The usual dosing schedule of Orenitram is 3 times a day with food*-roughly every 8 hours. That could mean a dose with breakfast, a dose with an afternoon snack, and a dose with a bedtime snack.



Orenitram should be taken with food because it helps your body absorb Orenitram. You don't have to take Orenitram with a full meal—you can take it with snacks as well. What's important is developing a routine that fits into your lifestyle. You can talk with your healthcare team about food choices and combinations that may work best for you. While it's important to take Orenitram with food, do not add it into your food.

IMPORTANT SAFETY INFORMATION for Orenitram

What are the possible side effects of Orenitram?

Orenitram can cause serious side effects, including worsening of PAH symptoms.

 Stopping Orenitram suddenly may cause worsening of your PAH symptoms. Do not change your dose or suddenly stop taking Orenitram without first talking to your healthcare provider.



^{*}Orenitram may also be taken 2 times a day (every 12 hours). Tablet strength may be increased depending on how well you tolerate treatment.

ABOUT ORENITRAM

Working side by side with your healthcare team



During treatment with Orenitram, you can be honest and open with your healthcare team about how you are feeling about treatment and any side effects you are experiencing. Your healthcare team is there to help you each step of the way, be the best source of information about your treatment, and work alongside you to make sure you get the most out of treatment.

Orenitram may cause side effects. Talking with your healthcare team about potential side effects and working with them to develop a plan can help you feel prepared. The most common side effects with Orenitram include:

- Headache
- Nausea
- Flushing

- Diarrhea
- Vomiting
- Pain in the arms, legs, and jaw



Let your healthcare team know about all of the medicines you are taking, including prescriptions, over-the-counter medicines, vitamins, and herbal supplements. It may be helpful to keep a list of the medicines you take and their doses so that you can discuss them with your healthcare provider and pharmacist.

To learn more about side effects and how you and your healthcare team can create a plan to manage them, please see the **Patient Treatment Journal** provided in this kit.



IMPORTANT SAFETY INFORMATION for Orenitram

What are the possible side effects of Orenitram? (cont)

• The most common side effects of Orenitram include headache, diarrhea, nausea, vomiting, flushing, and pain in arms, legs, and jaw. These are not all of the possible side effects of Orenitram. Tell your healthcare provider if you have any side effect that bothers you or does not go away.

GG I feel like I've taken back some control with Orenitram.

I don't have to think about my symptoms as much. I'm looking forward again to doing the things that I want to do.

- Angelie, an Orenitram patient

It can take time to find the dose that is right for you, and you may have side effects before you begin to feel better—but it's important to hang in there to give the medicine a chance to act in your body. Speak with your healthcare provider if side effects occur and work with them to help you stay on therapy.

IMPORTANT SAFETY INFORMATION for Orenitram

What are the possible side effects of Orenitram? (cont)

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





What support is available during treatment?

Support from the start–Get to know your Access Solutions and Support Team (ASSIST)



ASSIST is a team at United Therapeutics, the maker of Orenitram, committed to helping you with your prescription. Within 24 hours of receiving your Orenitram prescription, ASSIST will contact you so they can:

- Verify your insurance information
- Review next steps
- Discuss eligibility for financial assistance options such as the Orenitram co-pay program
- Connect you with a Specialty Pharmacy

IMPORTANT SAFETY INFORMATION for Orenitram

Who should not take Orenitram?

Do not take Orenitram if you have severe liver problems.



Be sure to answer or return any calls from ASSIST so you can get started on your treatment with Orenitram. The caller ID will be labeled as ASSIST, with a Melbourne, Florida, area code of 321.

You can reach an ASSIST Case Manager Monday through Friday, 8:30 AM-7:00 PM ET, by calling 1-877-864-8437

Or you can visit:

www.UTAssist.com/patient

An ASSIST team member will be available throughout the process to answer any questions you have.

IMPORTANT SAFETY INFORMATION for Orenitram

What should I tell my healthcare provider before taking Orenitram?

Tell your healthcare provider:

• If you have liver problems or diverticulosis.



What is a Specialty Pharmacy and how can it help?

After your initial call with ASSIST, they will have forwarded your prescription, insurance information, and financial program eligibility to your Specialty Pharmacy (SP).

The SP does more than your typical neighborhood pharmacy and will work with your healthcare team to help with various aspects of your treatment, such as:



Your SP is also there to help answer any questions you may have about your treatment.

At United Therapeutics, we work with two Specialty Pharmacies that specialize in PAH. Your Orenitram prescription will be handled and delivered by these SPs, instead of your local pharmacy.

Specialty Pharmacy providers:



IMPORTANT SAFETY INFORMATION for Orenitram

What should I tell my healthcare provider before taking Orenitram? (cont)

Tell your healthcare provider:

If you are pregnant, breastfeeding, and/or plan to become pregnant or breastfeed.
 It is not known if Orenitram will harm your unborn baby or if Orenitram passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with Orenitram.

EXTENDED-RELEASE TABLETS

Making the most out of SP nurse visits



Once your first shipment arrives, a registered nurse will visit you virtually or in the comfort of your own home, at a time that is convenient for you.

Topics you may want to talk about with your SP nurse:

Ouring your first nurse visit

- Discuss the plan that you and your healthcare team have developed to address possible side effects
- Meal and snack options when taking Orenitram
- Fitting Orenitram into your schedule
- The process of taking and dosing Orenitram
- How to know that Orenitram is starting to work

Ouring follow-up nurse visits or calls

- Available online or local support groups
- Keeping track of your progress with Orenitram

IMPORTANT SAFETY INFORMATION for Orenitram

What should I tell my healthcare provider before taking Orenitram? (cont)

Tell your healthcare provider:

• About all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Orenitram and other medicines may affect each other causing side effects. Do not start any new medicine until you check with your healthcare provider. Especially tell your healthcare provider if you take another medicine that contains treprostinil, such as Remodulin® or Tyvaso®.

Emergency contact cards

These cards can be helpful in case anyone needs to contact your healthcare provider immediately.

Fill in the cards with your important contact information and print them out so you can keep them handy in your wallet or purse.

IMPORTANT INFORMATION IN CASE OF EMERGENCY

I have a serious medical condition and am currently taking a prescribed oral medication called Orenitram® (treprostinil) Extended-Release Tablets. It is very important that I do not miss a dose or stop taking my medicine suddenly. Orenitram inhibits platelet aggregation and may cause an increased risk of bleeding, especially in patients on anticoagulation.

NAME:	DATE OF BIRTH:	1	1	
ADDRESS:				
CITY, STATE, ZIP:				
PHONE NUMBER:()				
IN THE EVENT OF AN EMERGENC OF THE PEOPLE LISTED ON TH	IE BACK OF THIS	CARE).	
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NAME:	DATE OF BIRTH:	1		
ADDRESS:				
CITY, STATE, ZIP:				
PHONE NUMBER:()				

IN THE EVENT OF AN EMERGENCY, PLEASE CONTACT ONE OF THE PEOPLE LISTED ON THE BACK OF THIS CARD.

Emergency contact cards

These cards can be helpful in case anyone needs to contact your healthcare provider immediately.

Fill in the cards with your important contact information and print them out so you can keep them handy in your wallet or purse.

		Orenitram® (treprostinil) Extended-Release Tablets medication.	
	DOCTOR:	Name:Phone number:()	
	SPECIALTY PHARMACY:	Name:Phone number:()	
	EMERGENCY CONTACT:	Name:Phone number:	
		DIAL 911 FOR IMMEDIATE ASSISTANCE.	
IN CASE OF EMERGENCY Please contact one of the following people regarding my Orenitram® (treprostinil) Extended-Release Tablets medication.			
	DOCTOR:	Name:Phone number:	
	SPECIALTY PHARMACY:	Name:Phone number:	
	EMERGENCY	Name:	

DIAL 911 FOR IMMEDIATE ASSISTANCE.

CONTACT:

Phone number: (

IN CASE OF EMERGENCY
Please contact one of the following people regarding my

Notes

Notes/Questions:

IMPORTANT SAFETY INFORMATION for Orenitram

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Orenitram Connect—Helpful information and resources



Orenitram Connect is a program that gives you access to helpful resources that will provide additional information about Orenitram. These resources include:

- E-newsletters, emails, and mailings with useful tips
- Information about your treatment
- Additional tools

Enroll today by visiting **www.orenitram.com**.

IMPORTANT SAFETY INFORMATION for Orenitram

How should I take Orenitram? (cont)

- Swallow Orenitram tablets whole. Do not split, chew, crush, or break your Orenitram tablets. Do not take Orenitram tablets that are damaged or broken. If Orenitram tablets are not taken whole, they may release too much medicine at one time. This can lead to side effects.
- If you miss your dose of Orenitram, take the missed dose as soon as possible with food.



SOOD days WITH ORENITRAM

Orenitram is proven to delay the progression of PAH and may help reduce symptoms to help you do more and help control your PAH. By working alongside your healthcare team, you can be prepared to get the most out of your treatment.



GG Every day feels like a victory for me. I can wake up and not be out of breath. I like that I don't have to ask someone for help to get a chore done.

– Angelie, an Orenitram patient



For additional information, visit **www.orenitram.com**, talk to your healthcare team, or call 1-877-UNITHER (1-877-864-8437).

IMPORTANT SAFETY INFORMATION for Orenitram

The risk information provided here is not comprehensive. To learn more about Orenitram, talk with your healthcare provider. Please see Full Prescribing Information and Patient Information at www.orenitram.com or call Customer Service at 1-877-UNITHER (1-877-864-8437).

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Please see complete Important Safety Information throughout and Full Prescribing Information and Patient Information for Orenitram at www.orenitram.com. orenitram treprostinil

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