Patient Information
Orenitram(R) (oh-REN-i-tram)
(treprostinil) extended-release tablets

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 may improve your ability to exercise.

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

Who should not take Orenitram?

Do not take Orenitram if you have severe liver problems.

What should I tell my healthcare provider before taking Orenitram?

Before you take Orenitram, tell your healthcare provider if you:

- have liver problems
- have diverticulosis
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if Orenitram will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Orenitram passes into your breast milk. You and your healthcare provider should decide if you will take Orenitram or breastfeed. You should not do both.

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®.

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

How should I take Orenitram?

- Take Orenitram exactly as your healthcare provider tells you to take it.
- Your healthcare provider will slowly increase your dose to find the dose of Orenitram that is right for you.
- If you take the medicine Remodulin and your healthcare provider is switching you to Orenitram, your healthcare provider will decrease your dose of Remodulin over a period of time when you start taking Orenitram.
- **Do not change your dose or suddenly stop taking Orenitram without first talking to your healthcare provider. Stopping Orenitram suddenly may cause worsening of your PAH symptoms.**
- Orenitram is usually taken 2 times a day (about every 12 hours) or three times a day (about every 8 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.
- 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.**
- 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.
- If you miss your dose of Orenitram, take the dose as soon as possible with food.
- If you miss two or more doses of Orenitram, call your healthcare provider to see if you need to change your dose.
- If you take too much Orenitram, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of Orenitram?

Orenitram can cause serious side effects, including an increased risk of bleeding.

The most common side effects of Orenitram include:

- headache
- nausea
- diarrhea
- flushing

The following side effects have also been observed in patients taking Orenitram after approval: dizziness, indigestion, vomiting, muscle pain, and joint pain.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Orenitram. For more information, ask your healthcare provider or pharmacist.

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 Orenitram?

- Store Orenitram at room temperature between 68°F to 77°F (20°C to 25°C).

Keep Orenitram and all medicines out of the reach of children.

General information about the safe and effective use of Orenitram.

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

What are the ingredients in Orenitram?

Active ingredient: treprostinil
Inactive ingredients: xylitol, maltodextrin, sodium lauryl sulfate, magnesium stearate, cellulose acetate, triethyl citrate, polyvinyl alcohol, titanium dioxide, polyethylene glycol, and talc. In addition tablets may contain colorants FD&C Blue #2, iron oxide yellow, and iron oxide red. The imprinting ink contains shellac glaze, ethanol, isopropyl alcohol, iron oxide black, n-butyl alcohol, and propylene glycol.

United Therapeutics Corp., Research Triangle Park, NC 27709 USA
Copyright 2017, United Therapeutics Corp. All rights reserved.
ORENITRAM is a registered trademark of United Therapeutics Corp.
For more information, go to www.ORENITRAM.com or call 1-877-864-8437.

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 06 2017