Orenitram is a prostacyclin vasodilator indicated for treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity.

The study that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (75%) or PAH associated with connective tissue disease (19%). When used as the sole vasodilator, the effect of Orenitram on exercise is about 10% of the deficit, and the effect, if any, on a background of another vasodilator is probably less than this.

orenitram®
treprostinil
EXTENDED-RELEASE TABLETS

The VA Medical Facilities Orenitram Referral Form

IMPORTANT SAFETY INFORMATION for Orenitram

CONTRAINDICATIONS

- Orenitram is contraindicated in patients with severe hepatic impairment (Child Pugh Class C)

WARNINGS AND PRECAUTIONS

- Abrupt discontinuation or sudden large reductions in dosage of Orenitram may result in worsening of PAH symptoms
- Orenitram inhibits platelet aggregation and increases the risk of bleeding
- The Orenitram tablet shell does not dissolve. In patients with diverticulosis, Orenitram tablets can lodge in a diverticulum

DRUG INTERACTIONS / SPECIFIC POPULATIONS

- Concomitant administration of Orenitram with diuretics, antihypertensive agents, or other vasodilators increases the risk of symptomatic hypotension
- Orenitram inhibits platelet aggregation; there is an increased risk of bleeding, particularly among patients receiving anticoagulants
- Co-administration of Orenitram and the CYP2C8 enzyme inhibitor gemfibrozil increases exposure to treprostinil; therefore, Orenitram dosage reduction may be necessary in these patients
- Pregnancy Category C. Animal reproductive studies with Orenitram have shown an adverse effect on the fetus. There are no adequate and well-controlled studies in humans
- It is not known whether treprostinil is excreted in human milk or absorbed systemically after ingestion. Because many drugs are excreted in human milk, choose Orenitram or breastfeeding
- Safety and effectiveness in patients under 18 years of age have not been established
- There is a marked increase in the systemic exposure to treprostinil in hepatically impaired patients

ADVERSE REACTIONS

- In the 12-week placebo-controlled monotherapy study, adverse reactions that occurred at rates at least 5% higher on Orenitram than on placebo included headache, diarrhea, nausea, flushing, pain in jaw, pain in extremity, hypokalemia, and abdominal discomfort

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Please see the accompanying Full Prescribing Information and Patient Information for Orenitram.

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

Orenitram® (treprostinil) Extended-Release Tablets
VA Medical Facilities Referral Form

ACCREDO
FAX: 1-800-711-3526
PHONE: 1-866-344-4874

CVS/CAREMARK
FAX: 1-877-943-1000
PHONE: 1-877-242-2738

A PATIENT INFORMATION

Name: First	Middle	Last
Date of Birth	Gender	
Home Address		
City	State	Zip
Telephone	Alternate Telephone	Best Time to Call
E-mail Address		
Caregiver/Family Member	Telephone	Alternate Telephone

B VA PHARMACY INFORMATION

Name of VA facility:

Address:	Suite:	City:	State:	Zip:
Contact name:		Contact phone #:	Contact fax #:	
Ship to address:	Suite:	City:	State:	Zip:
Purchase #:	Ship to:	◉ Patient	○ VA location	

C PRESCRIBER INFORMATION

Prescriber: First	Last	
NPI #	State License #	
Facility Name		
Address		
City	State	Zip
Office Contact Name	Telephone	Fax
E-mail Address	Preferred Method of Communication	

D MEDICAL INFORMATION / PATIENT EVALUATION

Patient UT PAH Product Therapy Status for the requested drug
☐ Naive/New ☐ Restart ☐ Transition

Patient Status
☐ Outpatient ☐ Inpatient

Allergies
☐ Yes ☐ No If yes _____

WHO Group

NYHA Functional Class
☐ I ☐ II ☐ III ☐ IV

Weight _____ kg/lb Height _____ Diabetic ☐ Yes ☐ No

Diagnosis - The following ICD-10

ICD-10 I27.0 Primary pulmonary hypertension

☐ Idiopathic PAH ☐ Heritable PAH ☐ Other _____

List PAH-specific medications patient is taking or has taken _____

E PRESCRIPTION INFORMATION (the prescription is only valid if received by fax)

Orenitram® (treprostinil) Extended-Release Tablets

STRENGTHS (Prior authorizations may be required for each strength and patient may need all strengths to reach target dose):

☐ 0.125 mg (NDC 66302-300-01) ☐ 0.25 mg (NDC 66302-302-01) ☐ 1 mg (NDC 66302-310-01) ☐ 2.5 mg (NDC 66302-325-01) ☐ 5 mg (NDC 66302-350-01)

DOSAGE (TID dosing may reduce peak-to-trough pharmacokinetic fluctuations):

○ **3 times/day (TID)** _____mg. Titrate by _____mg every _____days until goal of _____mg 3 times/day is achieved

OR ○ **2 times/day (BID)** _____mg. Titrate by _____mg every _____days until goal of _____mg 2 times/day is achieved

PRESCRIBER TO SPECIFY ANY ALTERNATIVE OR ADDITIONAL DOSING AND TITRATION INSTRUCTIONS HERE.

_____

DIRECTIONS: Take tablets by mouth with food

DISPENSE: Quantity sufficient for up to maximum allowable dose for One (1) month's supply. Refills _____12 Months OR Refills _____Time

For Orenitram dosing and titration information, please see the Dosage and Administration section of the Prescribing Information.

Specialty Pharmacy to contact Prescriber for adjustments to written orders specified above.

Nurse Visits (Optional)

CHECK HERE

Please select an option:

☐ **Specialty Pharmacy home healthcare RN visit(s)** to provide education on self-administration of Oreitram to include dose and titration *(Schedule – PAH RN Visits Day 1, Weeks 2, 4, 6, 8, and 12)*

OR

☐ **Prescriber directed Specialty Pharmacy home healthcare RN visit(s) as detailed below:**

_____

_____

F PRESCRIBER SIGNATURE: PRESCRIPTION AND STATEMENT OF MEDICAL NECESSITY

I certify that the medication ordered above is medically necessary and that I am personally supervising the care of this patient. I authorize United Therapeutics ASSIST to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the Patient utilizing their benefit plan.

SIGN HERE

PHYSICIAN SIGNATURE REQUIRED TO VALIDATE PRESCRIPTIONS.

Physician's signature_____ **Physician's signature**_____ **Date**_____

Dispense as Written Substitution allowed

(Physician attests this is his/her legal signature. NO STAMPS.) **PRESCRIPTIONS MUST BE FAXED.**

orenitram® treprostinil EXTENDED-RELEASE TABLETS

Please see Indication and Important Safety Information on the cover page and the accompanying Full Prescribing Information and Patient Information for Orenitram.

United Therapeutics CORPORATION