

RemunityPRO™ Pump for Remodulin® (treprostinil) Injection

Indication

The RemunityPRO Pump for Remodulin (treprostinil) Injection is intended for continuous subcutaneous delivery of Remodulin (treprostinil) Injection for use in patients, ages 17 and older.

Important Safety Information for RemunityPRO

Warnings and Cautions

Do not use the system outside the conditions listed in the User Guide. Retain the User Guide for future reference. Refer to the User Guide for all warnings and cautions. Failure to comply with the following warnings and cautions may result in harm.

Limited to use with Remodulin. Only RemunityPRO cassettes may be used with the RemunityPRO pump. RemunityPRO pump is for use only with FDA-cleared infusion sets: Medtronic Quick-set Infusion Set (MMT-392, MMT-393), Neria Guard (704060-5229, 704060-5226), Medtronic Silhouette Infusion Set (MMT-373), and Smiths Medical Cleo 90 Infusion Set (21-7230-24, 21-7220-24).

Do not use disposables from previously opened or damaged sterile packaging, damaged disposable components, or expired sterile components. If the pump or remote fail to work as detailed in the user guide, stop using the pump and remote and switch to the alternate pump and remote included with your system. Only use the supplied cables with your RemunityPRO system as other cables could interfere with pump function. Disconnect the infusion set tubing from your infusion site before removing the cassette from the pump. Avoid exposure of your pump and cassette to temperatures below 41°F (5°C) or above 104°F (40°C). The pump may affect nearby electrical and electronic devices, including medical devices, cell phones, Bluetooth devices, RFID readers, Wi-Fi equipment, and strong magnetic fields causing these devices to operate abnormally or to stop functioning. Keep the pump, remote, and battery charger at least 12 inches (30 cm) away from electrical, medical, and wireless devices. Do not open, crush, heat above 140°F (60°C), or incinerate the pump battery or remote, as doing so can lead to fire, burns, and property damage. This system supports flow rates between 8 µL/h and 225 µL/h. If the required flow rate is outside this range, discuss with your Specialty Pharmacy or healthcare provider.

Prescription Information

Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare provider. Use of this device without the training and supervision of a healthcare provider may lead to errors that result in harm.

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See the RemunityPRO Pump for Remodulin (treprostinil) Injection User Guide for further detailed important safety information including warnings, cautions, and instructions on how to properly use the system.

For further information, please call United Therapeutics Corp. at 1-844-864-8437.

The RemunityPRO Pump for Remodulin (treprostinil) Injection is manufactured for United Therapeutics Corp.

You may report side effects to the FDA at www.fda.gov/MedWatch or call 1-800-FDA-1088.

Remodulin® (treprostinil) Injection

What is Remodulin?

Remodulin is a prescription medication used to treat adults with pulmonary arterial hypertension (PAH; WHO Group 1), which is high blood pressure in the arteries of your lungs. Remodulin can reduce symptoms associated with exercise. Remodulin was studied mainly in patients with NYHA Functional Class II-IV symptoms. It is not known if Remodulin is safe and effective in children.

In people with PAH who need to switch from epoprostenol, Remodulin is approved to slow the worsening of symptoms.

Important Safety Information for Remodulin

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

- Have other medical conditions or take other medicines that may affect your use of Remodulin by increasing the risk of side effects or decreasing the drug's effectiveness.
- Have liver problems. Your Remodulin dose may need to be adjusted if you have liver problems.
- Have low blood pressure or bleeding problems.
- Are taking gemfibrozil (for high cholesterol), rifampin (for infection) or other drugs that affect liver enzymes. Your doctor may need to adjust your Remodulin dosage.
- Are pregnant, breastfeeding, or planning to become pregnant. It is not known if Remodulin will harm your unborn baby or if Remodulin passes into your breast milk.

What are the serious side effects of Remodulin?

- Continuous intravenous (IV) infusions of Remodulin delivered using an external infusion pump, with a tube placed in a central vein within the chest, are associated with the risk of blood stream infections and sepsis, which may be fatal. Therefore, continuous subcutaneous (SC) infusion delivered just beneath the skin is the preferred type of delivery.
- Worsening of PAH symptoms. Do not stop taking or greatly reduce your Remodulin dose without consulting your doctor.
- Low blood pressure (symptomatic hypotension). If you have low blood pressure or are taking drugs that lower your blood pressure, the risk of low blood pressure is increased.
- Bleeding problems. Remodulin may increase the risk of bleeding in people who take blood thinners (anticoagulants).

What are the possible side effects of Remodulin?

- In clinical studies of SC infusion of Remodulin, most people experienced infusion site pain and infusion site reaction (redness, swelling, and rash). These symptoms were sometimes severe and sometimes required treatment with narcotics or discontinuation of Remodulin.
- IV infusion of Remodulin delivered through an external pump has been associated with the risk of blood stream infections, arm swelling, tingling sensations, bruising, and pain.
- The most common side effects seen with either SC or IV Remodulin were headache, diarrhea, nausea, rash, jaw pain, widening of the blood vessels (vasodilatation), and swelling from fluid retention (edema). These are not all the possible side effects of Remodulin. Call your doctor 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.

The risk information provided here is not comprehensive. To learn more about Remodulin, talk with your healthcare provider. Please see [Full Prescribing Information](#) at www.remodulin.com or call Customer Service at 1-844-UNITHER (1-844-864-8437).