Remunity® Pump for Remodulin® (treprostinil) Injection

Indication

The Remunity Pump for Remodulin (treprostinil) Injection is intended for continuous subcutaneous delivery of Remodulin (treprostinil) Injection for use in adults (greater than 22 years of age).

Important Safety Information for Remunity

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 Remunity cassettes may be used with the Remunity pump. Remunity pump is for use only with FDA-cleared infusion sets: Medtronic Quick-set Infusion Set (MMT-392, MMT-393), 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. Discontinue use of the remote and switch to the spare remote in the event the remote fails to operate. The use of cables, batteries, and battery chargers other than those provided or specified may result in increased emission or decreased immunity of the Remunity pump infusion system. Do not disconnect the pump from the cassette while the cassette is connected to the catheter. 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. Do not open, crush, heat above 140°F (60°C), or incinerate the pump battery or remote, as doing so can lead to fire or rapid spreading of fire resulting in harm. This system supports flow rates between 16 µL/h and 225 µL/h. If your flow rate is outside this range, discuss with your healthcare practitioner.

Prescription Information

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

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See the Remunity 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 1-877-864-8437.

The Remunity 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

Indication or 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 or kidney 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 1-877-UNITHER (1-877-864-8437).

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