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.

Remodulin® (treprostinil) Injection

Indication

Remodulin is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%).

In patients with PAH requiring transition from epoprostenol, Remodulin is indicated to diminish the rate of clinical deterioration. Consider the risks and benefits of each drug prior to transition.

Important Safety Information for Remodulin

Warnings and Precautions

- Chronic intravenous (IV) infusions of Remodulin delivered using an external infusion pump with an indwelling central venous catheter are associated with the risk of blood stream infections (BSIs) and sepsis, which may be fatal. Therefore, continuous subcutaneous (SC) infusion is the preferred mode of administration.
- Avoid abrupt withdrawal or sudden large reductions in dosage of Remodulin, which may result in worsening of PAH symptoms.
- Titrate slowly in patients with hepatic or renal insufficiency, because such patients will likely be exposed to greater systemic concentrations relative to patients with normal hepatic or renal function.
- Remodulin is a pulmonary and systemic vasodilator. In patients with low systemic arterial pressure, treatment with Remodulin may produce symptomatic hypotension.
- Remodulin inhibits platelet aggregation and increases the risk of bleeding.

Adverse Reactions

- In clinical studies of SC Remodulin infusion, the most common adverse events reported were 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. The IV infusion of Remodulin with an external infusion pump has been associated with a risk of blood stream infections, arm swelling, paresthesias, hematoma, and pain. Other common adverse events (≥3% more than placebo) seen with either SC or IV Remodulin were headache (27% vs. 23%), diarrhea (25% vs. 16%), nausea (22% vs. 18%), rash (14% vs. 11%), jaw pain (13% vs. 5%), vasodilatation (11% vs. 5%), edema (9% vs. 3%), and hypotension (4% vs. 2%).

Drug Interactions

- Remodulin dosage adjustment may be necessary if inhibitors or inducers of CYP2C8 are added or withdrawn.

Specific Populations

- In patients with mild or moderate hepatic insufficiency, decrease the initial dose of Remodulin to 0.625 ng/kg/min of ideal body weight, and monitor closely. Remodulin has not been studied in patients with severe hepatic insufficiency.
- Safety and effectiveness of Remodulin in pediatric patients have not been established.
- It is unknown if geriatric patients respond differently than younger patients. Caution should be used when selecting a dose for geriatric patients.
- There are no adequate and well-controlled studies with Remodulin in pregnant women. It is not known whether treprostinil is excreted in human milk or if it affects the breastfed infant or milk production.

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Please see accompanying Full Prescribing Information for Remodulin.

For additional information, visit www.RemodulinPro.com or call Customer Service at 1-877-UNITHER (1-877-864-8437).