

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 Pharmacy-Filled 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.