



Remodulin® (treprostinil) – New formulation approval

- On July 31, 2018, [United Therapeutics announced](#) the FDA approval for the use of [Remodulin \(treprostinil\)](#) injection in [Medtronic's Implantable System for Remodulin \(ISR\)](#) for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to diminish symptoms associated with exercise, and to diminish the rate of clinical deterioration in patients with PAH who require transition from [Flolan® \(epoprostenol\)](#).
 - Remodulin was originally approved for continuous subcutaneous and intravenous (IV) routes of administration using external pumps.
- PAH is a severely debilitating and progressive disease that causes high blood pressure in the pulmonary arteries, ultimately resulting in right-heart failure and premature death. It predominantly affects women, who are typically diagnosed in their late 30s to early 50s.
- Treprostinil is also available as brand tablets ([Orenitram®](#)) and inhalation ([Tyvaso®](#)).
 - Orenitram and Tyvaso are approved for the treatment of PAH.
- Approval of the ISR was based on the [DeLIVery for PAH study](#), an open-label trial enrolling 64 patients with PAH.
 - The study met its primary objective of demonstrating a rate of catheter-related complications below 2.5 per 1,000 patient-days while using the fully implantable system ($p < 0.0001$).
- The initial dose of Remodulin for patients transitioning to the implantable IV infusion pump should be the same as the current dose the patient is receiving using the external infusion pump at the time of transition.
 - The ISR is implanted into the body and will be refilled by healthcare professionals at intervals of up to 16 weeks depending on the patient's dose, using a syringe needle through the patients' skin.
 - Refer to the Remodulin drug label for additional dosing details.
- United Therapeutics and Medtronic's launch plans are pending. Remodulin will be available as 20 mL vials containing 20, 50, 100, or 200 mg of treprostinil (1, 2.5, 5, or 10 mg/mL).



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