



Orenitram[®] (treprostinil) – Expanded indication

- On October 21, 2019, [United Therapeutics announced the FDA approval of Orenitram \(treprostinil\)](#), for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to delay disease progression and to improve exercise capacity.
 - The studies that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66%) or PAH associated with connective tissue disease (26%).
 - Previously, Orenitram was only indicated for the treatment of PAH to improve exercise capacity.
- The FDA approval for the expanded indication is based on data from a randomized, placebo-controlled study of 690 patients with WHO Group 1 PAH. The primary efficacy endpoint was the time to first clinical worsening (morbidity or mortality) event.
 - Treatment with Orenitram resulted in a significant increase in the time to first clinical worsening event vs. placebo, which was associated with a reduction in the risk of an event (HR = 0.75; 95% CI: 0.57, 0.99; p = 0.039).
 - The beneficial effect of Orenitram was primarily attributable to a delay in disease progression, defined as a 15% decline in six minute walk distance plus an increase in either WHO Functional Class or worsening of signs or symptoms of right heart failure (HR = 0.39; 95% CI: 0.23, 0.66). There was no effect on the other components of clinical worsening.
- The recommended initial dose of Orenitram is 0.125 mg orally three times daily with food taken approximately 8 hours apart or 0.25 mg twice daily with food, taken approximately 12 hours apart.
 - Refer to the Orenitram drug label for further titration instructions and dose modifications.



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