

Revatio[®] (sildenafil) – Expanded indication

- On January 31, 2023, the [FDA approved](#) Viatris' [Revatio \(sildenafil\)](#), in pediatric patients 1 to 17 years old, for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise.
- Revatio is also approved for the treatment of PAH (WHO Group I) in adults to improve exercise ability and delay clinical worsening.
- The use of Revatio for pediatric patients is supported by evidence from adequate and well-controlled studies in adults with additional pharmacokinetic and safety data in pediatric patients aged 1 year and older.
- During the conduct of the pediatric studies (STARTS-1 and STARTS-2), an imbalance in the number of deaths was noted: 5/55 (9.1%), 10/74 (13.5%), and 22/100 (22%) in the sildenafil low, medium, and high dose groups, respectively. The causes of death were related to the progression of PAH. This safety observation in pediatrics was not confirmed in a study conducted in adults designed to evaluate this risk (Study A1481324).
 - Given the beneficial effects on clinical worsening and death observed in adults with increasing doses (Study A1481324) and the expected similarity of disease in pediatrics and adults, a causal association for the observed dose-related effect on mortality in pediatric patients is unlikely, and therefore, the available data support dosing in pediatric patients > 45 kg up to a maximum of 40 mg three times a day.
 - For additional trial data, refer to the Revatio drug label.
- The most common adverse reaction with Revatio use in children was priapism.
- The recommended oral dose of Revatio for the treatment of PAH in pediatric patients ≤ 20 kg is 10 mg three times a day. For pediatric patients 20 kg to 45 kg, the recommended dosage is 20 mg three times a day. For pediatric patients ≥ 45 kg, the recommended dosage is 20 mg three times a day.
 - A maximum dose in pediatric patients has not been identified. Based on the experience in adults, dose may be titrated to a maximum of 40 mg three times a day for pediatric patients > 45 kg, if required, based on symptoms and tolerability.
 - Refer to the Revatio drug label for dosing in adults