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FDA Drug Safety Communication: FDA clarifies Warning about Pediatric Use of Revatio (sildenafil) for Pulmonary Arterial Hypertension


[En español](#)¹

This information is in follow-up to the [FDA Drug Safety Communication](#)² issued on August 30, 2012.

[03-31-2014] The U.S. Food and Drug Administration (FDA) is clarifying its previous recommendation related to prescribing Revatio (sildenafil) for children with pulmonary arterial hypertension (PAH). Revatio is FDA-approved only to treat PAH in adults, not in children; however, health care professionals must consider whether the benefits of treatment with the drug are likely to outweigh its potential risks for each patient.

FDA revised the Revatio drug label in August 2012, adding a warning stating that "use of Revatio, particularly chronic use, is not recommended in children." This recommendation was based on an observation of increasing mortality with increasing Revatio doses in a long-term clinical trial in pediatric patients with PAH. FDA also issued a [Drug Safety Communication](#)³ at that time.

The purpose of the recommendation was to raise awareness of clinical trial results showing a higher risk of mortality in pediatric patients taking a high dose of Revatio when compared to pediatric patients taking a low dose. This recommendation was **not** intended to suggest that Revatio should *never* be used in children; however, some health care professionals have interpreted this information as a contraindication, and have refused to prescribe or administer the drug. We recognize there may be situations in which the benefit-risk profile of Revatio may be acceptable in individual children, for example, when other treatment options are limited and Revatio can be used with close monitoring.

The evidence behind our initial recommendation has not changed; we are simply clarifying the strength of the warning communicated in the Revatio drug label. View the [Revatio drug label](#)⁴ ⁵ for more information.

Related Information

- [Revatio drug label](#)⁶
- [FDA Drug Safety Communication: FDA recommends against use of Revatio \(sildenafil\) in children with pulmonary hypertension](#)⁷
8/30/2012
- [Comunicado de la FDA sobre la seguridad de los medicamentos: la FDA aclara el uso pediátrico de Revatio \(sildenafil\) para la hipertensión arterial pulmonar](#)⁸

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