MedWatch The FDA Safety Information and Adverse Event Reporting Program

Revatio (sildenafil): Drug Safety Communication - Recommendation Against Use in Children

[Posted 08/30/2012]

美國FDA提醒，1至17歲兒童不應使用Revatio (sildenafil)治療肺動脈高壓。這項建議是根據一項長期臨床研究，研究結果顯示：(1)兒童使用高劑量revatio之組別較使用低劑量的sildenafil者，有較高的死亡風險；(2) 使用低劑量的revatio對於提昇活動能力(exercise ability)無效果。兒童使用sildenafil治療肺動脈高壓，為非核核准適應症（FDA未核准），且警訊建議，sildenafil的仿單不可宣稱此品項用於兒童。

父母或照護者不應未經醫療人員指示貿然停用revatio，醫療人員應了解「兒童使用sildenafil治療肺動脈高壓，為非核核准適應症」；且sildenafil不建議用於兒童。

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AUDIENCE: Pediatrics, Cardiology, Pulmonology

ISSUE: FDA notified healthcare professionals and their medical care organizations that Revatio (sildenafil) should not be prescribed to children (ages 1 through 17) for pulmonary arterial hypertension (PAH).This recommendation against use is based on a recent long-term clinical pediatric trial showing that: (1) children taking a high dose of Revatio had a higher risk of death than children taking a low dose and (2) the low doses of Revatio are not effective in improving exercise ability. Treatment of PAH in children with this drug is an off-label use (not approved by FDA) and a new warning, stating the use of Revatio is not recommended in pediatric patients has been added to the Revatio labeling.

BACKGROUND: Revatio is a phosphodiesterase-5 inhibitor used to treat pulmonary arterial hypertension by relaxing the blood vessels in the lungs to reduce blood pressure and is approved to improve exercise ability and delay clinical worsening of PAH in adult patients (WHO Group I).

RECOMMENDATION: Patients and caregivers are advised to not change the Revatio dose or stop taking Revatio without talking to a health care professional. Healthcare professionals were reminded that use of this product, particularly chronic use, in children is an off-label indication, not approved by FDA, and is not recommended.

See the Drug Safety Communication for the Data Summary from the randomized, double-blind, placebo-controlled clinical trial of 234 patients with PAH, 1 to 17 years of age with mild to moderate symptoms at baseline. http://www.fda.gov/Drugs/DrugSafety/ucm317123.htm