The United States: FDA Drug Safety Communication: FDA recommends against use of Revatio in children with pulmonary hypertension

The U.S. Food and Drug Administration (FDA) is recommending 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. Most deaths were caused by pulmonary hypertension and heart failure, which are the most common causes of death in children with PAH.

In US, Revatio has never been approved for the treatment of PAH in children, and in light of the new clinical trial information, off-label use of the drug in pediatric patients is not recommended by the FDA. A new warning, stating the use of Revatio is not recommended in pediatric patients and the results of the Revatio trial in pediatric patients have been added to the Revatio labeling.

Revatio is approved to improve exercise ability and delay clinical worsening of PAH in adult patients. The current Revatio label recommends avoiding doses higher than 20 mg, given three times a day. The effect of Revatio on the risk of death with long-term use in adults is unknown; FDA is requiring the manufacturer of Revatio (Pfizer) to evaluate Revatio’s effect on the risk of death in adults with PAH.

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, is not recommended in children. And an unexpectedly higher risk of mortality was found in pediatric patients taking a high dose of Revatio when compared to pediatric patients taking a low dose. Besides, the maximum recommended dose of Revatio for adult patients with PAH is 20 mg three times a day.

Please refer to the following website in FDA for details:
http://www.fda.gov/Drugs/DrugSafety/ucm317123.htm

In Hong Kong, Revatio Tab 20mg (HK-54170), containing sildenafil, is registered by Pfizer Corporation Hong Kong Limited. It is a prescription-only medicine. According to the approved product information, Revatio is indicated for the treatment of pulmonary arterial hypertension in adult patients (≥ 18 years) and the use of sildenafil is not recommended in children and adolescents (< 18 years). News related to Revatio
has been reported by the Department of Health and was posted on the website of Drug Office on 12 October 2011. A letter to inform healthcare professionals was issued on the same day. In view of the FDA’s current recommendation, a letter to inform healthcare professionals will be issued.

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