MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Sibutramine

[08/10/2010]

根據FDA建議持續使用Sibutramine造成新心血管的風險，美國FDA亦於 2010 年 10 月 8 公布，原廠藥商亞培公司自願將該成分藥品撤離美國市場。

FDA 於 1997 年 11 月核准 Sibutramine 用於減肥和維持體重，患者 BMI ≥30 kg/m^2 或 BMI ≥27 kg/m^2 伴隨有其他心血管危險因素。BMI ≥30 kg/m^2 被認為是肥胖。

FDA的建議基於Sibutramine Cardiovascular Outcomes (SCOUT) trial新的數據，和 placebo 比較，服用 Sibutramine 心血管的不良反應增加 16%，FDA 的結論是，Sibutramine的心血管不良反應已經和減重的治療效益互相抵消。

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Audience: Primary Care, Consumers

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The U.S. Food and Drug Administration (FDA) is recommending against continued prescribing and use of Meridia (sibutramine) because this drug may pose unnecessary cardiovascular risks to patients. FDA has requested that Abbott Laboratories—the manufacturer of Meridia—voluntarily withdraw this drug product from the United States market. Abbott has agreed to voluntarily stop marketing of Meridia in the United States.

Meridia was FDA-approved in November 1997 for weight loss and maintenance of weight loss in patients with a body mass index (BMI) greater than or equal to 30 (≥30) kg/m^2 or for patients with a BMI ≥27 kg/m^2 who have other cardiovascular risk factors. BMI is a measure of body fat in adults that is based on height and weight. Patients with a BMI ≥30 kg/m^2 are considered obese.

FDA's recommendation is based on new data from the Sibutramine Cardiovascular Outcomes (SCOUT) trial, which demonstrated a 16% increase in risk of major adverse cardiovascular events (a composite of non-fatal heart attack, non-fatal stroke, resuscitation after cardiac arrest and cardiovascular death) in patients treated with Meridia compared to patients taking a placebo (see Data Summary below). At the end of the trial (60 months), patients in the Meridia group lost a small amount of body weight compared to patients in the placebo group. FDA has concluded that the risk for an adverse cardiovascular event from Meridia in the population studied outweighed any benefit from the modest weight loss observed with the drug.