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August Safety Labeling Changes by FDA*

There has been a lot of media coverage regarding the safety of Meridia. The FDA has reviewed the product and has made some safety labeling changes that you should be aware of.

Meridia (sibutramine hydrochloride) capsule

CONTRAINDICATIONS

Meridia is contraindicated in patients:

- With a history of coronary artery disease (e.g., angina, history of myocardial infarction), congestive heart failure, tachycardia, peripheral arterial occlusive disease, arrhythmia or cerebrovascular disease (stroke or transient ischemic attack (TIA)).
- With inadequately controlled hypertension > 145/90 mm Hg.
- Over 65 years of age.
- Receiving monoamine oxidase inhibitors (MAOIs)
- With hypersensitivity to sibutramine or any of the inactive ingredients of Meridia.
- Who have a major eating disorder (anorexia nervosa or bulimia nervosa).
- Taking other centrally acting weight loss drugs.

WARNINGS

Concomitant Cardiovascular Disease

- Due to an increased risk of heart attack and stroke in patients with cardiovascular disease, MERIDIA should not be used in patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke

PRECAUTIONS

Geriatric Use

- Clinical studies of sibutramine did not include sufficient numbers of patients over 65 years of age. Sibutramine is contraindicated in this group of patients.

****Additional FDA Drug Safety Labeling Changes can be viewed at www.fda.gov***

*****The entire package insert can be viewed at www.dailymed.nlm.nih.gov***

FDA Significantly Restricts Access to the Diabetes Drug Avandia

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The U.S. Food and Drug Administration today announced that it will significantly restrict the use of the diabetes drug Avandia (rosiglitazone) to patients with Type 2 diabetes who cannot control their diabetes on other medications. These new restrictions are in response to data that suggest an elevated risk of cardiovascular events, such as heart attack and stroke, in patients treated with Avandia.