



[Home](#) [Drugs](#) [Drug Safety and Availability](#)

Drugs

FDA Drug Safety Communication: FDA Recommends Against the Continued Use of Meridia (sibutramine)

Safety Announcement

[Additional Information for Patients](#)

[Additional Information for Healthcare Professionals](#)

[Data Summary](#)

Safety Announcement

[10-8-2010] 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/m² or for patients with a BMI ≥ 27 kg/m² 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/m² 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.

In November 2009, and January 2010, FDA announced it was reviewing clinical trial data about a potentially serious effect on the heart from the use of Meridia. The links to these communications are listed below:

- [Early Communication about an Ongoing Safety Review of Meridia \(sibutramine hydrochloride\)](#)¹
- [Follow-Up to the November 2009 Early Communication about an Ongoing Safety Review of Sibutramine, Marketed as Meridia](#)²

Additional Information for Patients

If you currently take Meridia, you should:

- Stop taking Meridia and talk to your healthcare professional about alternative weight loss and weight loss management programs.
- Talk to your healthcare professional if you have any concerns about Meridia.
- Contact your healthcare professional right away if you experience pain in the chest, heart palpitations, abnormal heart rate or rhythm, or other symptoms including dizziness and lightheadedness.
- Dispose of unused Meridia in your household trash by following the recommendations outlined in the [Federal Drug Disposal Guidelines](#):³
 - Take your Meridia out of its original container and mix it with an undesirable substance, such as used coffee grounds or kitty litter. The medication will be less appealing to children and pets, and unrecognizable to people who may intentionally go through your trash.
 - Put the medication in a sealable bag, empty can, or other container to prevent it from breaking out of a garbage bag.
- Report any side effects with Meridia to FDA's MedWatch program using the information at the bottom of the page in the "Contact Us" box.

Additional Information for Healthcare Professionals

FDA recommends that healthcare professionals:

- Stop prescribing and dispensing Meridia to patients.
- Contact patients currently taking Meridia and ask them to stop taking the medication.
- Inform patients of the risks associated with Meridia.
- Discuss alternative weight loss strategies other than Meridia with your patients.
- Be aware of the possible risk of major adverse cardiovascular events with patients taking Meridia and assess patients for these events if they present with any signs or symptoms of cardiovascular disease.
- Report any side effects with Meridia to FDA's MedWatch program using the information at the bottom of the page in the "Contact Us" box.

Data Summary

The SCOUT trial was a randomized, double-blind, placebo-controlled multicenter trial conducted between January 2003 and March 2009 in Europe, Latin America, and Australia. The study population consisted of approximately 10,000 men and women aged ≥ 55 with a BMI between 27 kg/m² and 45 kg/m², or between 25 kg/m² and 27 kg/m² with an increased waist circumference. Patients were also required to have a history of cardiovascular disease (coronary artery disease, stroke, occlusive peripheral arterial disease) and/or type 2 diabetes mellitus with at least one other cardiovascular risk factor (hypertension, dyslipidemia, current smoking, or diabetic nephropathy). All patients underwent a 6-week lead-in period on Meridia 10 mg. Eligible patients were then randomized to either placebo or Meridia 10 mg daily. Titration to Meridia 15 mg daily was allowed for individuals with inadequate weight loss on 10 mg daily. The mean duration of exposure to Meridia and placebo was approximately 3.5 years.

There was a 16% increase in the relative risk of the primary outcome event (a composite of non-fatal myocardial infarction, non-fatal stroke, resuscitation after cardiac arrest, and cardiovascular death) in the Meridia group compared to the placebo group [Hazard Ratio (HR)=1.16; 95% CI, 1.03-1.31; p=0.02]. There was no between-treatment difference in cardiovascular death (HR=0.99; 95% CI, 0.82-1.19; p=0.90) or all-cause mortality (HR=1.04; 95% CI, 0.91-1.20; p=0.54). The primary outcome was driven by non-fatal myocardial infarction and non-fatal stroke (HR=1.28; 95% CI, 1.04-1.57; p=0.02; HR=1.36; 95% CI, 1.04-1.77; p=0.03, respectively).

The difference in mean percent change in body weight at Month 60 (end of the trial) between the Meridia and placebo groups was approximately 2.5%.

Subgroup analyses were also conducted on three defined cardiovascular risk groups composed of individuals with: (1) type 2 diabetes mellitus only; (2) a history of cardiovascular disease only; (3) a history of cardiovascular disease and type 2 diabetes mellitus. FDA's analysis demonstrated that the logrank test interaction p-value for the cardiovascular risk subgroup analysis was 0.56, indicating that the magnitudes of risk for major adverse cardiac events in the three subgroups were not statistically significantly different.

Data from the SCOUT trial was discussed at the Endocrinologic and Metabolic Drugs Advisory Committee Meeting, held on September 15, 2010 (for complete safety reviews and background information discussed at this meeting see: [September 15, 2010 AC meeting](#)⁴).

Related Information

- [Abbott Laboratories agrees to withdraw its obesity drug Meridia⁵](#) [ARCHIVED]
FDA News Release (10/8/2010)
- [Questions and Answers: FDA Recommends Against the Continued Use of Meridia \(sibutramine\)⁶](#)
10/8/2010
- [Memorandum: Recommendation on a regulatory decision for Meridia, 10/4/2010 \(PDF - 174KB\)⁷](#)
- [Meridia \(sibutramine hydrochloride\) Information⁸](#)

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Page Last Updated: 10/08/2010

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Links on this page:

1. [/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm191650.htm](#)
2. [/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm198206.htm](#)
3. [/NewsEvents/PublicHealthFocus/ucm226353.htm](#)
4. [/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm191113.htm](#)
5. [/NewsEvents/Newsroom/PressAnnouncements/2010/ucm228812.htm](#)
6. [/Drugs/DrugSafety/ucm228747.htm](#)
7. [/downloads/Drugs/DrugSafety/UCM228795.pdf](#)
8. [/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm191652.htm](#)
9. <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>
10. <http://www.fda.gov/downloads/Safety/MedWatch/DownloadForms/UCM082725.pdf>