



News

Abbott to Stop Marketing the Obesity Medicine Sibutramine in Canada

Montreal, Quebec, October 8, 2010 – Abbott will voluntarily withdraw sibutramine from the Canadian market after discussion with Health Canada. Sibutramine is marketed by Abbott in Canada as Meridia.

Media:
Eileen Murphy
Abbott Canada
(514) 832-7788
eileen.murphy@abbott.com

It is recommended that patients taking Meridia make an appointment with their doctor at the next convenient time to discuss alternatives for losing weight. Patients who wish to stop treatment before seeing their doctor can do so at any time. Patient and physician questions can be answered through the toll-free service number established by Abbott in Canada: 1-800-567-2226 or 514-832-7333 or by visiting www.abbott.ca.

Health Canada's recommendation was based on a review of results from the SCOUT study (Sibutramine Cardiovascular OUTcome Trial), which became available in November 2009. The approximately 10,000 patient, six-year SCOUT study was requested by European regulatory authorities as a post-marketing commitment to evaluate cardiovascular safety in high-risk patients. The majority of the patients in the SCOUT study had underlying cardiovascular disease and were ineligible to receive sibutramine under the current labeling and prescribing information.

Abbott's evaluation of the SCOUT study does not change its assessment that sibutramine has a positive benefit/risk profile when used appropriately in the approved patient population.

Sibutramine is approved in Canada for weight loss in patients who are obese, have no previous history of cardiovascular disease and have been unable to lose weight through diet and exercise.

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About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs nearly 90,000 people and markets its products in more than 130 countries. Serving the Canadian population since 1931, Abbott in Canada employs 2,000 individuals.

To learn more, visit www.abbott.com, www.abbott.ca.

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FAQs

Sibutramine Information

This information is intended for the Canada market only.

Abbott will voluntarily withdraw sibutramine from the Canadian market after discussions with Health Canada. Abbott offers sibutramine medicines under the brand name, Meridia in Canada. Sibutramine is also marketed under other names by other companies.

Below you will find answers to some of the most frequently asked questions about Meridia

For treatment advice, please contact your physician. For other questions, please call the dedicated freephone helpline 1-800-567-2226 or 514-832-7333

What are the recommendations for prescribers and patients?

- Doctors should stop prescribing Meridia (sibutramine) medicines to obese patients. They should also review the treatment of patients currently treated with this medicine.
- Pharmacists should no longer dispense Meridia (sibutramine).
- Patients who are taking Meridia (sibutramine) to help them lose weight should make an appointment with their doctor at the next convenient time to discuss alternative measures to lose weight.
- Patients who have any questions should speak to their doctor or pharmacist.

What should I do if I'm currently taking sibutramine?

- Please contact your doctor.

Why was sibutramine withdrawn in Canada?

- The discussion between Abbott and Health Canada was based on a review of results from the SCOUT study (Sibutramine Cardiovascular OUTcome Trial), which first became available in November 2009. The approximately 10,000 patient SCOUT study was requested by European regulatory authorities as a post-marketing commitment to evaluate cardiovascular safety in high-risk patients with a history of cardiovascular disease. The SCOUT study was not designed to directly assess the risk/benefit profile of the drug in patients from whom it is specifically intended. The majority of the patients in the study (more than 90 percent) had underlying cardiovascular disease and were ineligible to receive sibutramine under the current labeling and prescribing information.
- The study found that certain patients with pre-existing heart disease taking sibutramine had a 16% greater chance of experiencing a non-fatal cardiac adverse event compared to other patients not taking the drug.

What can I take instead of sibutramine?

Please contact your doctor to discuss other options, since your medical history and other medications need to be considered in the decision.

How do I know whether my medicine contains sibutramine?

- If you are taking Meridia, then you are taking sibutramine. If you are taking a different drug to treat obesity, then please consult your doctor to confirm whether or not your anti-obesity medication contains sibutramine. If it does, make an appointment with your doctor at the next convenient time to discuss alternatives for losing weight.

If my physician instructs me to stop taking sibutramine, what should I do with my remaining sibutramine capsules?

- Please return your unused supply of sibutramine to your pharmacy.

Can I replace my sibutramine with a different prescription?

- Please contact your doctor or pharmacist to discuss other treatment options.

Is there a telephone number or e-mail address where I can send my questions?

- For treatment advice, please contact your physician. For other questions, please call the dedicated freephone helpline 1-800-567-2226 or 514-832-7333.

If I purchased my sibutramine on the Internet, can I still get a refund?

- No. Abbott does not sell sibutramine on the Internet.

What are the side effects associated with sibutramine?

- In studies the most common side effects were: dry mouth, insomnia (inability to fall asleep) and constipation. Other side effects that may occur include: increased sweating, an increase in blood pressure, and an increase in heart rate.

About sibutramine

- Sibutramine is a treatment for patients who are obese/overweight, have no previous history of cardiovascular disease and have been unable to lose weight through diet and exercise.
- It is the active pharmaceutical ingredient in some medicines, including Abbott-branded medicines: Reductil, Meridia, Sibutral, Ectiva and Raductil.
- It acts centrally in the brain where the body's signal for hunger occurs. It reduces food intake by increasing patients' feeling of fullness.
- Sibutramine is not an appetite suppressant. Appetite suppressants suppress the appetite signal so patients do not begin eating.