











Questions for your doctor

-  How will I know if Myalept[®] is working?
-  How often will I need to have blood tests?
-  Which tests will I get?
-  What can I do if I experience side effects?
-  Will my dose need to be increased over time?
-  What should I be aware of if I am also taking insulin?
-  Will I need to change dosing of my other medications?
-  What can I do if the injections are too painful?

Notes

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For additional Important Safety Information, please see the following page, and refer to the Medication Guide at Myalept.com.

Important Safety Information for Myalept

What is Myalept?

Myalept (metreleptin) is a leptin replacement therapy used with a doctor-recommended diet to treat problems caused by not having enough leptin (leptin deficiency) in people with generalized lipodystrophy.

- It is not known if Myalept is safe and effective when used to treat problems (complications) caused by partial lipodystrophy or to treat liver disease, including non-alcoholic steatohepatitis (NASH)
- Myalept should not be used to treat people with HIV-related lipodystrophy or people with metabolic disease, including diabetes mellitus and hypertriglyceridemia, without signs or symptoms of congenital or acquired generalized lipodystrophy.

Important Safety Information

Myalept is only available through a restricted program called the Myalept Risk Evaluation and Mitigation Strategy (REMS) Program. Your doctor must be enrolled and certified in the program in order to prescribe Myalept.

Myalept may cause serious side effects, including:

- **risk for developing certain proteins called neutralizing antibodies** that may reduce how well your own leptin or Myalept works. Side effects of these antibodies may include infection, problems with blood sugar (including diabetes), or an increase in triglycerides
- **increased risk of a type of blood cancer called lymphoma**

You should not take Myalept if you

- have general obesity not caused by a congenital leptin deficiency
- are allergic to metreleptin or any of the ingredients in Myalept. Symptoms of an allergic reaction include rash, itching (hives), swelling of face, lips, tongue, or throat, problems breathing or swallowing, fainting or dizziness, rapid heartbeat

Before using Myalept, tell your doctor if you have any medical conditions including if you:

- have or have had problems with your blood cells, including low blood cell counts (especially your white blood cells), bone marrow, immune system, pancreas, swollen lymph nodes, lymphoma, high blood triglyceride levels, or use insulin or a sulfonylurea

- are pregnant or plan to become pregnant as it is unknown if Myalept will harm your unborn baby. If you become pregnant while using Myalept, talk to your healthcare provider about registering with a program to collect information about the outcomes of moms and babies exposed to Myalept during pregnancy. You can enroll in the Myalept program by calling 1-855-669-2537
- are nursing or plan to nurse. You should not nurse while you take Myalept

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Other possible side effects

The most common side effects of Myalept include headache, low blood sugar, decreased weight, and/or abdominal pain.

For newborns and infants, mix Myalept with sterile water for injection (preservative-free) (WFI). Serious side effects including death have happened in newborns or infants who have received the preservative benzyl alcohol. Bacteriostatic water for injection contains benzyl alcohol and it should not be used to mix Myalept for newborns and infants.

You may get low blood sugar (hypoglycemia) if you take Myalept with other medicines used to lower blood sugar, such as insulin or sulfonylurea. Your doses of these medications may need to be lowered while you use Myalept. Tell your doctor right away if you experience shakiness, sweating, headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, or a jittery feeling because these may be signs of low blood sugar (hypoglycemia).

Myalept may worsen symptoms caused by certain problems in your immune system (autoimmune disorder). Ask your doctor about what symptoms you should watch for that may require further testing.

Talk to your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of Myalept. For more information, speak to your doctor or pharmacist. Tell your doctor about all the medications you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Take Myalept exactly as your doctor instructs you.

For more detailed information please see the [Medication Guide](#) and [Instructions for Use](#).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.