



# Frequently asked questions about Myalept<sup>®</sup>

**Q Is Myalept approved by the FDA?**

**A** In 2014, Myalept was approved by the FDA to be used along with a doctor recommended diet to treat complications of not having enough leptin in people with generalized lipodystrophy (GL).

**Q How long has Myalept been used by people with GL?**

**A** Metreleptin has been used and studied since 2000. It was named Myalept when it was approved by the FDA in 2014.

**Q What diet should I follow while taking Myalept?**

**A** Your doctor is the best resource for nutrition recommendations. Work with your doctor to develop a nutrition plan that is best for you.

**Q Does Myalept restore fat tissue in people with GL?**

**A** While Myalept replaces the leptin missing in people with GL, it does not restore body fat.

**Q Can I get Myalept at my local pharmacy where I get all my other prescriptions?**

**A** Myalept is not available at local pharmacies. It is available only through certified pharmacies that are enrolled in the Myalept REMS Program. Myalept is delivered right to your door through one of our Specialty Pharmacy Partners.

**Q How much does Myalept cost?**

**A** Once your doctor has made the decision to prescribe Myalept, your Specialty Pharmacy will do a benefit verification with your insurance company to identify your out-of-pocket costs related to Myalept. Call ByMySide at 1-855-6MYALEPT (1-855-669-2537) to learn about your options including the ByMySide Copay Program,\* which covers costs of copayments or coinsurance at 100%, up to the program maximum, for eligible patients. If you are not eligible to participate in the ByMySide Copay Program, ByMySide, may refer you to third-party patient assistance programs that may be able to help you with your out-of pocket costs.

**For additional Important Safety Information, please see page 3, and refer to the Medication Guide at [Myalept.com](http://Myalept.com).**



# Frequently asked questions about Myalept<sup>®</sup>

**Q If I have questions about mixing, injecting, or storing Myalept, where can I get answers?**

**A** Please review the complete Instructions for Use included in each Myalept shipment. It is also enclosed in the pocket of this brochure. If you have trouble finding what you need, you can also contact ByMySide for assistance. You can schedule an in-person injection training session, at no cost to you, with a ByMySide registered nurse. The nurse will come to your home or to your doctor's office to teach you how to mix and inject Myalept.

**Q Are there smaller needles available for injecting my child?**

**A** Ask your doctor about prescribing the smallest possible needle to use for injecting Myalept to your child. Also, a ByMySide registered nurse can come directly to your home or doctor's office to provide training, at no cost to you, on how to properly inject Myalept.

**Q Can I stop taking Myalept at any time?**

**A** Do not stop taking Myalept without consulting with your doctor. Stopping Myalept suddenly may cause a serious problem with your pancreas (pancreatitis) and very high triglycerides. You should take Myalept once a day every day unless otherwise directed by your doctor.

**Q How should I travel with Myalept?**

**A** Myalept is portable, as long as you have a cool place to store it. Myalept should be stored between 36°F and 46°F (2°C and 8°C). Contact a ByMySide Coordinator at 1-855-6MYALEPT (1-855-669-2537) to learn how to travel with your Myalept.

\*The ByMySide Copay Program is not valid for prescriptions eligible to be reimbursed, in whole or in part, by state or federally funded healthcare programs such as Medicaid, Medicare, Tricare, VA/DOD, or any state prescription drug assistance programs. Other eligibility requirements may apply. Aegerion Pharmaceuticals, Inc. reserves the right to discontinue or modify the ByMySide Copay Program at any time.

**For additional Important Safety Information, please see page 3, 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](http://www.FDA.gov/medwatch) or call 1-800-FDA-1088.**