

What is the MYALEPT Risk Evaluation and Mitigation Strategy (REMS)?

A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the FDA to ensure that the benefits of the drug outweigh its risks. MYALEPT is available only under a restricted program called the MYALEPT REMS because of:

- the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or MYALEPT and the serious adverse events that may result
- the risk of lymphoma

Because of these risks, appropriate patient selection consistent with the approved indication of congenital or acquired generalized lipodystrophy for MYALEPT is required.

Appropriate Patient Selection

MYALEPT can only be prescribed in accordance with the FDA-approved indication:

MYALEPT is indicated as an adjunct to diet as replacement therapy to treat the complications of leptin-deficiency in patients with congenital or acquired generalized lipodystrophy.

Do not prescribe MYALEPT for any other indications including:

- Treatment of complications associated with partial lipodystrophy
- Treatment of liver disease, including nonalcoholic steatohepatitis (NASH)
- HIV-related lipodystrophy
- Metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of generalized lipodystrophy
- General obesity not associated with congenital leptin deficiency

Neutralizing Activity and Antibody Testing

- Prescribers must test for neutralizing activity in patients who experience severe infections, or if MYALEPT is no longer working.
- Contact Chiesi at 1-866-216-1526 for instructions on how to submit samples for neutralizing antibody testing.

MYALEPT REMS Requirements

For Prescribers

- Certify in the MYALEPT REMS to prescribe MYALEPT.
- Attest patients have a diagnosis consistent with congenital or acquired generalized lipodystrophy.
- Complete the **Prescription Authorization Form** for each new prescription.

For Outpatient Pharmacies

- Certify in the MYALEPT REMS to dispense MYALEPT.
- Verify prescriber is certified and a completed **Prescription Authorization Form** is received.

Certification of Prescribers of MYALEPT

1. Review the Prescribing Information and **Prescriber Training Module**.
2. Complete, sign, and submit the one-time **Prescriber Enrollment Form**.

REMS Resources

All materials can be downloaded from the MYALEPT REMS website: www.MYALEPTREMS.com.
Or request these materials by calling **1-855-669-2537**.

Please see accompanying full Prescribing Information including Boxed Warning, or visit www.MYALEPTREMS.com

IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT THE MYALEPT REMS

PHONE: 1-855-669-2537 | FAX: 1-877-328-9682 | WWW.MYALEPTREMS.COM