

Getting Started Guide

myalept[®]
 (metreleptin) for injection 11.3 mg per vial

To get a patient with Generalized Lipodystrophy started on Myalept[®] follow 3 steps outlined in this guide.

Dena, MYALEPT patient

IMPORTANT SAFETY INFORMATION

INDICATION: MYALEPT[®] (metreleptin) for injection is a leptin analog indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.

LIMITATIONS OF USE: The safety and effectiveness of MYALEPT for the treatment of complications of partial lipodystrophy or for the treatment of liver disease, including non-alcoholic steatohepatitis (NASH), have not been established.

MYALEPT is not indicated for use in patients with HIV-related lipodystrophy. MYALEPT is not indicated for use in patients with metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of generalized lipodystrophy.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

WARNING: RISK OF ANTI-METRELEPTIN ANTIBODIES WITH NEUTRALIZING ACTIVITY AND RISK OF LYMPHOMA

Anti-metreleptin antibodies with neutralizing activity have been identified in patients treated with MYALEPT. The consequences of these neutralizing antibodies are not well characterized but could include inhibition of endogenous leptin action and/or loss of MYALEPT efficacy. Severe infection and/or worsening metabolic control have been reported.

Test for anti-metreleptin antibodies with neutralizing activity in patients who develop severe infections or show signs suspicious for loss of MYALEPT efficacy during treatment. Contact Amryt Pharmaceuticals DAC at 1-866-216-1526 for neutralizing antibody testing of clinical samples.

T-cell lymphoma has been reported in patients with acquired generalized lipodystrophy, both treated and not treated with MYALEPT. Carefully consider the benefits and risks of treatment with MYALEPT in patients with significant hematologic abnormalities and/or acquired generalized lipodystrophy.

Because of these risks associated with the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or MYALEPT and the risk for lymphoma, MYALEPT is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MYALEPT REMS PROGRAM.

Visit chiesitotalcare.com
 or call 1-855-669-2537.
 We're ready to help!

 **Chiesi**
TOTAL
*care*SM


myalept[®]
(metreleptin) for injection 11.3 mg
per vial



Raeya, MYALEPT patient

STEP 1

REMS Training



Complete Risk Evaluation and Mitigation Strategy (REMS) training

Because of the risk of anti-metatreptin antibodies with neutralizing activity and risk of lymphoma, Myalept is available only through a restricted program **under a Risk Evaluation and Mitigation Strategy (REMS) called the Myalept REMS Program.**

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks.

To get your REMS certification:

- Visit the Myalept REMS Program website to review the Myalept REMS Program introductory information sheet and Prescribing Information
- Review the Myalept REMS Training Program, and fill out the Prescriber Enrollment Form. Fax completed forms to 1-877-328-9682.



Scan the code
to visit the site.

STEP 2

Prescription



Fill out the Prescription Forms

A prescription for Myalept can only be written on the Myalept REMS Authorization Form. Complete, sign, and fax the completed form to 1-877-328-9682 for each new prescription.



Scan the code
to download
the form.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS: Most common adverse reactions ($\geq 10\%$) in clinical trials were headache, hypoglycemia, decreased weight, and abdominal pain.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

INSTRUCTIONS

All fields are required.

For each new prescription, you must:

- Confirm the patient has a diagnosis consistent with generalized lipodystrophy.
- Complete this Prescriber Attestation by checking the box adjacent to each statement below to indicate that you attest to each statement.
- Sign and date at the bottom of the Attestation.
- THEN, complete the prescription and patient information on reverse side.

PRINT and FAX both pages of the completed form to MYALEPT REMS at 1-877-328-9682.

This prescription for MYALEPT is valid for dispensing only if received by fax.

PATIENT INFORMATION

Full Name (first, middle, last)	Date of Birth
<input type="checkbox"/> Existing Patient <input type="checkbox"/> New Patient	Indication for Use: <input type="checkbox"/> congenital generalized lipodystrophy <input type="checkbox"/> acquired generalized lipodystrophy

A

PRESCRIBER ATTESTATION

I understand that 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.

I affirm that my patient has a clinical diagnosis consistent with generalized lipodystrophy, and that my patient (or their caregiver) has been properly informed of the benefits and risks of MYALEPT therapy.

I understand that MYALEPT is not indicated for:

- the treatment of complications of partial lipodystrophy.
- the treatment of liver disease including non-alcoholic steatohepatitis (NASH)
- use in patients with HIV
- use in patients with metabolic syndrome

I understand that MYALEPT is not indicated for the treatment of partial lipodystrophy.

I understand that MYALEPT is not indicated for the treatment of liver disease including non-alcoholic steatohepatitis (NASH).

I understand that MYALEPT is not indicated for use in patients with HIV.

I understand that MYALEPT is not indicated for use in patients with metabolic syndrome.

I agree to test for neutralizing antibodies to MYALEPT (e.g., loss of glycoconjugate).

I understand that MYALEPT is not indicated for the treatment of partial lipodystrophy.

I understand that MYALEPT is not indicated for the treatment of liver disease including non-alcoholic steatohepatitis (NASH).

I understand that MYALEPT is not indicated for use in patients with HIV.

I understand that MYALEPT is not indicated for use in patients with metabolic syndrome.

B

SIGN HERE

Physician/Prescriber Signature

PRESCRIBER INFORMATION

Full Name (first, middle, last)

Practice/Facility Name

Address 1

Address 2 (optional)

Phone

OFFICE CONTACT

Full Name (first last)

If different from above: Phone

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C

PATIENT INFORMATION

Full Name (first, middle, last)	Gender <input type="checkbox"/> Male <input type="checkbox"/> Female	Date of Birth
Address	City	State Zip
Preferred Phone	Alternate Phone	Preferred time to contact (check one): <input type="checkbox"/> Day <input type="checkbox"/> Evening
Email	Parent/Guardian (if applicable)	

Alternate Caregiver/Contact Name	Alternate Caregiver/Contact Email
Alternate Caregiver/Contact Phone	OK to leave message with Alternate Caregiver/Contact? <input type="checkbox"/> Yes <input type="checkbox"/> No

INSURANCE INFORMATION - Please copy both sides and attach all medical and prescription insurance cards.

Insurance Company Phone	Insured Employer
Insured Name	Relationship to Patient
Insurance Policy #	Insurance Group # (if applicable)
Prescription Card? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, carrier _____	Is the patient eligible for Medicare? <input type="checkbox"/> Yes <input type="checkbox"/> No
Medicare Policy #	Medicare Group # (if applicable)

SHIPPING INFORMATION

Recipient Name (first last)	Send initial shipment to prescribing doctor's office <input type="checkbox"/> Yes <input type="checkbox"/> No
Address (if different from above)	City State Zip

MYALEPT 5 mg/mL INJECTION PRESCRIPTION

Starting Dose: 0.06 mg/kg 2.5 mg 5 mg ▶ Convert dose for syringe type _____ mL units

Maintenance Dose: _____ mg OR _____ mg/kg ▶ Convert dose for syringe type _____ mL units

Days Supply	Refills #	Patient Weight (lbs)	Date Weight Taken
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Directions: Inject _____ mL under the skin _____ times(s) daily (e.g., by subcutaneous injection)

Attach or List Concomitant Meds	Allergies	<input type="checkbox"/> No Known Drug Allergies (NKDA)
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MYALEPT SUPPLIES PRESCRIPTION

Required supplies (please note - the maximum number per supply is specified below. Pharmacy will adjust to individual patient needs).

For Reconstitution	QTY #	Refills #	For Administration	QTY #	Refills #
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A

Confirm patient diagnosis

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.

B

Complete prescriber attestation

Attest patients have a diagnosis consistent with congenital or acquired generalized lipodystrophy.

C

Complete the prescription and confirm dosing

Once you have completed the form

STEP 3

Chiesi Total Care



1. Attach copies of patient insurance and prescription cards - front and back.

2. First prescription for the patient:

ALL PRESCRIPTIONS MUST BE FAXED. Fax completed form to Chiesi Total CareSM at 1-877-328-9682. **Please complete one form per patient.**

3. Subsequent prescriptions:

All prescriptions must be faxed on the official REMS prescription form. Some states, such as New York, may also require an e-Rx. In these states, both the REMS form and e-Rx are required. The e-Rx cannot be used in place of the REMS Prescription Authorization Form. Please search for "Accredo" in your EMR/HMR's e-prescribing software.

4. Let your patients know they will be receiving a call from Chiesi Total Care.

A member of the Chiesi Total Care team will contact patients to complete and fulfill their prescriptions for Myalept.



The fillable PDF can be downloaded and saved for future use.
Scan the QR code to download a copy.

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CONTRAINDICATIONS: MYALEPT is contraindicated in general obesity not associated with congenital leptin deficiency. MYALEPT has not been shown to be effective in treating general obesity. The development of anti-metreleptin neutralizing antibodies have been reported in obese patients treated with MYALEPT. MYALEPT is contraindicated in patients with prior severe hypersensitivity reactions to metreleptin or to any of its components.

WARNINGS AND PRECAUTIONS: A dose adjustment, including possible large reductions, of insulin or insulin secretagogue may be necessary in some patients to minimize risk of hypoglycemia. Closely monitor blood glucose in patients on concomitant insulin, especially those on high doses, or insulin secretagogue.

Cases of progression of autoimmune hepatitis and membranoproliferative glomerulonephritis (associated with massive proteinuria and renal failure) were observed in some patients with acquired generalized lipodystrophy treated with MYALEPT. A causal relationship between MYALEPT and the development and/or progression of autoimmune disease has not been established. Carefully consider the benefits and risks of MYALEPT treatment in patients with autoimmune disease.

Hypersensitivity reactions (eg, anaphylaxis, urticaria or generalized rash) have been reported. Patient should promptly seek medical advice about discontinuation of MYALEPT if a hypersensitivity reaction occurs.

MYALEPT contains benzyl alcohol when reconstituted with Bacteriostatic Water for Injection. The preservative benzyl alcohol has been associated with serious adverse events and death in pediatric patients, particularly in neonates and premature infants. Preservative-free Water for Injection is recommended for use in neonates and infants.

ADVERSE REACTIONS: Most common adverse reactions ($\geq 10\%$) in clinical trials were headache, hypoglycemia, decreased weight, and abdominal pain.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information including Boxed Warning.

Reference: 1. Myalept[®] (metreleptin) Prescribing Information. Amryt, February 2022.

For more information, visit myalept.com.

Chiesi Total CareSM Program offered through Accredio Specialty Pharmacy.

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