myalept® (metreleptin) for injection 11.3 mg per vial

MYALEPT® REMS Program
Prescription Authorization Form

Instructions: Complete **both pages** of this form for each new prescription. All fields are required. Please Print.
Please FAX completed form to MYALEPT REMS Program at 1-877-328-9682.
The prescription for MYALEPT is only valid if received by fax.
For New York prescribers: In addition to this completed form, provide New York specific prescription blanks.

Patient Information

Full Name (first, middle, last) | Gender ☐ Male ☐ Female | Date of Birth

Address | City | State | ZIP Code

Preferred Phone | Alternate Phone | Preferred time to contact: (check one) ☐ Day ☐ Evening

Email | Alternate Contact and Phone

Parent/Guardian (if applicable)

Insurance Information – Please copy and attach the front and back of the insurance card.

Insurance Company Phone

Insured Name | Relationship to Patient

Insured Employer

Insurance Policy # | Insurance Group # (if appicable)

Prescription Card? ☐ Yes ☐ No If yes, carrier_____

Is the patient eligible for Medicare? ☐ Yes ☐ No

Medicare Policy # | Medicare Group # (if applicable)

Shipping Information

Full Name (first, middle, last)

Address (if different from above) | City | State | ZIP Code

Send initial shipment to prescribing doctor's office ☐ Yes ☐ No

Prescriber Information

Full Name (first, middle, last)

Practice/Facility Name | Office Contact Person

Address 1

Address 2 | City | State | Zip Code

Office Phone | Office Fax | License # | NPI #

AMRYT PHARMA

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Prescriber Attestations:

- 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.
    - for the treatment of liver disease, including non-alcoholic steatohepatitis (NASH).
    - for use in patients with HIV-related lipodystrophy.
    - for use in patients with metabolic disease including diabetes mellitus and hypertriglyceridemia without concurrent evidence of congenital or acquired generalized lipodystrophy.
- I understand that MYALEPT is contraindicated in patients with general obesity not associated with congenital leptin deficiency.
- I understand that MYALEPT is associated with serious adverse events due to the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or MYALEPT.
- I agree to test for neutralizing antibodies in patients who experience severe infections or if I suspect MYALEPT is no longer working (e.g., loss of glycemic control, or increases in triglycerides).
- I understand that MYALEPT is associated with a risk of lymphoma.
- I understand I must carefully consider the risks of treatment with MYALEPT in patients with significant hematological abnormalities and/or acquired generalized lipodystrophy.

Physician Signature _____ **Date** _____

MYALEPT 5mg/mL Injection Prescription

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

☐ **Maintenance Dose:** _____ mg/kg ▶ Convert dose for syringe type _____ ☐ mL ☐ units | Days Supply | Refills #

Directions (e.g., by subcutaneous injection once daily)

Attach or List Concomitant Meds | Allergies

Patient Information

Full Name (first, middle, last)

Prescriber Information

Full Name (first, middle, last)

Physician Signature_____ **Date**_____ **Physician Signature**_____ **Date**_____
Product Selection Permitted **Dispense as Written**

The following is a prescription form for the required ancillary supplies for MYALEPT reconstitution and administration. This can be faxed back to 1-877-328-9682 with the rest of this page and the previous page, or torn off and given to your patient to fill at another pharmacy.

Patient Information

Full Name (first, middle, last)

MYALEPT Supplies Prescription

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

For Reconstitution
☐ 62 of 3 mL syringe (22G x 1 in. needle) Refills #____
Water for reconstitution (select one):
☐ 5 of 30 mL vials of BWFI Refills #____
☐ 31 of 5 mL vials of SWFI (for neonates and infants) Refills #____

For Administration
☐ Nurse Injection Training Requested
☐ 1 mL tuberculin syringe Refills # ____
☐ 31G 6mm 1 mL insulin syringe Refills #____
☐ 31G 6mm 3/10 mL insulin syringe Refills #____
☐ Other syringe size and needle gauge:_____

Prescriber Information

Full Name (first, middle, last)

Addresss

City | State | ZIP Code | Office Phone

License # | NPI #

Physician Signature_____ **Date**_____ **Physician Signature**_____ **Date**_____
Product Selection Permitted **Dispense as Written**