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 number	Alternate phone number		Preferred time to contact: (check one) ☐ Day ☐ Evening	
Email		Alternate contact/phone #		
Parent/Guardian (if applicable)				

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

Insurance company phone number	
Insured Name	Relationship to patient
Insured Employer	
Prescription card ☐ Yes ☐ No If yes, carrier ______________________________	
Policy Number	
Is the patient eligible for Medicare? ☐ Yes ☐ No	
Policy number	Group Number

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 number	Office Fax number	License #	NPI #	

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Attestation of REMS Requirements. By completing this form, I attest that:

- 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.
- 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-related lipodystrophy.
- I understand that MYALEPT is not indicated 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 Prescription			
Starting Dose: [ ] 0.06 mg/kg [ ] 2.5 mg [ ] 5 mg [ ] **Maintenance Dose:** ____________			
Patient Weight	Days Supply	Refills #	
Directions (e.g., by subcutaneous injection once daily)			
List or Attach a List of Concomitant Medications		Allergies	
Patient Information			
Full Name (first, middle, last)			
Prescriber Information			
Full Name (first, middle, last)			
Address			
City	State	ZIP code	Office Phone
License #		NPI #	

Physician Signature: ____________ **Date** ________ **Physician Signature:** ____________ **Date** ________

Product Selection Permitted **Dispense as Written**

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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 ☐ 5 of 30 mL vials of BWFI Refills # __________ ☐ 31 of 5 mL vials of SWFI (use for neonates and infants) Refills # __________ ☐ 62 of 3mL syringe (22G x 1 in. needle) Refills # __________		**For Administration** ☐ 62 of 1mL tuberculin syringe (26 G x 3/8 in. needle) Refills # __________	
Prescriber Information			
Full Name (first, middle, last)			
Address			
City	State	ZIP code	Office Phone
License #		NPI #	

Physician Signature: ____________ **Date** ________ **Physician Signature:** ____________ **Date** ________

Product Selection Permitted **Dispense as Written**