

Risk Evaluation and Mitigation Strategy (REMS) Document

Myalept (metreleptin) REMS Program

I. Administrative Information

Application Number: BLA 125390
Application Holder: Amryt Pharmaceuticals DAC
Initial REMS Approval: 02/2014
Most Recent REMS Update: 10/2020

II. REMS Goal

The goal of the Myalept REMS is to mitigate (1) the risks of serious adverse sequelae (such as severe infections, excessive weight gain, glucose intolerance, diabetes mellitus) due to the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or Myalept, and (2) the risk of lymphoma by:

1. Educating prescribers about the development of neutralizing anti-metreleptin antibodies, the serious adverse sequelae that may result from these antibodies, and the risk for lymphoma associated with Myalept
2. Limiting the population exposed to Myalept by requiring prescriber certification, pharmacy certification, and prescriber attestation that each patient has a diagnosis consistent with the approved indication

III. REMS Requirements

Amryt Pharmaceuticals DAC must ensure that healthcare providers, patients, outpatient pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare Providers who prescribe Myalept must:

-
- | | |
|--|--|
| To become certified to prescribe | <ol style="list-style-type: none">1. Review the drug's Prescribing Information.2. Review the following: Prescriber Training Module.3. Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the REMS Program. |
| Before treatment initiation (first dose) | <ol style="list-style-type: none">4. Assess the patient to confirm the clinical diagnosis is consistent with the approved indication.5. Counsel the patient on the risks of Myalept.6. Order the prescription using the Prescription Authorization Form. |
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1. Healthcare Providers who prescribe Myalept must:

During treatment;
before each
prescription

7. Order the prescription using the [Prescription Authorization Form](#).

During treatment

8. Assess the patient's condition for the presence of neutralizing antibodies if a patient experiences severe infections or if you suspect Myalept treatment is no longer working (e.g., loss of glycemic control, increased triglycerides).

2. Patients who are prescribed Myalept:

Before treatment
initiation

1. Receive counseling from the prescriber on the risks of Myalept.

During treatment

2. Be monitored for neutralizing antibodies

3. Outpatient Pharmacies that dispense Myalept must:

To become
certified to
dispense

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy.

2. Train all relevant staff involved in dispensing of Myalept on the REMS Program requirements.

3. Establish processes and procedures to verify that the prescriber is certified and a completed [Prescription Authorization Form](#) is received for each new prescription.

Before dispensing

4. Verify that the prescriber is certified and a completed [Prescription Authorization Form](#) is received for each new prescription through the processes and procedures established as a requirement of the REMS Program.

At all times

5. Not distribute, transfer, loan, or sell Myalept.

6. Maintain and submit records of prescription data to the REMS program.

7. Maintain records that all REMS processes and procedures are in place and are being followed.

8. Comply with audits carried out by Amryt or a third party acting on behalf of Amryt, to ensure that all processes and procedures are in place and are being followed.

4. Wholesalers-distributors that distribute Myalept must:

To be able to distribute	<ol style="list-style-type: none">1. Establish processes and procedures to ensure the drug is distributed only to certified outpatient pharmacies, or to inpatient pharmacies authorized by the REMS Program call center.2. Train all relevant staff involved in distributing on the program requirements.
At all times	<ol style="list-style-type: none">3. Distribute only to outpatient certified pharmacies, or to inpatient pharmacies authorized by the REMS Program call center.4. Maintain records of drug distribution.5. Comply with audits carried out by Amryt Pharmaceuticals DAC or a third party acting on behalf of Amryt Pharmaceuticals DAC to ensure that all processes and procedures are in place and are being followed.

Amryt Pharmaceuticals DAC must provide training to healthcare providers who prescribe Myalept.

The training includes the following educational material: [Prescriber Training Module](#). The training must be available online or by contacting the REMS Program call center.

To inform healthcare providers about the REMS Program and the risks and safe use of Myalept, Amryt Pharmaceuticals DAC must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials and Dissemination Plans
Healthcare providers who prescribed Myalept within the 12 months prior to approval of the 12/11/2017 REMS modification and newly identified healthcare providers who prescribed or are likely to prescribe Myalept	<p>REMS Letter: REMS Letter for Health Care Providers (Infections)</p> <ol style="list-style-type: none">1. Mail within 30 calendar days of the approval of the REMS modification (12/11/2017) with a copy or link to the Prescribing Information.<ol style="list-style-type: none">a. Send by email within 30 calendar days after the initial letter was mailed if the letter is undeliverable.b. Send a second email within 30 calendars days of the date the first email was sent if the first email is marked as unopened.2. Disseminate through field-based sales and medical representatives upon request for 12 months after approval of the 12/11/2017 REMS modification with a copy or link to the Prescribing Information.

To support REMS Program operations, Amryt Pharmaceuticals DAC must:

1. Establish and maintain a REMS Program website, www.MYALEPTREMS.com. The REMS Program website must include the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and health care providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website(s).
 2. Make the REMS Program website fully operational and all REMS materials available through the REMS website or call center.
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3. Establish and maintain a REMS Program call center for REMS participants at 1-855-6MYALEPT (1-855-669-2537).
4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the Myalept REMS Program.
5. Ensure prescribers are able to enroll in the REMS Program by fax.
6. Ensure outpatient pharmacies are able to certify with the manufacturer and agreeing to comply with the requirements of the REMS Program.
7. Ensure inpatient pharmacies are able to contact the REMS Program call center for assistance in obtaining Myalept for a specific inpatient who has a certified prescriber and a [Prescription Authorization Form](#) on file with a certified pharmacy.
8. Provide the [Prescriber Training Module](#), [Prescriber Enrollment Form](#), [Myalept REMS Program: An Introduction](#), and the Prescribing Information to REMS participants who (1) attempt to prescribe Myalept and are not yet certified or (2) inquire about how to become certified.
9. Provide for 12 months after the approval of the 12/2017 REMS modification the [REMS Letter for Health Care Providers \(Infections\)](#) to REMS participants who (1) attempt to prescribe Myalept and are not yet certified or (2) inquire about how to become certified.
10. Notify prescribers and pharmacies within 48 hours after they become certified in the REMS Program.
11. Provide certified pharmacies access to the database of certified prescribers.

To ensure REMS participants' compliance with the REMS Program, Amryt Pharmaceuticals DAC must:

1. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: Myalept distribution and dispensing; certification of prescribers and pharmacies; and audits of REMS participants. These records must be readily available for FDA inspections.
 2. Establish a plan for addressing noncompliance with REMS Program requirements.
 3. Monitor certified prescribers and pharmacies on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.
 4. Audit certified pharmacies no later than 180 days after they become certified, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements. Thereafter, Amryt Pharmaceuticals DAC must include the certified pharmacies in their annual audit plan.
 5. Take reasonable steps to improve implementation of and compliance with the requirements in the Myalept REMS Program based on monitoring and evaluation of the Myalept REMS Program.
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IV. REMS Assessment Timetable

Amryt Pharmaceuticals DAC must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Amryt Pharmaceuticals DAC must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the Myalept REMS:

Enrollment Forms

Prescriber:

1. [Prescriber Enrollment Form](#)

Training and Educational Materials

Prescriber:

2. [Prescriber Training Module](#)
3. [Myalept REMS Program: An Introduction](#)

Patient Care Forms

4. [Prescription Authorization Form](#)

Communication Materials

5. [REMS Letter for Health Care Providers \(Infections\)](#)

Other Materials

6. [REMS Program Website \(www.MYALEPTREMS.com\)](http://www.MYALEPTREMS.com)
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MYALEPT will be available only through the MYALEPT REMS Program. To prescribe MYALEPT, a prescriber must: (1) review the Prescribing Information, review and complete the Prescriber Training Module, (2) complete this one-time MYALEPT REMS Program Prescriber Enrollment Form, and (3) complete and submit a MYALEPT REMS Prescription Authorization Form for each new prescription.

Complete this enrollment form and fax it to the MYALEPT REMS Program at 1-877-328-9682.

Prescriber Information (Please Print *indicates a required field.)

Full Name (first, middle, last)*			
Credentials* <input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> NP <input type="checkbox"/> PA <input type="checkbox"/> Other (specify) _____			
Physician Specialty*			
<input type="checkbox"/> Endocrinology	<input type="checkbox"/> Family Medicine	<input type="checkbox"/> Cardiology	
<input type="checkbox"/> General Internal Medicine	<input type="checkbox"/> Pediatrics	<input type="checkbox"/> Other _____	
Who do you treat? <input type="checkbox"/> Adults <input type="checkbox"/> Pediatrics <input type="checkbox"/> Both			
Practice / Facility Name			
Address 1*			
Address 2 (optional)		City*	State* ZIP code*
Phone number*	Alternate phone number*	Fax number*	
Email*		NPI #*	
Practice Setting* <input type="checkbox"/> Solo private practice <input type="checkbox"/> Group private practice <input type="checkbox"/> Academic/Hospital affiliated practice			
<input type="checkbox"/> Government Institution <input type="checkbox"/> Other _____			

Office Contact

Full Name (first, middle, last)*		
Phone number (if different from above)	Fax number (if different from above)	Email (if different from above)

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.

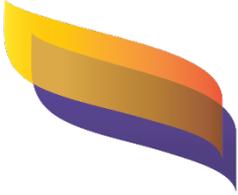
Signature* _____

Date* _____

If you have any questions, please contact the MYALEPT REMS Program.

Phone number: 1-855-669-2537 | Fax number: 1-877-328-9682 | www.MYALEPTREMS.com





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

Risk Evaluation and Mitigation Strategy (REMS) Program
Prescriber Training Module

Contents



- Introduction
- MYALEPT[®] (metreleptin) for injection Product Information
 - **Boxed Warning:** risk of development of anti-metreleptin antibodies that neutralize endogenous leptin and/or MYALEPT
 - **Boxed Warning:** risk of lymphoma
 - Appropriate patient selection
- MYALEPT REMS Program Information
- Knowledge Assessment



Introduction

Introduction



MYALEPT® (metreleptin) for injection is available only through a restricted program called the MYALEPT REMS Program.

- Prescribers must complete this training module and enroll in the MYALEPT REMS Program prior to prescribing MYALEPT.

The purpose of this training module is to educate prescribers about

- the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or MYALEPT and the serious adverse events that may result from these antibodies,
- the risk of lymphoma, and
- appropriate patient selection

Because of these risks, appropriate patient selection consistent with the approved indication for MYALEPT is very important.



MYALEPT[®] (metreleptin) for injection Product Information

Indication



MYALEPT® (metreleptin) for injection 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**

Serious Risks Associated with MYALEPT



Serious Risks Associated with the use of MYALEPT:

1. Development of anti-metereptin antibodies that neutralize endogenous leptin and MYALEPT
2. Lymphoma

Boxed Warning: Anti-metresleptin Antibodies with Neutralizing Activity - Serious Adverse Events



- Anti-metresleptin antibodies with neutralizing activity associated with adverse events consistent with loss of endogenous leptin activity, including loss of efficacy and/or severe infections, have been identified among patients with generalized lipodystrophy
 - 2 of 33 patients who underwent antibody testing
 1. tested positive for anti-metresleptin antibodies with neutralizing activity
and
 2. reported adverse events consistent with neutralizing activity, including:
 - Severe infections,
 - Loss of glycaemic control, and
 - Increases in triglycerides.

Boxed Warning: Anti-metresleptin Antibodies with Neutralizing Activity - Serious Adverse Events (continued)



■ In other populations

- 3 of 563 patients who underwent antibody testing
 1. tested positive for anti-metresleptin antibodies with neutralizing activity
and
 2. reported adverse events consistent with neutralizing activity, including excessive weight gain and development of glucose intolerance or diabetes mellitus

The clinical implications associated with development of anti-metresleptin antibodies with neutralizing activity are not well-characterized at this time due to the small number of reports.

Antibody Testing in MYALEPT Trials - Data



- Anti-metresleptin antibodies were detected in 84% (36/43) of patients with generalized lipodystrophy studied in the MYALEPT trials
- Total anti-metresleptin antibody titers ranged between 1:5 and 1:1,953,125
- Anti-metresleptin antibodies with neutralizing activity associated with adverse events consistent with loss of endogenous leptin activity and/or loss of MYALEPT efficacy were observed in 6% (2/33) of the patients with generalized lipodystrophy tested

Antibody Testing in MYALEPT Trials - Limitations



- The immunogenicity assays utilized in clinical trials lacked sensitivity, resulting in potential underestimation of the number of samples positive for anti-metresreptin antibodies with neutralizing activity
 - The observed incidence of an antibody assay (including neutralizing antibody assays) positivity may be influenced by several factors including assay sensitivity and specificity, assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease.

Antibody Testing in MYALEPT Trials – Limitations (continued)



- Antibody testing was not performed uniformly in the MYALEPT trials. The incompleteness of the current immunogenicity database precludes understanding of the magnitude and persistence of the observed anti-metresreptin antibody responses.
- Comparison of the incidence of antibodies to metresreptin with the incidence of antibodies to other products may be misleading.

Neutralizing Activity - What is My Role?



- **Test for neutralizing activity in patients who experience severe infections, or if you suspect that MYALEPT is no longer working.**
- Contact Amryt Pharmaceutical DAC (Amryt) at 1-866-216-1526 for instructions on how to submit samples for neutralizing antibody testing. The assay is not commercially available.

Amryt will ask you to:

1. Obtain written consent from your patient to release the sample and send a copy of the consent to Amryt.
2. Complete a questionnaire to explain why you are requesting neutralizing activity testing and send it to Amryt.
3. Send the sample to the designated laboratory for testing.
 - The results are generally available within 60 days
4. Amryt will contact you to provide and discuss the results.

Boxed Warning: Lymphoma



- Three cases of T-cell lymphoma have been reported in the MYALEPT lipodystrophy program
 - All 3 patients had **acquired generalized lipodystrophy (out of a total of 20 patients with acquired generalized lipodystrophy)**.
 - Two of these patients were diagnosed with peripheral T-cell lymphoma while receiving MYALEPT.
 - Both had immunodeficiency and significant hematologic abnormalities, including severe bone marrow abnormalities, before the start of MYALEPT treatment.
 - A separate case of anaplastic large cell lymphoma was reported in a patient receiving MYALEPT who did not have hematological abnormalities before treatment.

Lymphoma – What is My Role?



- Take a careful medical history for past or current hematologic abnormalities
- Carefully consider the benefits and risks of treatment with MYALEPT in patients with:
 - significant hematologic abnormalities, and/or
 - acquired generalized lipodystrophy

Adverse Reaction Reporting



To report SERIOUS ADVERSE REACTIONS, please call/contact:

- 1-855-669-2537 and/or
- FDA at 1-800-FDA-1088 or www.fda.gov/medwatch



Appropriate Patient Selection

Appropriate Patient Selection



Contraindication – General Obesity

MYALEPT is contraindicated in patients with general obesity not associated with congenital leptin deficiency.

- MYALEPT has not been shown to be effective in treating general obesity, and the development of anti-metreleptin antibodies with neutralizing activity has been reported in obese patients treated with MYALEPT
- Adverse events consistent with loss of endogenous leptin activity have been identified in three patients without lipodystrophy who received metreleptin (excessive weight gain, development of glucose intolerance or diabetes mellitus).

The clinical implications associated with development of anti-metreleptin antibodies with neutralizing activity are not well-characterized at this time due to the small number of reports.

Appropriate Patient Selection



Important Limitations of Use

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

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



MYALEPT[®] (metreleptin) for injection

REMS PROGRAM INFORMATION

MYALEPT[®] (metreleptin) for injection

REMS Program



Key program elements:

- Certification of Prescribers of MYALEPT,
 - Certification consists of training, and enrolling in the MYALEPT REMS Program.
- Completion of a Prescription Authorization Form for each new prescription, and the
- Restricted distribution of MYALEPT through certified pharmacies.

MYALEPT[®] (metreleptin) for injection

REMS Program



**Before prescribing MYALEPT,
prescribers must complete the following steps:**

1. Review the Prescribing Information and this Prescriber Training Module.
2. Complete, sign, and submit the one-time MYALEPT REMS Program Prescriber Enrollment Form.
3. Complete, sign, and submit the MYALEPT REMS Program Prescription Authorization Form for each new prescription.

Note: All Materials can be downloaded from the MYALEPT REMS website at:
www.MYALEPTREMS.com

Or request these materials by calling 1-855-669-2537

1. Review Prescriber Education Materials



Review the following Prescriber Education Materials:

- a) MYALEPT[®] (metreleptin) for injection Prescribing Information,
and
- b) This Prescriber Training Module

2. Enroll in MYALEPT[®] (metreleptin) for injection REMS Program



To enroll in the MYALEPT REMS Program:

- Download the MYALEPT REMS Program Prescriber Enrollment Form at www.MYALEPTREMS.com or request a copy by calling 1-855-669-2537
- Complete the enrollment form
- Sign & submit the enrollment form
 - Fax to 1-877-328-9682

3. Submit Prescription Authorization Form

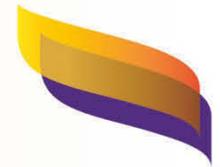


When prescribing MYALEPT® (metreleptin) for injection, a prescriber must complete a Prescription Authorization Form for each new prescription.

As part of completing the Prescription Authorization Form, you 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.

3. Submit Prescription Authorization Form (continued)



- 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-related lipodystrophy.
 - use in patients with metabolic disease including diabetes mellitus and hypertriglyceridemia without concurrent evidence of congenital or acquired generalized lipodystrophy.

3. Submit Prescription Authorization Form (continued)



- 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 hematologic abnormalities and/or acquired generalized lipodystrophy.

3. Submit Prescription Authorization Form



Each new prescription for MYALEPT must be written using the MYALEPT Prescription Authorization Form.

1. Download the Prescription Authorization Form at www.MYALEPTREMS.com or request a copy by calling 1-855-669-2537
2. Complete the Prescription Authorization Form
3. Sign & submit the Prescription Authorization Form
 - Fax to 1-877-328-9682



Knowledge Assessment

Knowledge Assessment



- The following questions about MYALEPT[®] (metreleptin) for injection are provided to reinforce learning.
- If you have difficulty answering these questions, review the previous slides and refer to the Prescribing Information.

Knowledge Assessment



1. Which of the following statements is true?
 - MYALEPT (metreleptin) for injection is indicated for use in patients with HIV-related lipodystrophy.
 - MYALEPT is indicated for use in patients with metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of inherited or acquired generalized lipodystrophy.
 - MYALEPT is a recombinant analog of murine leptin.
 - 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.

Knowledge Assessment



1. Which of the following statements is true?
- MYALEPT (metreleptin) is indicated for use in patients with HIV-related lipodystrophy.
 - MYALEPT is indicated for use in patients with metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of inherited or acquired generalized lipodystrophy.
 - MYALEPT is a recombinant analog of murine leptin.
 - 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.

Answer: 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

(continued on next slide)



(continued from previous slide)

- **The safety and effectiveness of MYALEPT for the following conditions have not been established**
 - The treatment of complications of partial lipodystrophy
 - The treatment of liver disease including non-alcoholic steatohepatitis (NASH)

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

- **MYALEPT is contraindicated in patients with general obesity not associated with congenital leptin deficiency.**

Knowledge Assessment



2. The risks and benefits of MYALEPT® (metreleptin) for injection treatment should be carefully considered in patients with significant hematologic abnormalities (for example, leukopenia, neutropenia, bone marrow abnormalities, lymphoma and/or lymphadenopathy) and/or acquired generalized lipodystrophy.

True

False

Knowledge Assessment



2. The risks and benefits of MYALEPT® (metreleptin) for injection treatment should be carefully considered in patients with significant hematologic abnormalities (for example, leukopenia, neutropenia, bone marrow abnormalities, lymphoma and/or lymphadenopathy) and/or acquired generalized lipodystrophy.

True

False

- Answer:
 - Peripheral T-cell lymphoma was diagnosed in two patients with acquired generalized lipodystrophy while receiving MYALEPT.
 - Both had immunodeficiency and significant hematologic abnormalities including severe bone marrow abnormalities before the start of MYALEPT treatment.
 - A separate case of anaplastic large cell lymphoma was reported in a patient with acquired generalized lipodystrophy who did not have hematologic abnormalities before MYALEPT treatment.

Knowledge Assessment



3. Developing neutralizing activity to metreleptin could:
- affect endogenous leptin
 - result in loss of efficacy
 - result in increased susceptibility to severe infection
 - all of the above
 - none of the above

Knowledge Assessment



3. Developing neutralizing activity to metreleptin could:
- affect endogenous leptin
 - result in loss of efficacy
 - result in increased susceptibility to severe infection
 - all of the above
 - none of the above

Answer: Developing neutralizing activity to metreleptin could affect endogenous leptin and could result in loss of efficacy and could increase susceptibility to severe infection.

Knowledge Assessment



4. If a patient is experiencing severe infections and/or I suspect Myalept is no longer working, I will contact Amryt Pharmaceuticals DAC for instructions on how to send a blood sample to test for anti-metereptin antibodies with neutralizing activity.
- True
 - False

Knowledge Assessment



4. If a patient is experiencing severe infections and/or I suspect Myalept is no longer working, I will contact Amryt Pharmaceuticals DAC (Amryt) for instructions on how to send a blood sample to test for anti-metereptin antibodies with neutralizing activity.

True

False

Answer: If you suspect your patient is experiencing complications from the development of anti-metereptin neutralizing antibodies, you can submit a request and obtain results from Amryt at no cost.

1. Call 1-866-216-1526
 - Amryt will provide you information on the requirements for sample collection and shipment.
2. Amryt will instruct you to:
 - a. Obtain written consent from your patient to release the sample and send a copy of the consent to Amryt.
 - b. Complete a questionnaire to explain why you are requesting neutralizing activity testing.
 - c. Send the sample and paperwork to the designated laboratory for testing.
 - The results are generally available within 60 days
3. Amryt will contact you to provide and discuss the results.

Knowledge Assessment



5. How often should the Prescription Authorization Form be completed?
- Each new prescription
 - Only on the first prescription
 - Every refill
 - Once a year

Knowledge Assessment



5. How often should the Prescription Authorization Form be completed?
- ✓ Each new prescription
 - Only on the first prescription
 - Every refill
 - Once a year

Answer: For each new prescription, the prescriber must submit a Prescription Authorization Form.

Knowledge Assessment



6. MYALEPT® (metreleptin) for injection is available only through certified pharmacies.
- True
 - False

Knowledge Assessment



6. MYALEPT® (metreleptin) for injection is available only through certified pharmacies.
- True
- False

Answer: MYALEPT is available only through pharmacies that are specially certified and agree to follow REMS requirements. For a list of certified pharmacies call: 1-855-669-2537.

Completion of Training for the MYALEPT[®] (metreleptin) for injection REMS Program



You have completed training for the MYALEPT REMS Program.

To enroll in the MYALEPT REMS Program, complete the Enrollment Form and return via fax at 1-877-328-9682.

For more information on the MYALEPT REMS Program, please call 1-855-669-2537 or visit www.MYALEPTREMS.com.



Myalept is a registered trademark and the property of the Amryt Pharma Group.

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

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 Program 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 for MYALEPT is very important.

MYALEPT REMS Program Requirements

- Certification of Prescribers of MYALEPT
- Completion of a Prescription Authorization Form for each new prescription
- Restricted distribution of MYALEPT through certified pharmacies

Certification of Prescribers of MYALEPT

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

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

Completion of Prescription Authorization Form

Each new prescription for MYALEPT must be written using the MYALEPT Prescription Authorization Form.

- Download the Prescription Authorization Form at www.MYALEPTREMS.com or request a copy by calling 1-855-669-2537
- Complete the Prescription Authorization Form

Restricted Distribution of MYALEPT through Certified Pharmacies

Prescription Authorization Form must be signed and submitted by fax to 1-877-328-9682.

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

If you have any questions, please contact the MYALEPT REMS Program.

Phone number: 1-855-669-2537 | Fax number: 1-877-328-9682 | www.MYALEPTREMS.com

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 <input type="checkbox"/> Male <input type="checkbox"/> Female		Date of Birth	
Address		City		State	ZIP Code
Preferred Phone		Alternate Phone		Preferred time to contact: (check one) <input type="checkbox"/> Day <input type="checkbox"/> 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 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

Full Name (first, middle, last)				
Address (if different from above)		City	State	ZIP Code
Send initial shipment to prescribing doctor's office <input type="checkbox"/> Yes <input type="checkbox"/> 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 #	

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: <input type="checkbox"/> 0.06 mg/kg <input type="checkbox"/> 2.5 mg <input type="checkbox"/> 5 mg ▶ Convert dose for syringe type _____ <input type="checkbox"/> mL <input type="checkbox"/> units	Patient Weight
<input type="checkbox"/> Maintenance Dose: _____ mg/kg ▶ Convert dose for syringe type _____ <input type="checkbox"/> mL <input type="checkbox"/> 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).

<p>For Reconstitution</p> <input type="checkbox"/> 62 of 3 mL syringe (22G x 1 in. needle) Refills # _____ Water for reconstitution (select one): <input type="checkbox"/> 5 of 30 mL vials of BWFI Refills # _____ <input type="checkbox"/> 31 of 5 mL vials of SWFI (for neonates and infants) Refills # _____	<p>For Administration</p> <input type="checkbox"/> Nurse Injection Training Requested <input type="checkbox"/> 1 mL tuberculin syringe Refills # _____ <input type="checkbox"/> 31G 6mm 1 mL insulin syringe Refills # _____ <input type="checkbox"/> 31G 6mm 3/10 mL insulin syringe Refills # _____ <input type="checkbox"/> Other syringe size and needle gauge: _____
--	--

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

FDA REQUIRED SAFETY INFORMATION
RISK OF SEVERE INFECTIONS
MYALEPT[®] (metreleptin) for Injection

Dear Certified Prescriber:

A recent assessment of the Myalept REMS (Risk Evaluation Mitigation Strategy) Program has demonstrated that prescribers are not fully aware of the 1) serious risk of severe infections associated with the use of MYALEPT and 2) the availability of neutralizing antibody testing.

Therefore, Aegerion has made updates to the MYALEPT REMS Prescriber Training Module to emphasize:

- **the risk of severe infections that may result from the development of anti-metreleptin antibodies, and**
- **the availability of testing for neutralizing activity in patients who experience severe infections, or if you suspect that Myalept is no longer working**

We remind you that the purpose of the MYALEPT REMS Prescriber Training Module is to educate prescribers about:

- The development of anti-metreleptin antibodies that neutralize endogenous leptin and/or Myalept and the serious adverse events that may result from these antibodies, including:
 - severe infections,
 - loss of glycemic control
 - increases in triglycerides
- The risk of lymphoma, and
- Appropriate patient selection

For instructions on how to submit samples for neutralizing antibody testing contact Aegerion Pharmaceuticals, Inc. (Aegerion) at 1-866-216-1526.

Certified Prescribers are encouraged to review the revised prescriber training program that is now located on the MYALEPT REMS website: www.myaleptREMS.com. However, no action is required to maintain your certification.

If you have any questions on the above, please contact the MYALEPT REMS Program at 1-855-669-2537.

Sincerely,



Dr. Charles Gerrits
Aegerion Pharmaceuticals, Inc.

Attachment: Myalept Prescribing Information

MYALEPT® REMS Program

Program Requirements | Training & Enrollment

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.

The MYALEPT REMS Program was developed with the FDA:

To educate prescribers about:

- the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or MYALEPT and the serious adverse events that may result from these antibodies,
- the risk of lymphoma, and
- appropriate patient selection

Program Requirements

MYALEPT is available only through the MYALEPT REMS Program. The MYALEPT REMS Program requirements include:

For Prescribers:

- **Certification** of prescribers of MYALEPT
 - Certification consists of completion of **training, and enrollment** in the MYALEPT REMS Program
- **Completion** of a Prescription Authorization form for **each** new prescription.

Find out more about [Training & Enrollment](#).

For Pharmacies:

- **Restricted distribution** of MYALEPT to patients with completed Prescription Authorization Forms from prescribers who are certified in the MYALEPT REMS Program.

Training & Enrollment

Healthcare providers who prescribe MYALEPT must review the prescriber training materials to enroll in the MYALEPT REMS Program.

Steps to Prescriber Certification

1. Review the Prescriber Education Materials

- [MYALEPT Prescribing Information](#)
- [Prescriber Training Module](#)

2. Complete and submit the MYALEPT REMS Program Prescriber Enrollment Form

- Print and sign the [Prescriber Enrollment Form](#) or request a copy by calling 1-855-669-2537
- Submit the form via Fax to 1-877-328-9682

By completing the Prescriber Enrollment Form, the prescriber agrees to comply with the MYALEPT REMS Program requirements. A confirmation of your certification in the MYALEPT REMS program will be sent to you so you can begin to prescribe MYALEPT.

Reporting Adverse Reactions

Healthcare providers should report all suspected adverse events.

Please contact the company at 1-855-669-2537 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.com.

REMS Materials

-  [MYALEPT REMS Program: An Introduction](#)
-  [MYALEPT REMS Program Prescriber Training Module](#)
-  [MYALEPT REMS Program Prescriber Enrollment Form](#)
-  [MYALEPT REMS Program Prescription Authorization Form](#)
-  [Prescribing Information](#)
-  [Myalept REMS Letter for HCPs \(Infections\)](#)

MYALEPT REMS Program Contact Us

Phone: 1-855-669-2537

Fax: 1-877-328-9682

Hours of Operation:
Monday - Friday,
8:00am-8:00pm
Eastern Time

MYALEPT[®] REMS Program

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Last Updated 09/2020
MYA/US/144 09-20

MYALEPT[®] REMS Program

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REMS Materials

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