

Dosing and Administration Guide

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

Troy, 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.

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Dena, MYALEPT patient

Myalept® is a once-daily subcutaneous injection

- Myalept should be administered once daily at the same time every day, without regard to the timing of meals.
- If a dose is missed, patients should be instructed to administer the dose as soon as noticed, and resume the normal dosing schedule the next day.

Recommended daily dose of Myalept for pediatric and adult patients			
Baseline weight	Starting daily dose (injection volume)	Dose adjustments (injection volume)	Maximum daily dose (injection volume)
≤40 kg (males and females)	♂♀ 0.06 mg/kg (0.012 mL/kg)	0.02 mg/kg (0.004 mL/kg)	0.13 mg/kg (0.026 mL/kg)
Males >40 kg	♂ 2.5 mg (0.5 mL)	1.25 mg-2.5 mg (0.25 mL-0.5 mL)	10 mg (2 mL)
Females >40 kg	♀ 5 mg (1 mL)		

Based on clinical response (e.g., inadequate metabolic control) or other considerations (e.g., tolerability issues, excessive weight loss [especially in pediatric patients]), Myalept dose may be decreased or increased to the maximum dose listed in the table above.

Sample dosing for patients ≤40 kg

Example Dosing for Patients ≤40 kg			
Weight	Starting Dose	Dose Adjustment	Maximum Dose
5 kg	0.30 mg (0.06 mL or 6 Units)	0.10 mg (0.02 mL or 2 Units)	0.65 mg (0.13 mL or 13 Units)
10 kg	0.60 mg (0.12 mL or 12 Units)	0.20 mg (0.04 mL or 4 Units)	1.3 mg (0.26 mL or 26 Units)
15 kg	0.90 mg (0.18 mL or 18 Units)	0.30 mg (0.06 mL or 6 Units)	1.95 mg (0.39 mL or 39 Units)
20 kg	1.2 mg (0.24 mL or 24 Units)	0.40 mg (0.08 mL or 8 Units)	2.6 mg (0.52 mL or 52 Units)
25 kg	1.5 mg (0.3 mL or 30 Units)	0.50 mg (0.1 mL or 10 Units)	3.25 mg (0.65 mL or 65 Units)
30 kg	1.8 mg (0.36 mL or 36 Units)	0.60 mg (0.12 mL or 12 Units)	3.9 mg (0.78 mL or 78 Units)
35 kg	2.1 mg (0.42 mL or 42 Units)	0.70 mg (0.14 mL or 14 Units)	4.55 mg (0.91 mL or 91 Units)
40 kg	2.4 mg (0.48 mL or 48 Units)	0.80 mg (0.16 mL or 16 Units)	5.2 mg (1.03 mL or 103 Units)

See Instructions for Use for more information on conversion of Myalept dose to unit measurement for injection.

IMPORTANT SAFETY INFORMATION

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

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



In patients at risk for hypoglycemia

- Dosage adjustments, including possible large reductions, of insulin or insulin secretagogue may be necessary in some patients to minimize the risk of hypoglycemia.
- When treating patients concomitantly with Myalept and insulin therapy, close monitoring of blood glucose levels is recommended.



In patients at risk for pancreatitis

- Tapering of the dose over a 1-week period is recommended.
- During tapering, monitor triglyceride levels and consider initiating or adjusting the dose of lipid-lowering medications as needed.
- Signs and/or symptoms consistent with pancreatitis should prompt an appropriate clinical evaluation.

Myalept Storage and Preparation



Healthcare professionals should provide proper training to patients and caregivers

- Prior to self-use, patients and caregivers should prepare and administer the first dose of Myalept under the supervision of a qualified healthcare professional.



Myalept storage and reconstitution

- Healthcare professionals should instruct patients to store the vials of lyophilized powder in the refrigerator as soon as they receive them.
- Myalept can be reconstituted aseptically with 2.2 mL of sterile Bacteriostatic Water for Injection (BWFI), USP (0.9% benzyl alcohol), or with 2.2 mL of sterile Water for Injection (WFI).

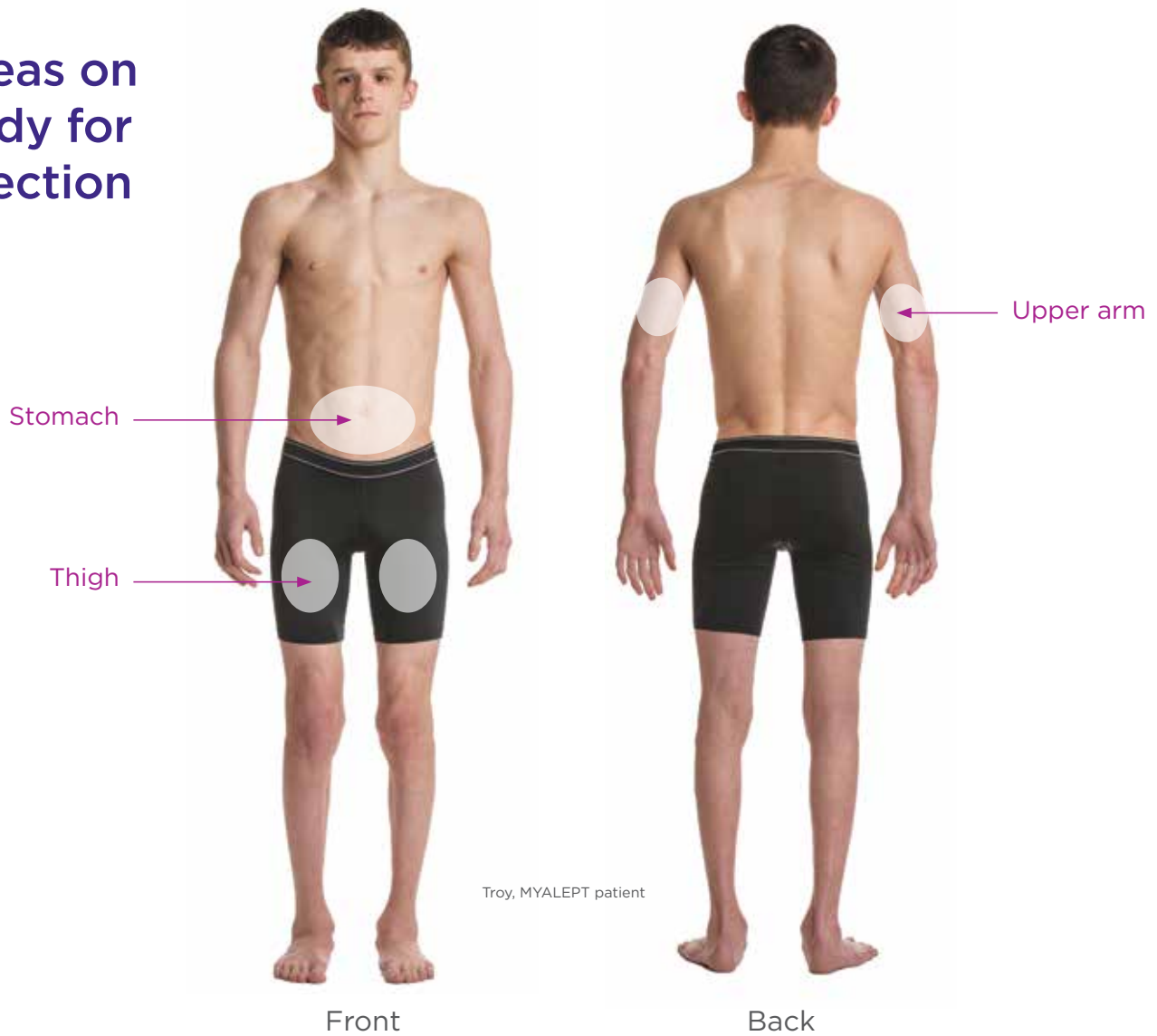
Myalept reconstitution and storage guidelines	
Diluent for reconstitution	Storage guidelines and recommendations
WFI	<ul style="list-style-type: none"> • For use in neonates and infants, reconstitute with preservative-free sterile WFI. When reconstituted with sterile WFI, Myalept should be administered immediately. • Unused reconstituted solution cannot be saved for later use and should be discarded.
BWFI	<ul style="list-style-type: none"> • For use in pediatric and adult patients, reconstitute with BWFI. When reconstituted with BWFI, Myalept solution can be used within 3 days when stored in the refrigerator between 36°F and 46°F (2°C and 8°C) and protected from light. • Discard unused reconstituted solution after 3 days. Attach the supplied sticker to the vial and enter the discard date.

Myalept administration

Myalept is given as a subcutaneous injection

Healthcare professionals should instruct patients and caregivers on the proper subcutaneous injection technique, using care to avoid intramuscular injection in patients with minimal subcutaneous adipose tissue.

Areas on body for injection



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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.

For more information, visit myalept.com.

Chiesi Total CareSM Program offered through Accredo Specialty Pharmacy.

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