Pr MYALEPTA™

(metreleptin for injection)

DOSE AND PRESCRIBING INFORMATION: SPECIALIST PRESCRIBER GUIDE

This brochure should be read in conjunction with the Product Monograph.

Pr myalepta™ metreleptin for injection

Questions or concerns: **1-800-696-1341**

Chiesi

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Introduction

MYALEPTA is provided as a powder for solution for injection for administration subcutaneously. Following treatment initiation, MYALEPTA is to be self-administered by the patient or caregiver on a daily basis at home. It is important that patients and carers are provided with training on the reconstitution of the product and proper subcutaneous injection technique, to avoid intramuscular injection in patients with minimal subcutaneous adipose tissue.

The brochure provides information on:

- Determining the right dose of MYALEPTA
- Training the patient to prepare and inject MYALEPTA
- Prescribing MYALEPTA and the required ancillary items

The brochure should be read in conjunction with the Product Monograph and with the brochure on Important Risk Minimization Information: Guide for Healthcare Professionals.

Indications

MYALEPTA is indicated as an adjunct to diet as a replacement therapy to treat the complications of leptin deficiency in lipodystrophy (LD) patients:[1]

- With confirmed congenital generalised LD (Berardinelli-Seip syndrome) or acquired generalised LD (Lawrence syndrome) in adults and children 2 years of age and above
- with confirmed familial partial LD (PL) or acquired PL (Barraquer-Simons syndrome), in adults and children 12 years of age and above with persistent significant metabolic disease for whom standard treatments have failed to achieve adequate metabolic control.

Treatment with MYALEPTA should be initiated and monitored by a healthcare professional experienced in the diagnosis and management of metabolic disorders associated with lipodystropy.

Serious Warnings and Precautions

Anti-metreleptin antibodies with neutralizing activity have been identified in patients treated with Myalepta. The consequences are not well characterized but could include inhibition of endogenous leptin action and loss of Myalepta efficacy. Worsening metabolic control and/or severe infection have been reported. Test for anti-metreleptin antibodies with neutralizing activity in patients with severe infections or loss of efficacy during Myalepta treatment. Contact medinfo@medisonpharma.com or 1-800-696-1341 for neutralizing antibody testing

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

Important advice to patients on risk minimization

Healthcare professionals should advise patients about the key risks associated with MYALEPTA. These are detailed in the brochure on Important Risk Minimization Information: Guide for Healthcare Professionals and the guide for patients and their caregivers (Patient Care Guide: Important Risk Minimization Information for Patients and their Carers).

They include:

- Hypoglycaemia with concomitant use of insulin and other anti-diabetics.
- Acute pancreatitis associated with abrupt discontinuation of MYALEPTA.
- Unplanned pregnancy due to improvement of hormonal dysfunction with MYALEPTA.
- Autoimmune disorder progression.
- Medication errors.
- Serious and severe infections or loss of efficacy secondary to neutralising antibodies despite adherence to Myalepta administration.
- T-cell lymphomas.
- Hypersensitivity.
- Benzyl alcohol toxicity

Determining the right dose of MYALEPTA

The recommended daily dose of MYALEPTA is based on body weight as provided in Table 1.

- In order to ensure patients and carers understand the correct dose to be injected, **the prescriber should prescribe the appropriate dose both in milligrams (mg) and the volume in millilitres (mL).**[1]
- In order to avoid medication errors including overdose, the dose calculation and dose adjustment guidelines below should be followed.[1]
- Actual body weight at initiation of treatment should always be used when calculating the dose of MYALEPTA.[1]

Table 1: MYALEPTA recommended dose[1]

Baseline weight	Starting daily dose (injection volume)	Dose adjustments (injection volume)	Maximum daily dose (injection volume)
Males and females ≤ 40 kg	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 to 2.5 mg (0.25 to 0.5 mL)	10 mg (2 mL)
Females > 40 kg	5 mg (1 mL)	1.25 to 2.5 mg (0.25 to 0.5 mL)	10 mg (2 mL)

The starting dose calculator is shown in Table 2.

Table 2: Dose calculation[1]

Weight and gender	Starting dose calculation
Males and females ≤ 40 kg once daily dose	Weight (kg) x 0.06 mg/kg = Individual patient daily starting dose in mg Weight (kg) x 0.012 mL/kg = Individual patient daily starting volume to inject in mL **Example:** 25 kg patient is initiated at 0.06 mg/kg of MYALEPTA. The individual patient dose = 1.5 mg 25 kg patient is initiated at 0.012 mL/kg = 0.3 mL of MYALEPTA solution to inject
Males > 40 kg once daily dose	Individual patient once daily dose in mg = 2.5 mg Amount to inject once daily dose = 0.5 mL
Females > 40 kg once daily dose	Individual patient once daily dose in mg = 5 mg Amount to inject once daily dose = 1 mL

Dose adjustments should be made as described in the Product Monograph which also includes a dose increase calculator.

For patients weighing less than 40 kg, actual body weight at initiation of therapy should be used to calculate dose; of these, in patients weighing less than or equal to 25 kg, refer to Table 3 for the starting dose.

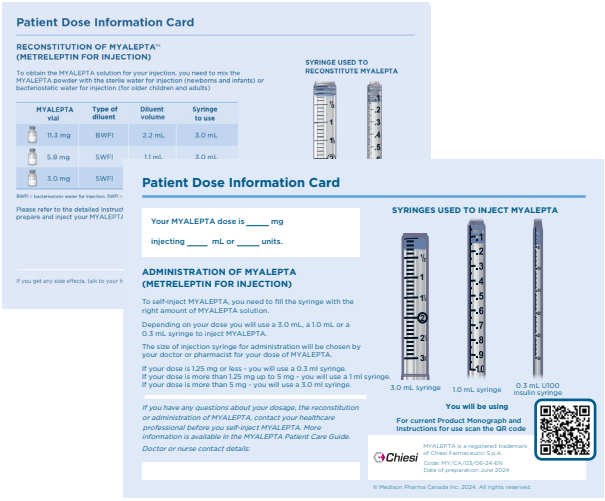
Table 3: Conversion of dose to units with U100 0.3 mL syringe

Weight of child	Dose of MYALEPTA	Actual amount of solution*	Rounded amount of solution	'Unit' measurement volume in 0.3 mL syringe to inject
9 kg	0.54 mg	0.108 mL	0.10 mL	10
10 kg	0.60 mg	0.120 mL	0.12 mL	12
11 kg	0.66 mg	0.132 mL	0.13 mL	13
12 kg	0.72 mg	0.144 mL	0.14 mL	14
13 kg	0.78 mg	0.156 mL	0.15 mL	15
14 kg	0.84 mg	0.168 mL	0.16 mL	16
15 kg	0.90 mg	0.180 mL	0.18 mL	18
16 kg	0.96 mg	0.192 mL	0.19 mL	19
17 kg	1.02 mg	0.204 mL	0.20 mL	20
18 kg	1.08 mg	0.216 mL	0.21 mL	21
19 kg	1.14 mg	0.228 mL	0.22 mL	22
20 kg	1.20 mg	0.240 mL	0.24 mL	24
21 kg	1.26 mg	0.252 mL	0.25 mL	25
22 kg	1.32 mg	0.264 mL	0.26 mL	26
23 kg	1.38 mg	0.276 mL	0.27 mL	27
24 kg	1.44 mg	0.288 mL	0.28 mL	28
25 kg	1.50 mg	0.300 mL	0.30 mL	30

*Note: Initial and dose increments should be rounded down to the nearest 0.01 mL

Dose Cards

Patients should be provided with their daily dosage both in mg and mL and, if the dose is ≤1.5 mg (0.3 mL) and the 0.3 mL U100 insulin syringe is used, the equivalent units. Patients and/or caregivers should be given Dose Cards, completed with their daily dosage, to take home with them.



Training the patient to prepare and inject MYALEPTA

The first injection of MYALEPTA should always be supervised by a healthcare professional and it is important that the patient and/or caregiver is appropriately trained before self-administering MYALEPTA at home.[1]

MYALEPTA should be administered subcutaneously at approximately the same time every day.[1] It can be administered any time of the day without regard to the timing of meals. If the patient misses a dose, MYALEPTA should be administered as soon as the omission is noticed, and the normal dosing schedule resumed the next day.[1]

IMPORTANT INFORMATION TO ADVISE YOUR PATIENTS ON:

- MYALEPTA should be stored in the refrigerator at 2°C to 8°C and protected from light until preparing for use.
- Keep MYALEPTA vials in the carton when not in use.
- MYALEPTA should not be used past the expiration date.
- Do not freeze MYALEPTA.
- Do not use if the white lyophilized cake is discoloured.
- Use with bacteriostatic water for injection (BWFI): when 11.3 mg Myalepta is reconstituted with BWFI, the vial can be used for multiple doses within 3 days when stored in the refrigerator at 2°C to 8°C and protected from light.
- Use with Sterile water for injection (SWFI): when Myalepta is reconstituted with SWFI, the vial can be used for a single dose only and should be administered immediately. Unused reconstituted solution cannot be saved for later use and should be discarded.
- After reconstitution, the vials should not be frozen (below 0°C) or shaken vigorously. If the reconstituted product is inadvertently frozen, it should be thrown away.
- Keep out of reach and sight of children.

Other measures to support risk minimization

Chiesi has initiated a programme of educational activities including a brochure on Important Risk Minimization Information: Guide for Healthcare Professionals and a brochure for patients and their carers (Patient Care Guide: Important Risk Minimization Information for Patients and their Caregivers).

In addition, information on correct preparation and injection techniques, in the form of an Instructions for Use guide are provided in the Product Monograph.

The Patient Care Guide (Patient Care Guide: Important Risk Minimization Information for Patients and their Caregivers) and the Dose Cards should be provided to every patient.

Prescribing MYALEPTA and the required ancillary items

Ensure your patient has supplies of MYALEPTA and all ancillary items needed to reconstitute and administer MYALEPTA.

MYALEPTA

MYALEPTA is available in 3 vial sizes:

- MYALEPTA 3 mg powder for solution for injection: Each vial contains 3 mg of metreleptin.
  After reconstitution with 0.6 mL water for injections, each mL contains 5 mg of metreleptin.
- MYALEPTA 5.8 mg powder for solution for injection: Each vial contains 5.8 mg of metreleptin.
  After reconstitution with 1.1 mL water for injections, each mL contains 5 mg of metreleptin.
- MYALEPTA 11.3 mg powder for solution for injection: Each vial contains 11.3 mg of metreleptin.
  After reconstitution with 2.2 mL water for injections, each mL contains 5 mg of metreleptin.

Ancillary Items

- A vial with liquid for mixing MYALEPTA -
  Sterile water for injection should be used in infants less than 3 years of age, or in adults with a known hypersensitivity to benzyl alcohol
  Bacteriostatic water for injection should be used for older children and adults
- A 3 mL syringe with a longer needle for mixing MYALEPTA
- A vial with MYALEPTA powder
  3 mg and 5.8 mg vial are for single use reconstituted with SWFI. Should be used immediately and any remaining reconstituted solution should be discarded.
  11.3 mg vial is for multi use reconstituted with BWFI. Should be used within 3 days of reconstitution when stored at 2°C to 8°C and protected from light.
- A syringe for injecting the MYALEPTA medicine under the skin – this syringe has a much shorter needle.
  The size of this second syringe will be chosen by your doctor or pharmacist for your dose of MYALEPTA.
  If your dose is 1.25 mg or less - you will use a 0.3 ml syringe.
  If your dose is more than 1.25 mg up to 5 mg - you will use a 1 ml syringe.
  If your dose is more than 5 mg - you will use a 3.0 ml syringe.
- 2 alcohol wipes
- 1 sharps container for throwing away used needles and syringes. For Disposal Instructions - Refer to Instructions for Use in the Product Monograph by scanning the QR Code provided in this document.
- Stickers to note discard date for mixed medicine

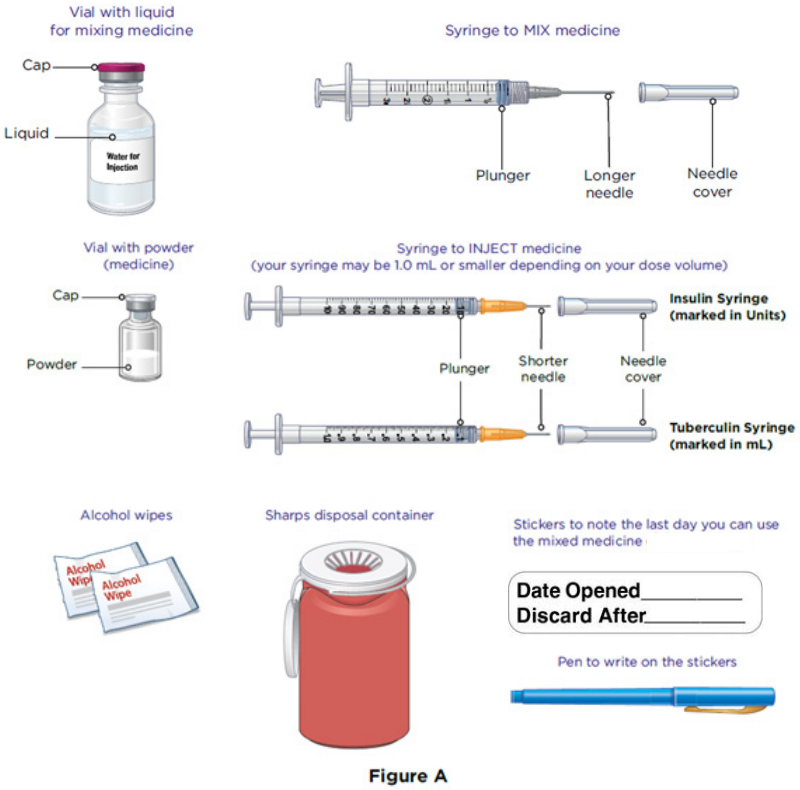


Figure A

For current Product Monograph and Instructions for use scan the QR code

References

1. Chiesi Farmaceutici S.p.A. Myalepta Product Monograph, available at https://health-products.canada.ca/dpd-bdpp/

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