



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Educational material for patients and healthcare professionals to ensure Myalepta is used correctly

Material will include training video on how to prepare and give medicine

Educational materials will be provided to patients and healthcare professionals to ensure that the medicine Myalepta (metreleptin) is prepared and injected correctly, and to prevent the risk of medication errors.

Myalepta is a medicine used to treat lipodystrophy, where patients have loss of fatty tissue under the skin and build-up of fat elsewhere in the body such as in the liver and muscles. Myalepta is given as a daily injection under the skin of the abdomen (belly), thigh or upper arm. The medicine comes as a vial of powder to which water is added to make a solution for injection. The recommended daily dose depends on the patient's bodyweight and sex, which the doctor can then adjust based on the patient's response to treatment. Patients, their parents or carers can inject the medicine once they have been trained by their doctor or nurse.

With each vial of Myalepta the pharmacist will dispense an ampoule or vial of water for injection to prepare the solution as well as two syringes (one to make up the medicine and one to give it) and needles.

Using the wrong syringe to make up the medicine or not withdrawing the correct dose could cause dosing errors. This might result in the patient receiving too much or too little of the active substance. In addition giving the medicine in the muscle instead of under the skin could lead to the medicine being absorbed faster than recommended which can change the effects of the medicine.

To avoid medication errors, healthcare professionals and patients will be given educational material with detailed instructions on how to prepare the solution and how to inject the correct dose. This includes written training materials as well as a video with instructions on how to prepare the solution for injection and how to inject it.

More information on Myalepta can be found on the Agency's website: ema.europa.eu/Find_medicine.

Information for patients and their parents or carers

- Myalepta is available as a vial of powder to which water for injection is added to make a solution for injection.
- The dose depends on your body weight and may be different for men than women. It will be adjusted by your doctor according to your response to treatment.



- Together with the vial containing Myalepta powder, your pharmacist will give you a vial or ampoule of water for injection as well as a 3 ml syringe. You will need to use the 3 ml syringe to withdraw the water from the vial or ampoule and transfer it into the vial containing Myalepta powder. Your pharmacist will give you detailed instructions on how to do this.
- Your pharmacist will also give you a second syringe (the size of syringe to use varies depending on the dose prescribed and is either 0.3 mL, 1.0 mL or 2.5 mL) that you must use to give the injection. Once you have made up the solution you must draw the amount prescribed by your doctor (this may be in **units or in ml** depending on the syringe) using the second syringe. Your pharmacist will give you detailed instructions on how to do this. Any remaining solution should be discarded.
- You must then inject the medicine **under the skin**. It is important that you follow the instructions given to you by your doctor, pharmacist or nurse.
- You should speak to your doctor, pharmacist or nurse if you have any questions about your treatment.

Information for healthcare professionals

- Myalepta (metreleptin), used treat lipodystrophy, is given as a daily **subcutaneous injection** in the abdomen, thigh or upper arm. It is available as a vial that contains a powder that is made into a solution for injection.
- The recommended daily dose depends on the patient's bodyweight and sex as shown in the following table, and is adjusted based on the patient's response to treatment. The dose should be prescribed in both **milligrams and milliliters**:

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 mg to 2.5 mg (0.25 mL to 0.5 mL)	10 mg (2 mL)
Females > 40 kg	5 mg (1 mL)	1.25 mg to 2.5 mg (0.25 mL to 0.5 mL)	10 mg (2 mL)

- Patients, their parents or carers can inject the medicine once they have been trained. They must however always prepare and give the first dose under supervision of the doctor or nurse. Patients should be reviewed every 6 months to ensure that their injection technique is correct. With every prescription of Myalepta the pharmacist should dispense:
 - Water for injection to reconstitute the powder (2.2 ml of water for injection are needed);

- A 3 ml syringe (21 gauge and 40 mm) to draw up the water for injection and reconstitute the powder.
- A second syringe to inject the dose. The size of the syringe depends on the dose prescribed and is determined as follows:

Myalepta dose range to be administered daily	Syringe	Needle gauge and length
For daily doses ≤ 1.5 mg (≤ 0.3 mL)	0.3 mL 100 UI insulin	30 gauge 8 mm needle
For daily doses > 1.5 mg – 5 mg (0.3 – 1.0 mL)	1.0 mL	30 gauge 13 mm needle
For daily doses > 5 mg (> 1.0 mL)	2.5 mL	30 gauge 13 mm needle

- The pharmacist must also dispense the corresponding needles, alcohol swabs and sharps bin.

Healthcare professionals must carefully explain to the patient or carer how the solution for injection is prepared and how the prescribed dose should be measured (in ml or units). In order to convert the dose for the 0.3 mL U100 insulin syringe the following table should be used:

Weight of child	Dose of Myalepta in mg	Dose of Myalepta in mL	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