MYALEPTA®▼

(metreleptin powder for solution for injection)

INFORMATION FOR HEALTHCARE PROFESSIONALS

This brochure should be read in conjunction with the Summary of Product Characteristics.

Adverse events should be reported to HPRA Pharmacovigilance. Website: **www.hpra.ie.** Adverse events should also be reported to Chiesi Limited on **1800 817459(IE)** or **PV.UK@Chiesi.com.**

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

This medicinal product has been authorised under 'exceptional circumstances'. This means that due to the rarity of the disease it has not been possible to obtain complete information on this medicinal product.

myalepta®
metreleptin

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Objectives and details of the use of the brochure

This educational material has been developed as part of the risk minimisation efforts that form a commitment to the Myalepta Risk Management Plan, with the aim to:

- Provide clinicians with guidance that ensures Myalepta is only prescribed to appropriate patients
- Inform clinicians, nurses and pharmacists about the benefits and risks of Myalepta to allow an informed discussion with the patient or caregiver about proceeding with Myalepta therapy
- Educate healthcare professionals about identifying and communicating the correct dosage, Myalepta preparation and administration, and the importance of patient training to ensure effective, error-free treatment with Myalepta by patients and carers in the home setting
- Educate clinicians, nurses and pharmacists on the appropriate prescription and provision of ancillary items required for the preparation and administration of Myalepta

What is Myalepta used for and what are the potential clinical outcomes?

DISEASE BACKGROUND

Lipodystrophies are a heterogeneous group of rare disorders characterised by partial or complete absence of adipose tissue and can either be inherited or acquired.[1] Patients with lipodystrophy often suffer from early-onset metabolic consequences which are caused by lack of adipose tissue and accompanying leptin deficiency.[2,3] In healthy individuals, leptin is a key hormone secreted by adipose tissue and exerts a range of metabolic functions.[2,4]

The lack of adipose tissue and leptin in patients with lipodystrophy can cause a range of disorders such as hypertriglyceridaemia and ectopic fat accumulation, hyperglycaemia due to insulin resistance, and insatiable hunger due to missing satiety signals.[1,2] Without addressing the underlying leptin deficiency in lipodystrophy, treatment with diet, antidiabetic and lipid lowering therapies may have only limited clinical success.[5]

MYALEPTA AND THE TREATMENT OF LIPODYSTROPHY

Myalepta (metreleptin) is a leptin-replacement therapy used in combination with diet to treat the consequences of leptin deficiency in patients with lipodystrophy.[6] By addressing leptin deficiency, an improvement is observed in the complications of leptin deficiency: hyperphagia, hypertriglyceridaemia, insulin resistance and diabetes, with some patients being able to reduce their dose or even discontinue anti-diabetic and lipid-lowering medications.[6]

Indication for use of Myalepta

Myalepta is indicated as an adjunct to diet as a replacement therapy to treat the complications of leptin deficiency in lipodystrophy patients:

- With confirmed congenital generalised lipodystrophy (*Berardinelli-Seip syndrome*) or acquired generalised lipodystrophy (*Lawrence syndrome*) in adults and children 2 years of age and above
- With confirmed familial partial lipodystrophy or acquired partial lipodystrophy (*Barraquer-Simons syndrome*), in adults and children 12 years of age and above for whom standard treatments have failed to achieve adequate metabolic control[6]

Treatment with Myalepta should be initiated and monitored by a physician experienced in the diagnosis and management of metabolic disorders.[6]

Key points to be considered before prescribing Myalepta

Before prescribing Myalepta, there are several key points that need to be considered. The information given below should be read in conjunction with the Summary of Product Characteristics (SmPC).

APPROPRIATE PATIENT SELECTION[6]

- Myalepta is only indicated to treat the complications of leptin deficiency in lipodystrophy patients
- There are limited data about the response to Myalepta in **patients aged 65 and older**. Dose selection and modification for elderly patients should be cautious, although no specific dose adjustment is recommended
- Myalepta is not recommended during pregnancy and in **women of childbearing potential** not using contraception. Abortions, stillbirths and preterm deliveries have been reported in women exposed to Myalepta during pregnancy, though there is currently no evidence to suggest a causal link with the treatment. Studies in animals have shown some evidence of reproductive toxicity
- Myalepta has not been studied in **patients with impaired renal or hepatic function**. No dose recommendations can be made
- Data from clinical trials do not support safety and efficacy in **patients with HIV-related lipodystrophy**

CONTRAINDICATIONS

Myalepta is contraindicated in patients with a known hypersensitivity to metreleptin or to any of its excipients.[6]

Clinical and management information to reduce patient risk

Lipodystrophy causes significant metabolic and neuroendocrine dysfunction, leading to hyperlipidaemia, difficult-to-treat diabetes, reduced immunological response and hormonal dysfunction, all of which are driven by reductions in leptin secretion.[1,4,7,8] Some of the potential risks associated with Myalepta use (or discontinuation of use in the case of acute pancreatitis as listed below) are in the following areas:

- Hypersensitivity
- Acute pancreatitis associated with discontinuation of Myalepta
- T-cell lymphoma
- Hypoglycaemia with concomitant use of insulin and other anti-diabetics
- Unplanned pregnancy due to improvement of hormonal dysfunction with Myalepta
- Loss of efficacy, potentially due to neutralising antibodies
- Serious and severe infections secondary to neutralising antibodies
- Autoimmune disorder progression
- Medication errors

This brochure provides further guidance on these risks including actions, where possible, to minimise them and to support discussions with patients.

Specific areas of risk

HYPERSENSITIVITY REACTIONS

There have been reports of generalised hypersensitivity (e.g. anaphylaxis, urticaria or generalised rash) in patients using Myalepta.[6] Anaphylactic reactions may follow immediately after administration of Myalepta. If an anaphylactic reaction or other serious allergic reaction occurs, administration of Myalepta should be permanently discontinued immediately and appropriate therapy initiated.[6]

HOW TO REDUCE THE RISK OF HYPERSENSITIVITY REACTIONS

As described in the SmPC, patients and/or carers should prepare and administer the first dose of the medicinal product under the supervision of a qualified healthcare professional.

In the Patient Information Leaflet, patients are instructed to contact their doctor straight away if they notice any signs of a severe allergic reaction[6] including:

- Breathing problems
- Swelling and reddening of the skin, hives
- Swelling of the face, lips, tongue or throat
- Stomach pain, feeling sick (nausea) and being sick (vomiting)
- Fainting or feeling dizzy
- Severe pain in your stomach (abdomen)
- Very fast heartbeat

ACUTE PANCREATITIS ASSOCIATED WITH DISCONTINUATION OF MYALEPTA

Non-compliance with, or abrupt discontinuation of Myalepta may result in worsening hypertriglyceridaemia and associated pancreatitis, particularly in patients with risk factors for pancreatitis (e.g. history of pancreatitis, severe hypertriglyceridaemia).[6] If a patient develops pancreatitis whilst being treated with Myalepta, it is advised that Myalepta be continued uninterrupted, as stopping treatment abruptly may exacerbate the condition.[6]

If Myalepta must be stopped for any reason, tapering of the dose over a two-week period is recommended in conjunction with a low-fat diet.[6] During tapering, monitor triglyceride levels and consider initiating or adjusting the dose of lipid-lowering medicinal products as needed. Signs and/or symptoms consistent with pancreatitis should prompt an appropriate clinical evaluation.[6]

HOW TO REDUCE THE RISK OF ACUTE PANCREATITIS

Myalepta reduces the hypertriglyceridaemia seen in lipodystrophy patients.[6] Studies showed that patients are most at risk when discontinuing treatment with Myalepta as this may result in a sudden increase in hypertriglyceridaemia. Therefore, it is recommended to encourage patients to be compliant with daily treatment and, if Myalepta treatment is to be stopped, to steadily taper down the dose of Myalepta over a two-week period in conjunction with a low-fat diet and adjustment of other lipid-lowering medicinal products as needed.[6]

In the Patient Information Leaflet, patients are instructed to talk to a doctor straight away if they notice any signs of pancreatitis,[6] including:

- Sudden severe pain in the stomach (abdomen)
- Feeling sick (nausea) or being sick (vomiting)
- Diarrhoea

HYPOGLYCAEMIA WITH CONCOMITANT USE OF INSULIN AND OTHER ANTI-DIABETICS

There is a risk of hypoglycaemia in patients treated with Myalepta who are on anti-diabetic medicinal products, in particular insulin or insulin secretagogues (e.g. sulphonylureas).[6] Large dose reductions of 50% or more of baseline insulin requirements may be needed in the first two weeks of treatment. Once insulin requirements have stabilised, dose adjustments of other anti-diabetic therapies may also be needed in some patients to minimise the risk of hypoglycaemia.[6]

Closely monitor blood glucose in patients on concomitant insulin therapy, especially those on high doses, or insulin secretagogues and combination treatment. Patients and carers should be advised to be aware of the signs and symptoms of hypoglycaemia.[6]

In clinical studies, hypoglycaemia has been managed with food/drink intake and by modifying the dose of anti-diabetic medicinal product. In case of hypoglycaemic events of a non-severe nature, food intake management may be considered as an alternative to dose adjustment of anti-diabetics according to the treating physician's opinion.[6]

Rotation of injection sites is recommended in patients co-administering insulin (or other subcutaneous medicinal products) and Myalepta.[6]

HOW TO REDUCE THE RISK OF HYPOGLYCAEMIA

Reduce insulin and other anti-diabetic medications as per the recommendations in the SmPC on initiation of Myalepta and alert the patient of the risk and signs of hypoglycaemia and the need for close monitoring of blood sugar.

In the Patient Information Leaflet, patients are instructed to talk to their doctor straight away if they notice any of the following signs of low blood sugar:[6]

- Feeling dizzy
- Feeling more sleepy or confused
- Being clumsy and dropping things
- Feeling more hungry than normal
- Sweating more than normal
- Feeling more irritable or more nervous

T-CELL LYMPHOMA

Acquired lipodystrophies are associated with autoimmune disorders, and autoimmune disorders are associated with an increased risk of malignancies including lymphomas.[9] Lymphoproliferative disorders, including lymphomas, have been reported in patients with acquired generalised lipodystrophy not treated with Myalepta. Cases of T-cell lymphoma have been reported while using Myalepta in clinical studies. A causal relationship between Myalepta treatment and the development and/or progression of lymphoma has not been established.[6]

The benefits and risks of Myalepta treatment should be carefully considered in patients with acquired generalised lipodystrophy and/or in patients with significant haematological abnormalities (including leukopenia, neutropenia, bone marrow abnormalities, lymphoma, and/or lymphadenopathy).[6] An association between the developmentof neutralising antibodies and serious and severe infections cannot be excluded and the continuation of Myalepta should be at the discretion of the prescriber.[6]

UNPLANNED PREGNANCY

Unplanned pregnancies may occur due to restoration of luteinising hormone release.[6] Myalepta is not recommended during pregnancy and in women of childbearing potential not using contraception. Abortions, stillbirths and preterm deliveries have been reported in women exposed to metreleptin during pregnancy though there is currently no evidence to suggest a causal relationship with the treatment. Studies in animals have shown some evidence of reproductive toxicity. Animal studies showed no adverse effects on male or female fertility.[6] Since it cannot be excluded that Myalepta may reduce exposure to substrates of CYP3A through enzyme induction, the the efficacy of hormonal contraceptives may be reduced if co-administered with Myalepta. Therefore, an additional non-hormonal contraceptive method should be considered during treatment.[6] Myalepta may increase fertility, due to effects on luteinising hormone, and thus the chances of unplanned pregnancy. Women of childbearing potential should be advised that Myalepta may increase fertility and should be encouraged to use contraception.[6]

LOSS OF EFFICACY, POTENTIALLY DUE TO NEUTRALISING ANTIBODIES

Loss of efficacy, potentially due to neutralising antibodies, may occur in patients on Myalepta therapy. However, it may also be associated with poor compliance which should also be considered. While the impact of neutralising antibodies on efficacy has not been confirmed, consideration should be given by the prescriber to have patients tested for the presence of neutralising antibodies if there is significant loss of efficacy despite Myalepta administration.[6]

For further information on how to submit samples for neutralising antibody testing, please contact PV.UK@Chiesi.com.

As testing individual patient samples can take up to 4 months, and the clinical consequences of developing *in vitro* neutralising antibodies to Myalepta are still not well understood, any clinical decision regarding whether to continue or stop treatment of Myalepta should be considered in the context of the patient's condition and the overall clinical situation.

SERIOUS AND SEVERE INFECTIONS SECONDARY TO NEUTRALISING ANTIBODIES

An association between the development of neutralising antibodies or blocking activity and loss of efficacy and serious and severe infections cannot be excluded. In patients with serious and severe infections, continuation of Myalepta should be at the discretion of the prescriber. Patients who develop serious and severe infections should be tested for neutralising activity.[6]

AUTOIMMUNE DISEASES

Autoimmune disorder progression/flares, including severe autoimmune hepatitis, have been observed in some patients treated with Myalepta but a causal relationship between Myalepta treatment and progression of autoimmune disease has not been established. Close monitoring for underlying autoimmune disorder flares (sudden and severe onset of symptoms) is recommended. The potential benefits and risks of Myalepta treatment should be carefully considered in patients with autoimmune diseases.[6]

MEDICATION ERRORS

In order to avoid medication errors including overdose, dose calculation and dose adjustment guidelines should be followed. A review of the patient's self-administration technique is recommended every six months whilst using Myalepta.[6]

Healthcare professionals should provide patients and carers with training on the reconstitution of the product and proper subcutaneous injection technique, so as to avoid intramuscular injection in patients with minimal subcutaneous adipose tissue. Patients and/or carers should prepare and administer the first dose of the medicinal product under the supervision of a qualified healthcare professional.[6]

HOW TO REDUCE THE RISK OF MEDICATION ERRORS

Myalepta must be reconstituted correctly with water for injection before use and the correct amount of the reconstituted product measured into an appropriate syringe and then injected subcutaneously on a daily basis.[6] As there is a potential for error in each of these steps, it is essential that the patient is appropriately instructed before self-administration.[6]

The following section of the brochure covers the prescription of the correct dose, the prescription and provision of other components to prepare and administer Myalepta and training of the patient or carer.

Prescribing Myalepta and ancillary items

SELECTION AND PRESCRIBING OF THE INITIAL DOSE

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 and the volume in millilitres.[6] In order to avoid medication errors including overdose, the dose calculation and dose adjustment guidelines below should be followed.[6]

Actual body weight at initiation of treatment should always be used when calculating dose of Myalepta.[6]

Table 1: Myalepta recommended dose[6]

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

Dose adjustments should be made as described in the SmPC, which also includes a starting dose and dose increase calculator.

IMPORTANT: After reconstitution, the solution must be administered immediately and cannot be stored for later use. One vial of Myalepta and one vial/ampoule of water for injection must therefore be prescribed per day and the patient should be instructed to dispose of any unused medicine and unused water for injection. The smallest appropriate size of water for injection (5 ml or less) should be prescribed to reduce the risk of reuse.

PRESCRIBING ANCILLARY ITEMS TO RECONSTITUTE AND ADMINISTER MYALEPTA

To enable the patient to prepare and administer Myalepta, they will need to be prescribed or supplied with the following items (Table 2). The quantities will support a 30 vial pack of Myalepta. Please note that to deliver a dose of Myalepta ≤ 1.5 mg (0.3 ml), the Chiesi administration kit will include a Beckton Dickinson 305937 SafetyGlide Safety Insulin (U100) Syringe 0.3 ml with 31 g x 8 mm Needle, as insulin syringes are the only commercially available ones suited to accurate dosing up to 0.3 ml.

Table 2: Ancillary items

Action	Item	Quantity	Notes
Reconstitution of Myalepta vials	3 ml syringe for the 11.3 mg and 5.8 mg vials	30	Example: Becton Dickinson 309658 Luer-Lok 3 ml Syringe
	1 ml syringe for the 3.0 mg vial	30	Example: Becton Dickinson 303172 Plastipak 1 ml syringe
	21 G x 40 mm needle	30	Becton Dickinson 305895 Eclipse Safety Needle with 21 G x 40 mm Needle Green hub
	Water for injection	30	Of an appropriate size (e.g. container of 5 ml or less) for single use of 0.6 ml to 2.2 ml
	Alcohol swabs	60	
	Sharps bin	1	
Administration of doses > 5 mg (1.0 ml)	2.5 ml syringe	30	Example: Terumo SS02SE1 Syringe Concentric Luer Tip 2.5 ml 3-Part
	30 G x 13 mm needle	30	Example: Becton Dickinson 305771 SmartSlip Hypodermic Safety Needle 30 G x 13 mm Yellow Hub
Administration of doses > 1.5 mg (0.3 ml) to 5 mg (1.0 ml)	1 ml syringe	30	Example: Becton Dickinson 303172 Plastipak 1 ml Hypodermic Syringe 3 Piece Luer Slip Sterile Latex Free
	30 G x 13 mm needle	30	Example: Becton Dickinson 305771 SmartSlip Hypodermic Safety Needle 30 G x 13 mm Yellow Hub
Administration of doses ≤ 1.5 mg (0.3 ml)	0.3 ml U100 insulin syringe with combined 31 G x 8 mm needle	30	Beckton Dickinson 305937 SafetyGlide Safety Insulin (U100) Syringe 0.3 ml 31 G x 8 mm Needle

For ease of prescribing and to reduce the risk of medication errors, Chiesi will supply reconstitution and administration kits as indicated in Table 3. **Note: The water for injection, alcohol swabs and sharps bin need to be prescribed/supplied separately and are not included in the Chiesi kits.**

Table 3: Administration kits

Kit name	Contents	Local provision logistics
Myalepta reconstitution kit for 11.3 mg and 5.8 mg vials	• 30 x 3 ml syringes • 21 G x 40 mm needle	*(To be tailored to local logistical information including where necessary product codes, source of supply)*
Myalepta reconstitution kit for 3.0 mg vials	• 30 x 1 ml syringes • 21 G x 40 mm needle	*(To be tailored to local logistical information including where necessary product codes, source of supply)*
Myalepta administration kit for doses > 5 mg (1.0 ml)	• 30 x 2.5 ml syringe • 30 needles 30 G x 13 mm	*(To be tailored to local logistical information including where necessary product codes, source of supply)*
Myalepta administration kit for doses > 1.5 mg (0.3 ml) to 5 mg (1.0 ml)	• 30 x 1.0 ml syringe • 30 needles 30 G x 13 mm	*(To be tailored to local logistical information including where necessary product codes, source of supply)*
Myalepta administration kit for doses ≤ 1.5 mg (0.3 ml)	• 30 x 0.3 ml U100 insulin syringe with integrated 31 G x 8 mm needle	*(To be tailored to local logistical information including where necessary product codes, source of supply)*

INSTRUCTION OF THE PATIENT

The first injection of Myalepta should always be supervised by a healthcare provider and it is important that the patient or carer is appropriately trained before self-administering Myalepta at home.[6] A follow-up of injection technique should be performed six monthly.[6]

The instructions provided in the Instructions for Use are clear with images at every key step to remind the patient about correct usage. Additionally, the risk management plan includes a 'Patient Care Guide', 'Patient Dose Card' and a 'Patient Instruction Video' demonstrating the correct reconstitution and injection technique plus preparation of the prescribed dose.

To reduce the risk of dosing errors, 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. A dose conversion to units is given below.

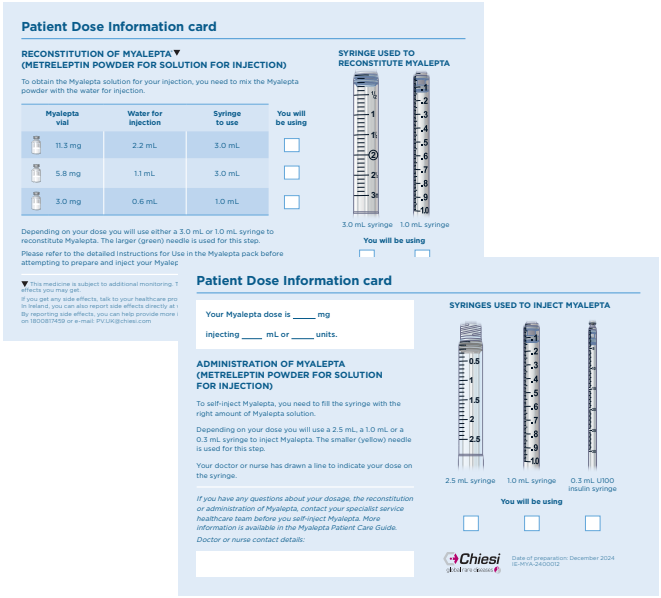
When using the 0.3 ml U100 insulin syringe, the dose will need to be converted (Table 4).

Table 4: Conversion of dose to units with U100 0.3 ml syringe[6]

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

A card is provided as part of the risk management programme materials for communicating the dose and syringe use to the patient.



Patient Dose Information card

RECONSTITUTION OF MYALEPTA▼ (METRELEPTIN POWDER FOR SOLUTION FOR INJECTION)

To obtain the Myalepta solution for your injection, you need to mix the Myalepta powder with the water for injection.

Myalepta vial	Water for injection	Syringe to use	You will be using
11.3 mg	2.2 mL	3.0 mL	☐
5.8 mg	1.1 mL	3.0 mL	☐
3.0 mg	0.6 mL	1.0 mL	☐

Depending on your dose you will use either a 3.0 mL or 1.0 mL syringe to reconstitute Myalepta. The larger (green) needle is used for this step.

Please refer to the detailed Instructions for Use in the Myalepta pack before attempting to prepare and inject your Myalep

▼This medicine is subject to additional monitoring. T effects you may get.
If you get any side effects, talk to your healthcare pro In Ireland, you can also report side effects directly at By reporting side effects, you can help provide more on 1800874459 or e-mail: PV.UK@chiesi.com

SYRINGE USED TO RECONSTITUTE MYALEPTA

3.0 mL syringe 1.0 mL syringe

You will be using ☐ ☐

Patient Dose Information card

Your Myalepta dose is ____ mg

injecting ____ mL or ____ units.

ADMINISTRATION OF MYALEPTA (METRELEPTIN POWDER FOR SOLUTION FOR INJECTION)

To self-inject Myalepta, you need to fill the syringe with the right amount of Myalepta solution.

Depending on your dose you will use a 2.5 mL, a 1.0 mL or a 0.3 mL syringe to inject Myalepta. The smaller (yellow) needle is used for this step.

Your doctor or nurse has drawn a line to indicate your dose on the syringe.

If you have any questions about your dosage, the reconstitution or administration of Myalepta, contact your specialist service healthcare team before you self-inject Myalepta. More information is available in the Myalepta Patient Care Guide.

Doctor or nurse contact details:

SYRINGES USED TO INJECT MYALEPTA

2.5 mL syringe 1.0 mL syringe 0.3 mL U100 insulin syringe

You will be using ☐ ☐ ☐

Chiesi

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ADMINISTRATION OF MYALEPTA

Myalepta should be administered subcutaneously at approximately the same time every day.[6] 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.[6]

EDUCATIONAL AND TRAINING ACTIVITIES

Chiesi has initiated a programme of educational activities containing a healthcare professional booklet and a patient booklet. In addition, information on correct injection techniques in the form of a video and a booklet are available. These materials are designed for prescribers, pharmacists, patients and caregivers with aim to:

- Educate healthcare professionals and patients on key prescribing information
- Explain the risks and benefits of Myalepta with ways to reduce these risks
- Ensure that the patient receives the appropriate ancillary items to reconstitute and administer Myalepta
- Highlight the need for appropriate training and follow-ups with the patient or care giver
- Give guidance on correct instruction techniques to promote a safe use of Myalepta

Further supplies of these materials are available from Chiesi or can accessed via the QR code below. From the landing page, please click on the required dose and from here choose the Ed Materials - HCP or Ed Materials - Patient tab. You can also access the landing page at: **https://www.medicines.ie/medicines/list/all/page-1/per-page-25?query=myalepta**

ENTERING PATIENTS INTO THE MYALEPTA PATIENT REGISTRY

Chiesi has committed, as a condition of its marketing authorisation for Myalepta in the EU, to establish a registry including all patients with generalised or partial lipodystrophy treated with Myalepta according to an agreed protocol. This registry will further evaluate the long-term safety profile and effectiveness of Myalepta under normal conditions of clinical practice. Participation in the registry should be offered to all eligible patients. Patients should be reassured that all data that is collected will be anonymised.

Please contact **PV.UK@Chiesi.com** for further information about the registry and your participation.

Advice to patient checklist

The information outlined in Table 5 should be discussed with the patient and a record of this should be placed in the patient's notes.

Table 5: Key information for the patient

	Points to discuss
	Myalepta should be administered at the same time every day independent of meals
	If hypersensitivity occurs, the patient should be informed to contact their physician to discuss their management with Myalepta
	If a dose is missed, the patient should administer Myalepta as soon as the omission is noticed
	While taking Myalepta, patients should follow the diet recommended by their physician
	Women should tell their doctor immediately if they suspect that they might be pregnant
	Effective contraception should be used in women of child bearing potential prior to initiating Myalepta
	Myalepta should not be stopped suddenly without consulting the physician
	In patients with diabetes, blood glucose levels should be monitored closely
	Patients should not self-administer Myalepta until trained and confident in its preparation and use

Dispensing Myalepta and ancillary items

INFORMATION FOR PHARMACISTS

When dispensing Myalepta vials, the patient will also need to receive ancillary items to enable them to prepare and administer Myalepta and to dispose safely of syringes and needles. The ancillary items required are as follows and are described in detail in Table 2 on page 7:

- Appropriate syringes and needles to prepare Myalepta
- Appropriate syringes and needles to administer Myalepta
- Alcohol swabs
- Water for injection
- A sharps bin

For ease of prescribing and to reduce the risk of medication errors, Chiesi supplies reconstitution and administration kits as indicated in Table 3 on page 7:

Note: The water for injection, alcohol swabs and sharps bin need to be prescribed/supplied separately and are not included in the Chiesi kits.

To reduce the risk of reuse of water for injection, the smallest appropriate vial/ampoule size (e.g. 5 ml or less to permit extraction of 0.6 ml – 2.2 ml) to be used to reconstitute the 3.0 mg, 5.8 mg or 11.3 mg vials of Myalepta should be dispensed.

Supplies of Myalepta and the reconstitution and administration kits are available through the following routes. Please order the kits appropriate for the dose prescribed by the physician.

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