myalepta®▼

metreleptin

(metreleptin powder for solution for injection)

PATIENT CARE GUIDE: IMPORTANT RISK MINIMISATION INFORMATION FOR PATIENTS AND THEIR CARERS

This brochure should be read in conjunction with the Summary of Product Characteristics.[1]

Adverse events should be reported. Reporting forms and information can be found at: **https://yellowcard.mhra.gov.uk/** or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Chiesi Limited on **0800 0092329 (UK)** or **PV.UK@Chiesi.com.**

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

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Chiesi
global rare diseases

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Introduction

Your doctor at the Specialist Service has diagnosed you with lipodystrophy and prescribed Myalepta to treat the complications of lipodystrophy in addition to your recommended diet. This Patient Care Guide will help you and your carer(s) understand what Myalepta is, to make you aware of potential risks associated with its use and how to use Myalepta as correctly as possible to minimise risks. This Patient Care Guide also includes information about potential side effects associated with Myalepta treatment and the importance of reporting any symptoms of these side effects to your Specialist Service Healthcare Professional team. It is important that you also read the Package Leaflet contained in each pack of Myalepta. If there is anything you do not understand or if you have further questions, please ask your Specialist Service Healthcare Professional team.

What is Myalepta and does it treat?

Myalepta is a medicine that contains the active substance metreleptin, which is similar to a human hormone called leptin. Myalepta is used to treat the complications of not having enough leptin in patients with lipodystrophy.

What is lipodystrophy?

Lipodystrophy is a disease where the body has abnormal distribution of fat (adipose) tissue. It can refer to both fat loss (lipoatrophy) and abnormal storage of fat tissue. Not all people are equally affected: lipodystrophy may affect your whole body (generalised) or only parts of it (partial). It can either be caused by inherited genes or acquired during life. Not having enough fat tissue may lead to reduced levels of a hormone called leptin.

What is leptin?

Leptin is called the "satiety or anti-hunger hormone" of the body, although its effects are not limited to food intake.

It is produced by the fat cells of your body and has a range of effects. Actions of leptin include:

- Keeps your blood triglyceride (fat) and sugar levels controlled
- Prevents fat storage in your liver, kidney, muscles and other organs
- Regulates your energy balance by signalling that you have eaten enough
- Affects puberty and fertility
- Helps your body in fighting infections

In some forms of lipodystrophy, such as yours, leptin is absent or is present at levels lower than normal (leptin deficiency). This is because you do not have enough fat to produce adequate leptin levels resulting in a number of potential complications, which may include:

- Development of diabetes
- High fat (triglyceride) levels in your blood which, over time, can cause damage to the liver and other organs
- Insatiable hunger (constantly feeling hungry)
- Late puberty
- Difficulty becoming pregnant (being infertile or problems with fertility)

How is lipodystrophy treated?

- Your doctor at the Specialist Service* will have advised you to follow a strict diet and avoid certain foods
- Your doctor at the Specialist Service may also have prescribed medicines to treat some of the complications described above (e.g. for diabetes, high triglyceride levels or problems with puberty)
- You have also been prescribed Myalepta in addition to your recommended diet and your other medicines
- Your existing medicines may be modified by your doctor at the Specialist Service

***Ask your Specialist Service Healthcare Professional team for the best number to contact them on and note it here:**

What are the safety considerations related to Myalepta?

Your Specialist Service Healthcare Professional team will inform you of the main risks of Myalepta. This Patient Care Guide will help you understand these important safety considerations. Please also read carefully the Package Leaflet (in the Myalepta pack) for more information about Myalepta.

1. Hypoglycaemia (low blood sugar) can occur when Myalepta is given with medicines that are used to treat diabetes

Using insulin and other anti-diabetic medicines

To treat your diabetes, you may have been prescribed insulin and/or other anti-diabetic medicines. Myalepta may reduce blood sugars, so to stop them becoming too low (hypoglycaemia), your doctor at the Specialist Service may modify your existing treatment for diabetes.

If you use anti-diabetic medicines, including insulin, it's important to closely monitor your blood sugar levels. Talk with your Specialist Service Healthcare Professional team about how often to check your blood sugar and what to do if your blood sugar becomes too low.

Signs and symptoms of hypoglycaemia

Signs and symptoms of hypoglycaemia may include:

- 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

Tell your Specialist Service Healthcare Professional team if your blood sugar starts to become too low or if you experience signs and symptoms of hypoglycaemia as your doctor at the Specialist Service may need to adjust your anti-diabetic medicines.

You should not stop using your diabetes medicines - only your doctor at the Specialist Service should make adjustments to your diabetes medicines.

2. Myalepta might increase fertility in women with lipodystrophy

Contraception

If you are female and could get pregnant (even if you think you might be infertile because of your lipodystrophy), you need to know that Myalepta can increase your fertility. Therefore, **it is strongly recommended that you use effective contraception while using Myalepta**.

Please note that hormonal contraceptives, such as the contraceptive pill, may be less effective with Myalepta treatment and therefore **additional non-hormonal methods should be considered**. Talk to your GP/practice nurse about the best contraceptive options for you.

Pregnancy

Myalepta should not be used during pregnancy. The effect of Myalepta on the unborn baby is not known. Talk to your Specialist Service Healthcare Professional team if you are pregnant or breast-feeding, or think you may be pregnant. **Do not stop using Myalepta without first consulting your Specialist Service Healthcare Professional team**. Should you wish to plan for a family, then please speak with your Specialist Service Healthcare Professional team who will be able to advise you further.

3. Abrupt discontinuation of Myalepta (suddenly stopping your medicine) may increase the risk of developing acute pancreatitis

What is pancreatitis?

The pancreas is a large gland in the abdomen that is involved in digestion and sugar regulation. Pancreatitis is a serious condition, where the pancreas becomes inflamed and sometimes may be triggered by high levels of triglyceride (fat) in the blood. Patients with lipodystrophy have a high risk of developing pancreatitis as part of their condition.

Abrupt discontinuation of Myalepta (suddenly stopping your medicine) could cause sudden onset pancreatitis

Myalepta normally lowers your blood triglyceride levels. So, if you suddenly stop using Myalepta, your triglyceride levels could rise again and this may cause acute pancreatitis.

- **Therefore, do not stop using Myalepta without consulting your Specialist Service Healthcare Professional team first**
- **It is important to inject your Myalepta on a daily basis as prescribed by your doctor at the Specialist Service**
- **If you forget to inject a dose, inject it as soon as you remember. Then inject your normal dose the next day**

If your doctor at the Specialist Service decides that you need to stop using Myalepta, they will gradually lower your dose over a two-week period to minimise the risk of acute pancreatitis. They will also ask you to adjust your diet. If you develop pancreatitis while using Myalepta, your doctor at the Specialist Service may continue the treatment as stopping Myalepta could make it worse.

Signs and symptoms of pancreatitis

Signs and symptoms of pancreatitis may include:

- Sudden severe pain in your stomach
- Feeling sick (nausea) or vomiting
- Diarrhoea

Please contact your Specialist Service Healthcare Professional team straight away if you experience any of these signs and symptoms.

4. Myalepta might worsen existing autoimmune disease

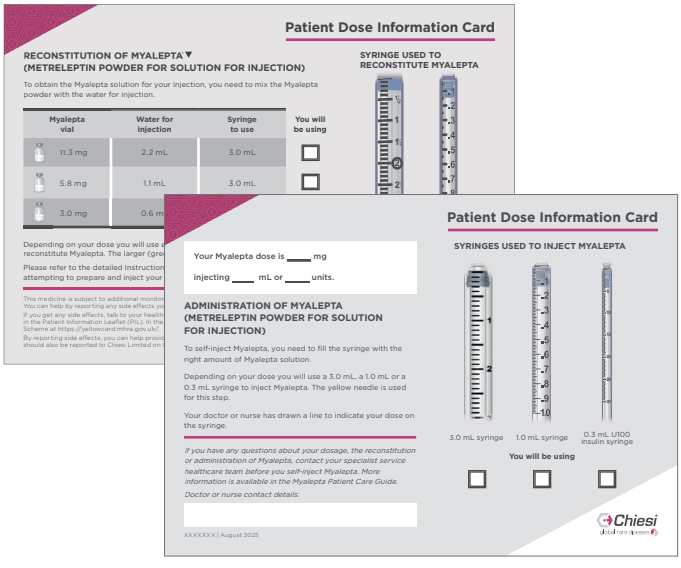
People who have or have had problems with their immune system (autoimmune disease, including autoimmune-related liver problems) may have worsening of their symptoms with Myalepta. **Tell your prescriber if you have symptoms of autoimmune disease which worsen during treatment. If you are unsure speak to your healthcare provider.**

5. Medication errors can occur if Myalepta is not prepared and used correctly

Your dose of Myalepta

Your doctor at the Specialist Service will calculate your dose of Myalepta, they will tell you what your dose of Myalepta is in milligrams (mg) or in units (U). This will depend on the dose. Units (U) are used if you only have to inject a very small amount, using a specific sized syringe. They will also tell you how much solution to inject in millilitres (mL). This will be clearly explained to you by your doctor at the Specialist Service. They will give you a Dose Card with this information on it. If your doctor at the Specialist Service changes your dose at a later date (dose adjustments) you will be given a new Dose Card – please remember to use the new Dose Card.

The Dose Card, which will be completed with your daily dosage is shown below:



Preparing and injecting the correct dose of Myalepta

Myalepta comes in a powdered form and needs to be dissolved before injecting. Your doctor at the Specialist Service will arrange for you to receive training on how to prepare and measure your dose of Myalepta and how to inject the product correctly and safely under the skin (subcutaneously). You will first receive training on how to prepare and measure your dose of Myalepta by a member of your Specialist Service Healthcare Professional team. A Homecare Nurse will then visit you at your home to help you when you first inject yourself. **Therefore, the first time you inject yourself should be in the presence of the Homecare Nurse, to make sure you understand how to do everything correctly.**

What you will need

In addition to your Myalepta vials containing the drug powder, you will also need other items to dissolve the medicine into a solution and to inject it. You should always make sure that you have all the following necessary items before you start preparing your injection:

- Myalepta powder – one vial per day
- Water for injection – one ampoule/vial per day
- Syringes and needles to make up the Myalepta solution – provided as a kit, one set per day
- Alcohol swabs to clean the vials and your skin at the injection site
- Syringes and needles to inject your Myalepta dose – provided as a kit, one set per day
- A sharps bin to safely dispose of used vials, needles and syringes

All of the items you need, with the exception of alcohol swabs, will be sent to your home. Your Specialist Service Healthcare Professional team will discuss the home delivery service with you and arrange for alcohol swabs to be provided.

Please contact your Specialist Service Healthcare Professional team if the syringe size you have been given does not match with the size you are expecting. If you lose anything in your kit or need extra kits before you go on holiday, please contact your Specialist Service Healthcare Professional team.

Important things to remember while using Myalepta

It is important to follow the instructions from your training and the Instructions for Use guide on preparing, measuring and injecting Myalepta. **If you are unsure about how to prepare Myalepta, measure your dose or how to inject your dose, speak with your Specialist Service Healthcare Professional team**. Below are some important things to keep in mind while using Myalepta.

- **Store Myalepta in a refrigerator (2 °C-8 °C) and away from light**
- **Allow time for the vial to warm up before preparing the solution - you will need to allow the vial to warm for 10 minutes to reach room temperature before adding the water for injection**
- **Use immediately after adding the water for injection - Myalepta cannot be stored for future use once you have added water**
- **Each Myalepta vial and water for injection are sterile and are for single use only - discard any unused Myalepta solution and remaining water for injection after injecting the dose. You have been provided with a sharps disposal bin for this**
- **Myalepta should be injected once a day, at the same time each day**
- **If you inject too much Myalepta you should talk to your Specialist Service Healthcare Professional team or go to a hospital straight away. Your doctor at the Specialist Service will monitor you for side effects**
- **Inject Myalepta just under the skin in the upper arm, thigh, or abdomen**
- **Do not inject into the same site every time - use different spots even on the same body part – this is called "rotating" injection sites and it will give each site the opportunity to recover properly and will make injections more comfortable and effective**
- **If Myalepta and insulin are both administered, different injection sites for injecting Myalepta and insulin should be used**
- **Syringes and needles are sterile and are for single use only - do not use syringes or needles more than once**
- **Place used needles, vials and syringes in the sharps bin and dispose as instructed by your doctor or pharmacist**
- **Keep out of reach of children**

Where to find information

Each pack of Myalepta contains a Package Leaflet which includes very detailed pictures and Instructions for Use on how to prepare, measure the dose and inject Myalepta. During your initial training, your Specialist Service Healthcare Professional team will have shown you this Package Leaflet whilst administering the first dose.

The Package Leaflet is available in every pack of Myalepta for you to follow each time you inject it. You can also access a digital version using the QR code and clicking on the Patient Leaflet (PIL) that matches the dose you have been prescribed. You can also access the landing page at: https://www.medicines.org.uk/emc/search?q=Myalepta

There is also a video which shows the various steps involved in preparing, measuring the dose and injecting Myalepta. This video is available via the QR code below. From the landing page, please click on Risk Materials next to the dose you have been prescribed and from here you will see the video within the list.
You can also access the landing page at: https://www.medicines.org.uk/emc/search?q=Myalepta

Are there other safety considerations while I am on Myalepta?

Serious side effects and risks that you need to be aware of

T- cell lymphoma

Lymphoma is a cancer of the type of white blood cells called lymphocytes. People with lipodystrophy can get lymphoma, whether or not they are using Myalepta. Lymphoma is very rare and it is not known whether Myalepta increases your risk of developing lymphoma. However, you may be at higher risk of developing lymphoma when using Myalepta.

If you have acquired lipodystrophy and/or certain blood abnormalities, your doctor at the Specialist Service will discuss the benefits and risks of using Myalepta with you in order to decide whether you should use it.

Serious and severe infections

Leptin is involved in the immune system and the body's ability to fight infections; patients with lipodystrophy have an increased risk of developing serious and severe infections due to low leptin levels. Myalepta helps replace your leptin. However, sometimes, the body reacts against Myalepta and produces "neutralising" antibodies which stop it being so effective. This can lead to serious and severe infections.

Tell your Specialist Service Healthcare Professional team straight away if you develop a high temperature. Your doctor at the Specialist Service will carefully monitor you and decide whether or not to continue Myalepta.

Allergic reactions

An allergic reaction can occur to any of the ingredients in Myalepta, as can happen with any medicine. In clinical trials of Myalepta, some patients experienced an allergic reaction. Your first injection of Myalepta should be administered in the presence of the Homecare Nurse who will visit you at your home in case you have an allergic reaction.

Signs of an allergic reaction include the following:

- Breathing problems
- Swelling and reddening of your skin, hives
- Swelling of your 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

Please contact your Specialist Service Healthcare Professional team straight away if you notice any allergic reactions.

Common side effects

Every medicine has the potential to cause side effects, which you may or may not experience. If you are affected by one of the following side effects, or any other side effects, please contact your Specialist Service Healthcare Professional team immediately. This can be any side effect, including those not listed in this Patient Care Guide or the Package Leaflet in the Myalepta pack.

Common side effects of Myalepta*

Very common	Common
• Weight loss	• Loss of interest in food • Headache • Hair loss • Unusually heavy or long periods • Feeling tired • Bruising, reddening, itching or hives where the injection is given • Development of antibodies to metreleptin which may increase the risk of serious or severe infections

*Please refer to the Package Leaflet for the full list of side effects.

Enrolling in the Myalepta Registry

A patient registry has been set up to collect medical information on patients treated with Myalepta. This is a type of study which will help us to learn more about any long-term effects of Myalepta. If you agree to take part in this study you do not have to make any extra visits to your doctor or have any further investigations, and your treatment will always be what your doctor considers to be best for you.

The registry is very important as it will collect information on a large number of patients over a longer period of time than has been studied in clinical trials. This will provide valuable information on the long-term safety and effectiveness of Myalepta.

The aim is to enrol all patients treated with Myalepta into the registry. You should discuss this with your doctor, who has also been asked to take part in the registry. We will only collect your information if you give your agreement, in writing, to be enrolled. You will not be able to be identified from the information you provide.

We very much hope you will agree to taking part in the study. However, if you decide not to take part, this will not affect the care you receive from your doctor. If your doctor considers Myalepta to be the right treatment for you, they will still prescribe this for you and look after you in just the same way.

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