



MYALEPTA[®] ▼

(metreleptin powder for
solution for injection)

PATIENT CARE GUIDE



▼ This medicine is subject to additional monitoring.
This will allow quick identification of new safety
information. You can help by reporting any side effects
you may get.

If you get any side effects, talk to your healthcare
professional. This includes any possible side effects not
listed in the Patient Information Leaflet (PIL). In Ireland, you
can also report side effects directly at www.hpra.ie

By reporting side effects, you can help provide more
information on the safety of this medicine. Side effects
should also be reported to Chiesi Limited on **1800817459**
or e-mail: PV.UK@chiesi.com

**Always refer to your patient information leaflet provided
with your medicine.**


myalepta[®]
metreleptin

Why you have been given this booklet?

You have been prescribed Myalepta for the treatment of lipodystrophy. This booklet is designed to answer many of your questions about your new treatment. It will help you to understand how to correctly use Myalepta, make you aware of potential risks associated with its use and ways

to minimise them where possible. It is important that you also read the Patient Information Leaflet supplied with Myalepta. If there is anything you do not understand or if you have further questions, please ask your doctor, nurse or pharmacist.

Why you were prescribed Myalepta and what does it do?

WHAT IS LIPODYSTROPHY?

Lipodystrophies are diseases where the body has abnormal distribution of fat (adipose) 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 AND LEPTIN DEFICIENCY?

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 on it:

- Keeping your blood lipid and sugar levels controlled
- Avoiding fat accumulation in your liver, kidney, muscles and other organs
- Regulating your energy balance by signalling that you have eaten enough
- Has a role in puberty and fertility
- Has a role in helping your body in fighting infections.

In some forms of lipodystrophy, leptin is absent or present in levels lower than normal (leptin deficiency). This is because you do not have enough fatty tissue to produce adequate leptin levels resulting in a number of symptoms:

- Having high fat (triglyceride) levels in your blood which, over time, can cause damage to the liver and other organs
- Developing diabetes at a young age
- Feeling an insatiable hunger caused by insufficient leptin levels
- Having difficulty becoming pregnant or starting puberty later than other people.

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.

WHAT IS MYALEPTA AND WHAT IS IT USED FOR?

Myalepta contains the active substance metreleptin, which is similar to leptin. Myalepta is used to treat the complications of not having enough leptin in patients with lipodystrophy. It is used in adults, adolescents and children 2 years or over:

- Who have generalised lipodystrophy (the whole of your body does not have enough fatty tissue).

It is used, when other treatments have been ineffective, in adults, and adolescents 12 years or over:

- Who have partial lipodystrophy which is inherited (also called congenital or familial lipodystrophy)
- Or partial lipodystrophy has been caused by your body's response to something such as a viral illness (also called acquired lipodystrophy).

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

Potential risks and possible side effects

WARNINGS AND PRECAUTIONS

It is important to recognise potential risks and communicate with your doctor, pharmacist, or nurse before using Myalepta if:

- you are pregnant
- you have ever had a type of cancer called lymphoma
- you have ever had problems with your blood (such as low blood count)
- you have ever had inflammation of an organ called the pancreas ('pancreatitis')
- you have or ever have had problems with your immune system (autoimmune disease including autoimmune-related liver problems).

It is also important to communicate with your doctor if you have taken too much or too little Myalepta or if you have forgotten to take your Myalepta.

Please refer to the Patient Information Leaflet for more information on the warnings and precautions.

OTHER MEDICINES AND MYALEPTA

Myalepta can affect the way some other medicines work, also some other medicines may affect the way Myalepta works. It is important that you tell your doctor the medicines you are using, have recently used, or may use. For example:

- hormonal contraceptives
- theophylline used in lung problems such as asthma
- blood-thinning medicines (such as warfarin or phenprocoumon)
- medicines which suppress the immune system (such as cyclosporine)
- anti-diabetic medicines (such as insulin or insulin secretagogues).

Some medicines may need to be monitored when you are using Myalepta since the dose may need to be changed.

POSSIBLE SIDE EFFECTS

Potential side effects:		Tell your doctor straight away if you notice any of the following potential signs:	
Serious side effects	Low blood sugar	<ul style="list-style-type: none">• feeling dizzy• feeling sleepier or confused• being clumsy and dropping things	<ul style="list-style-type: none">• feeling more hungry than normal• sweating more than normal• feeling more irritable or more nervous
	Increased blood sugar	<ul style="list-style-type: none">• feeling very thirsty or hungry• going to the toilet to pass urine more often• feeling sleepier, feeling or being sick	<ul style="list-style-type: none">• blurred vision• pain in the chest or back• feeling out of breath
	Blood clot in your veins (deep vein thrombosis)	<ul style="list-style-type: none">• pain• swelling	<ul style="list-style-type: none">• warmth and redness
	Fluid in your lungs	<ul style="list-style-type: none">• difficulty breathing	<ul style="list-style-type: none">• cough
	Feeling sleepy or confused		
Allergic reactions		<ul style="list-style-type: none">• breathing problems• swelling and reddening of the skin, hives• swelling in your face, lips, tongue, or throat• fainting or feeling dizzy	<ul style="list-style-type: none">• stomach pain, feeling or being sick• severe pain in your stomach• very fast heartbeat
Inflamed pancreas ('pancreatitis')		<ul style="list-style-type: none">• sudden severe pain in your stomach• feeling or being sick	<ul style="list-style-type: none">• diarrhoea
Very common side effect (may affect more than 1 in 10 people)		<ul style="list-style-type: none">• weight loss	
Common side effects (may affect up to 1 in 10 people)		<ul style="list-style-type: none">• loss of interest in food• headache• hair loss• unusually heavy or long menstrual bleeding	<ul style="list-style-type: none">• feeling tired• bruising, reddening, itching or hives where the injection is given• serious or severe infections (high temperature/increased tiredness)

This is not a complete list of possible side effects, please refer to the Patient Information Leaflet for further information. The following areas of risk are covered in more detail in this guide: allergic reaction, pancreatitis, low blood sugar levels (with insulin or other anti-diabetic medicines), lymphoma, unplanned pregnancy, serious and severe infections, autoimmune disorder progression and medication errors.

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

ALLERGIC REACTIONS

An allergic reaction can occur to any of the components of Myalepta as it can happen with any drug. In clinical trials of Myalepta, some patients experienced an allergic reaction.

HOW CAN I IDENTIFY AN ALLERGIC REACTION?

While being treated with Myalepta, you may get an allergic reaction. Allergic reactions may manifest themselves through a wide range of symptoms. Signs of a severe allergic reaction include the following:

- Breathing problems
- Swelling and reddening of the 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 doctor straight away if you notice any allergic reactions.

HOW CAN THE RISK OF DEVELOPING ALLERGIC REACTIONS BE REDUCED?

Whether you will have an allergy to the components of Myalepta cannot usually be predicted unless you already have had a reaction to any of them before. If you know that you are allergic to metreleptin or any of the other ingredients in Myalepta (glycine, sucrose, polysorbate 20, glutamic acid, sodium hydroxide), you should not take Myalepta but tell your doctor. Your first injection of Myalepta should be administered in the presence of your doctor or nurse to minimise the consequences of an allergic reaction should one occur.

PANCREATITIS

The pancreas is a large gland in the abdomen that is involved in digestion and sugar regulation. Patients with lipodystrophy have an increased risk of developing pancreatitis which is an inflammation of the pancreas due to the high fat (triglyceride) levels in the blood. A sudden increase in the levels of triglycerides can cause sudden onset (acute) pancreatitis.

HOW TO IDENTIFY IF YOU HAVE PANCREATITIS?

You may experience the following symptoms if you have pancreatitis:

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

Please contact your doctor straight away if you experience any of these symptoms.

WHO IS AT INCREASED RISK OF DEVELOPING PANCREATITIS?

All patients with lipodystrophy have a naturally high risk of developing pancreatitis as part of their condition. This risk may be especially high if you:

- Have already had pancreatitis before starting Myalepta
- Suffer from hypertriglyceridemia, a condition where there is too much fat (triglycerides) in your blood
- Suddenly stop Myalepta as this will increase the fat (triglyceride) levels in your blood.

These points should be discussed with your doctor before you start taking Myalepta.

HOW CAN THE RISK OF PANCREATITIS BE REDUCED?

Myalepta lowers your blood triglyceride levels. Therefore, you are most at risk when you stop using Myalepta as the triglyceride levels in your blood may rise due to its discontinuation. To minimise the risk of pancreatitis when stopping Myalepta, your doctor will gradually lower your dose over a two-week period. Do not stop taking Myalepta without consulting your doctor first. It is important to take your Myalepta on a daily basis as prescribed by your doctor.

If you develop pancreatitis while taking Myalepta, your doctor may continue the treatment as stopping Myalepta may make the pancreatitis worse.

HYPOGLYCAEMIA (LOW BLOOD SUGAR) IN PATIENTS USING DIABETES MEDICATION

High blood sugar levels and diabetes that does not respond sufficiently to medication are potential consequences of lipodystrophy. To treat your diabetes, you may have been prescribed insulin or other anti-diabetic drugs. Myalepta increases the action of insulin and, if your insulin doses and other anti-diabetic drugs are not adjusted, blood sugar levels may become too low (hypoglycaemia). However, this does not mean you should stop taking your diabetes medication. Only your doctor should make these decisions, and only they can make adjustments to your diabetes medication when required.

TALK TO YOUR DOCTOR ABOUT HOW TO MANAGE YOUR BLOOD SUGAR LEVELS

Talk to your doctor about managing your blood sugar levels, especially if you notice the following symptoms:

- 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.

WHO IS AT INCREASED RISK OF HYPOGLYCAEMIA?

You may have a higher risk of hypoglycaemia if you are taking high doses of insulin or other anti-diabetic drugs, and your doctor will have reviewed your other diabetes drugs when you start Myalepta. Lower blood sugar levels are a sign that your condition is improving with Myalepta, but the levels should not be allowed to go too low.

HOW CAN THE RISK OF HYPOGLYCAEMIA BE REDUCED?

When you start Myalepta, you may need dose reductions of insulin. After that, other diabetic medication may also need to be reduced to avoid low blood sugar levels.

If you experience any of the above signs of hypoglycaemia, talk to your doctor straight away as they may need to change your treatment.

RISK OF LYMPHOMA

Lymphoma is a cancer of a type of white blood cells called lymphocytes. People with lipodystrophy can get lymphoma, whether or not they are using Myalepta.

However, you may be at higher risk of getting a lymphoma when using the medicinal product. Your doctor will decide if you should use Myalepta and will monitor you during treatment.

HOW CAN I IDENTIFY LYMPHOMA?

Symptoms of lymphoma are often not specific. Talk to your doctor if you experience the following symptoms:

- Swelling of lymph nodes (found in places like in the armpits, in the neck, in the groin), which are most often painless
- Moderate fever with night-time sweats
- Unexplained weight loss
- Coughing or trouble breathing
- Lack of energy
- Itching, red or purple lumps under the skin.

WHO IS AT INCREASED RISK OF DEVELOPING LYMPHOMA?

You may have an increased risk for lymphoma if you have a form of acquired lipodystrophy (those that are not congenital or inherited). Acquired lipodystrophies are associated with autoimmune disorders, and autoimmune disorders have an increased risk of cancer even in patients not treated with Myalepta. However, having one or more risk factors does not necessarily mean that you will be affected by lymphoma.

HOW CAN THE RISK OF LYMPHOMA BE REDUCED?

If you have acquired lipodystrophy and/or significant, specific abnormalities in your blood, your doctor will decide whether you should take Myalepta and discuss the risk and benefits of Myalepta with you.

UNPLANNED PREGNANCY IN WOMEN

Myalepta might increase fertility in women with lipodystrophy resulting in unanticipated pregnancy.

Myalepta may reduce how well hormonal contraceptives work at preventing pregnancy.

Myalepta is not recommended during pregnancy and you should not take Myalepta if you are pregnant or may become pregnant as it is not known how Myalepta will affect the unborn baby.

HOW CAN THE RISK OF AN UNPLANNED PREGNANCY BE REDUCED?

If you are female and could get pregnant it is recommended you use effective contraception. Myalepta may reduce how well hormonal contraceptives work, therefore you should discuss appropriate methods of contraception with your doctor, these may include non-hormonal methods such as condoms. If you wish to plan a family, please ask your doctor for advice before using Myalepta.

SERIOUS AND SEVERE INFECTIONS

Leptin is involved in the immune system and our ability to fight infections; patients with lipodystrophy have an increased risk of developing serious and severe infections due to low leptin levels.

However, your body may regard metreleptin, the active ingredient in Myalepta, as a foreign substance and develop antibodies to attack it. In some cases, these may be classed as "neutralising antibodies" and reduce the effectiveness of Myalepta. These antibodies to metreleptin may increase your risk of developing serious and severe infections.

HOW CAN THE RISK OF SERIOUS AND SEVERE INFECTIONS BE REDUCED?

Tell your doctor straight away if you develop a high temperature accompanied by increased tiredness and inform them that you are on Myalepta. Your doctor will carefully monitor you and decide whether or not to continue Myalepta. Your doctor may perform a blood test to assess the presence of neutralising antibodies.

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. Talk to your healthcare provider about what symptoms you should watch for that would warrant further testing.

MEDICATION ERRORS

Due to Myalepta being provided to you as a powder in one package, and the need for other items to prepare the product before use, there is a risk of you not preparing Myalepta correctly. There is also a risk that you could inject the wrong dose or in the wrong way.

HOW CAN THE RISK OF MEDICATION ERRORS BE REDUCED?

To reduce the risk of medication errors, the following steps have been put in place to help you prepare your Myalepta medicine, measure the correct dose and then correctly inject the Myalepta under the skin:

- Initial training
 - Your doctor will arrange for you to receive training on how to prepare, measure your dose of Myalepta and inject yourself (or your child) with the product. The first injection should always be made in the presence of a doctor or nurse, so that you understand how to do it yourself in future.
 - Your doctor will confirm the details of your specific dose in milligrams and what volume of prepared Myalepta solution to inject (as either millilitres (mL) or units). Most doses will be in millilitres, however, in the case of very small doses, the volume your doctor will tell you to administer will be provided as the number of units to inject from the smallest 0.3 mL U100 insulin syringe. Your doctor will clearly explain this to you.
- Follow-up training
 - Each pack of Myalepta contains a Patient Information Leaflet which includes very detailed pictures and instructions on how to prepare, measure and inject Myalepta. During your initial training, your doctor or nurse will have shown you this leaflet whilst administering the first dose. Provided in every pack of Myalepta, you will be able to follow the instructions every time you inject Myalepta and they will be available even when you feel you are very familiar with what to do. For convenience, these instructions are reproduced inside the back cover of this booklet.
 - Chiesi have also prepared a video which shows the various steps involved in preparing, measuring the dose and injecting Myalepta. This video is available via the QR code opposite. From the landing page, please click on your dose of Myalepta and from here choose the Ed Materials - Patient tab. The video will be listed.
You can also access the landing page at: <https://www.medicines.ie/medicines/list/all/page-1/per-page-25?query=myalepta>

- Preparation and administration materials
 - 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 – 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 – one set per day
 - A sharps bin to safely dispose of used vials, needles and syringes.

The Myalepta, water for injection, alcohol swabs and sharps bin are supplied separately by the pharmacist. The remaining items are provided together in kits prepared by Chiesi and supplied via the pharmacist.

KEY INFORMATION TO REMEMBER

- Do not attempt to inject yourself with Myalepta until you have been trained.
- Follow the instructions from the training and the package insert on preparing and administering Myalepta.
- Each Myalepta vial and water for injection vial/ampoule is for single use only, discard any unused Myalepta solution and remaining water for injection after injecting the dose.
- If you are unsure about how to prepare Myalepta, measure your dose or how to inject your dose, speak with your doctor.
- Do not use syringes or needles more than once – use new ones each time.
- Place used needles, vials and syringes in the sharps bin and dispose as instructed by your doctor or pharmacist. Keep out of sight and reach of children.





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