

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### MYALEPTA

#### Metreleptin for injection

Read this carefully before you start taking **Myalepta** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Myalepta**.

#### Serious Warnings and Precautions

- Risk for loss of naturally-occurring (endogenous) leptin activity or loss of Myalepta efficacy due to neutralizing antibodies. Antibodies are made in the blood of people who use Myalepta that may reduce how well the leptin in your body (endogenous) works or how well Myalepta works. Side effects may include:
  - infection
  - problems with blood sugar, including diabetes
  - an increase in the amount of fat in your blood (triglycerides)If you experience these effects while taking Myalepta you should talk to your healthcare provider about contacting the manufacturer for neutralizing antibody testing (contact: [medinfo@medisonpharma.com](mailto:medinfo@medisonpharma.com) or 1-800-696-1341).
- Risk of lymphoma (a type of blood cancer) in people with generalized lipodystrophy whether or not they are using Myalepta. You may be at higher risk of getting a lymphoma when using Myalepta.

#### What is Myalepta used for?

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 there is ongoing metabolic disease and 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).

#### How does Myalepta work?

Natural leptin is produced by fatty tissue and has many functions in the body including:

- controlling how hungry you feel and your energy levels
- helping the insulin in your body manage sugar levels.

Myalepta works by copying the effects of leptin. This improves the ability of the body to control energy levels.

## **What are the ingredients in Myalepta?**

Medicinal ingredients: metreleptin

Non-medicinal ingredients: Glutamic acid, glycine, polysorbate 20, sodium hydroxide, sucrose

## **Myalepta comes in the following dosage forms:**

Powder for solution, 3 mg/ vial, 5.8 mg/ vial and 11.3 mg/ vial

## **Do not use Myalepta if you:**

- are allergic to any ingredients in this drug
- have general obesity that is not caused by generalised or partial lipodystrophy
- Have HIV-related lipodystrophy

## **To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Myalepta. Talk about any health conditions or problems you may have, including if you:**

- you are pregnant
- you have ever had problems with your blood (such as a 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)
- you have ever had a type of cancer called lymphoma

## **Other warnings you should know about:**

### *Lymphoma*

- People with lipodystrophy can get a type of blood cancer called 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.

### *Serious and severe infections*

- While being treated with Myalepta, your body produces antibodies that may increase the risk of developing serious or severe infections. Tell your doctor straight-away if you develop a high temperature, accompanied by increasing tiredness.

### *Low blood sugar with insulin or other antidiabetic medicines*

- If you are using a medicine such as insulin or other medicines to treat diabetes, your doctor will closely monitor your blood sugar. Your doctor will change your dose of insulin or other medicines if needed.
- This is to prevent your blood sugar from getting too low ('hypo-glycaemia'). Signs of low blood sugar include shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood.

### *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.

#### *Allergic reactions*

- While being treated with Myalepta, you may get an allergic reaction. Tell your doctor straight-away if you have any symptoms of an allergic reaction.

#### *Fertility*

- Myalepta might increase fertility in women with lipodystrophy.

#### *Pregnancy and breast-feeding*

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.
- You should not use Myalepta if you are pregnant or might become pregnant. This is because it is not known how Myalepta will affect your unborn baby.
- Women who could get pregnant should use effective contraception, including non-hormonal methods such as condoms, while using Myalepta.
- Talk to your doctor if you are breast-feeding. You and your doctor will decide whether or not to continue breast-feeding while using this medicine.
- It is not known if Myalepta will pass into breast milk.

#### *Driving and using machines*

- Myalepta has minor influence on the ability to drive and use machines. You might feel dizzy or tired when using this medicine. If this happens, do not drive or use any tools or machines. Talk to your doctor if you are not sure.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

#### **The following may interact with Myalepta:**

- statins for reducing cholesterol (such as atorvastatin)
- blood pressure medicines called 'calcium channel blockers'
- theophylline used in lung problems such as asthma
- blood-thinning medicines (such as warfarin or phenprocoumon)
- medicines for epilepsy or fits (such as phenytoin)
- medicines which suppress the immune system (such as cyclosporine)
- medicines for sleep or anxiety called 'benzodiazepines'

#### **How to take Myalepta:**

- Myalepta is an injection once a day under the skin ('subcutaneous injection'). This medicine is for use in children aged 2 years and above, adolescents and adults with generalised lipodystrophy; it is also for use in children aged 12 years and above, adolescents and adults with partial lipodystrophy.
- While using this medicine, you or your child will be monitored by your doctor, who will decide the dose you or your child should use.
- See INSTRUCTIONS FOR USE for full administration instructions.

Your doctor may decide that you inject yourself. Your doctor, nurse or pharmacist will show you how to prepare and inject this medicine.

- Do not try to prepare the medicine or inject yourself if you have not been trained.

**Usual dose:**

*How much to inject*

Your dose of Myalepta may change over time depending on how this medicine works for you. The Myalepta powder is dissolved by mixing it with water for injections to make the solution for injecting. 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. Read the INSTRUCTIONS FOR USE for how to make the solution before injecting.

Your doctor will have prescribed the correct dose for you, based on the following:

- If you weigh 40 kg or less:
  - A starting dose is 0.06 mg (0.012 mL of solution) for each kilogram of body weight.
- If you are male and weigh more than 40 kg:
  - A starting dose is 2.5 mg (0.5 mL of solution).
- If you are female and weigh more than 40 kg:
  - A starting dose is 5 mg (1 mL of solution).

Your doctor or pharmacist will tell you how much of the solution to inject. If you are not sure how much of the solution to inject, talk to your doctor or pharmacist before injecting.

The syringe you need to use to inject this medicine depends on the dose prescribed for you.

- See the INSTRUCTIONS FOR USE to find out which syringe to use.

To know how much medicine to inject (in mL), you divide your dose (in mg) by 5.

- For example, if you have been prescribed a 5 mg dose of Myalepta, 5 mg divided by 5 gives you 1 mL which is the amount you need to inject of the solution, using a 1 mL syringe.

If your dose is 1.50 mg (0.30 mL of solution) or less, you will need to use a 0.3 mL syringe.

- The 0.3 mL syringe will show the injection amount in 'Unit' instead of 'mL'. See the INSTRUCTIONS FOR USE for more information on reading and using the different syringes.
- To know how much solution to inject (in Units), divide your dose (in mg) by 5, and then multiply it by 100.

If you need to inject 1 mL or more of Myalepta solution, your doctor might tell you to give the dose as two separate injections. This can help make the injections more comfortable.

- You must use a clean syringe and needle for both injections.

If you are not sure how much of the solution to inject, talk to your doctor or pharmacist before injecting.

**Overdose:**

In one case, an infant received a 10-fold overdose of Myalepta for 8 months. This led to large weight loss causing vitamin deficiency, low iron (anaemia) and malnutrition. The infant got better when the dose was changed.

If you think you, or a person you are caring for, have taken too much Myalepta, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to inject a dose, inject it as soon as you remember. Then have your normal dose the next day.

Do not use a double dose to make up for a forgotten dose.

If you have injected less Myalepta than you should, talk to your doctor straight away. Your doctor will monitor you for side effects.

**What are possible side effects from using Myalepta?**

These are not all the possible side effects you may have when taking Myalepta. If you experience any side effects not listed here, tell your healthcare professional.

- loss of interest in food
- headache
- hair loss
- feeling tired
- weight loss
- joint pain
- back pain
- arm or leg pain
- cough
- constipation
- abdominal pain
- stuffy or runny nose
- vomiting
- ear pain
- a faster than normal heart rate
- chest infection

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>UNKNOWN</b>			
Low Blood Sugar: dizzy, sleepy or confused, clumsy, feeling mor		X	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
hungry than normal, feeling irritable or nervous			
Inflamed pancreas (pancreatitis): sudden severe pain in your stomach, feeling sick, diarrhoea		X	
Allergic reaction: breathing problems, swelling and redness of the skin, hives, swelling of your face, lips tongue or throat, stomach pain, fainting or feeling dizzy, very fast heartbeat		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

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.

Do not freeze Myalepta.

Do not use this medicine if the solution is not clear, is coloured or has bits or lumps in it.

Use with 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. The BWFI diluent contains 0.9% benzyl alcohol as a preservative.

Use with 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.

**If you want more information about Myalepta:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; or by calling 1-800-696-1341 or emailing [medinfo@medisonpharma.com](mailto:medinfo@medisonpharma.com).

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