



Package leaflet: Information for the patient

Myalepta 11.3 mg powder for solution for injection

metreleptin

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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What **Myalepta** is and what it is used for
- What you need to know before you use **Myalepta**
- How to use **Myalepta**
- Possible side effects
- How to store **Myalepta**
- Contents of the pack and other information
- Instructions for use

1. What Myalepta is and what it is used for

Myalepta contains the active substance metreleptin.

- Metreleptin is similar to a human hormone called leptin.

What Myalepta is 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)
- 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)

How Myalepta works

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.

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

2. What you need to know before you use Myalepta

Do not use Myalepta if:

- you are allergic to metreleptin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to 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 a low blood count)

- you have ever had inflammation of an organ called the pancreas ('pancreatitis')

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 might produce antibodies which 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 (see section 4).

Low blood sugar with insulin or other anti-diabetic 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'). For signs of low blood sugar levels, see section 4 under 'Signs of high and low blood sugar'.

High blood sugar and fat levels

You may have higher amounts of sugar ('hyper-glycaemia') or fat ('hyper-triglyceridaemia') in your blood while on Myalepta, which may be a sign that this medicine is not working as well as it should. Signs of high blood sugar levels and high fat levels are listed in section 4 under "Signs of high and low blood sugar" and "Signs of high fat".

If you notice any of the symptoms referred to above and described further in section 4 of this leaflet, or you are not sure, talk to your doctor straight away. Your doctor might need to change your treatment.

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. Signs of an allergic reaction can be seen in section 4 under "Allergic reactions".

Fertility

Myalepta might increase fertility in women with lipodystrophy (see section "Pregnancy, breast-feeding and fertility").

How to stop using Myalepta

If you need to stop using Myalepta, your doctor will gradually reduce the dose over two weeks before stopping it altogether. Your doctor will also ask you to follow a reduced fat diet.

- It is important to gradually reduce the dose over two weeks because this can help prevent a sudden increase in the levels of fat (called 'triglycerides') in your blood.
 - A sudden increase in the amount of triglyceride in your blood can make your pancreas inflamed ('pancreatitis'). Gradually reducing your dose, and following a reduced fat diet may help to prevent this.
- You should not stop using Myalepta unless your doctor tells you to.

Children and adolescents

Do not give this medicine to children below the age of 2 years with generalised lipodystrophy, or below the age of 12 years with partial lipodystrophy. This is because it is not known how this medicine will affect children under these ages.

Other medicines and Myalepta

Tell your doctor if you are using, have recently used or might use any other medicines. Myalepta can affect the way some other medicines work. Also some other medicines can affect the way this medicine works.

In particular, tell your doctor if you are taking any of the following medicines:

- 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'

If any of the above apply to you (or you are not sure), talk to your doctor before using Myalepta. Some medicines need to be monitored while you are using Myalepta since the dose of these medicines might need to be changed.

Pregnancy, breast-feeding and fertility

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 metreleptin 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 metreleptin will pass into breast milk.

Myalepta might increase fertility in women with lipodystrophy.

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.

3. How to use Myalepta

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

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.

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.

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. Read the "Instructions for Use" (see section 7) 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.
 - Your pharmacist will give you the correct syringe for injecting.
 - 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" (section 7) 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 times 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.

When small doses/volumes are prescribed (e.g. in children), the vials will remain almost completely filled with product after withdrawal of the required dose. Remaining solution should be discarded after use.

If you use more Myalepta than you should

If you use more Myalepta than you should, talk to your doctor or go to a hospital straight away. Your doctor will monitor you for side effects.

If you forget to use Myalepta

- 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.

If you stop using Myalepta

Do not stop using Myalepta without talking to your doctor. Your doctor will decide if you should stop using this medicine.

If you need to stop using Myalepta, your doctor will gradually reduce the dose over two weeks. See section 2 "How to stop using Myalepta" for more information.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects with this medicine:

Serious side effects

Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment. If you cannot contact your doctor, you should seek emergency medical help:

- low blood sugar (glucose)
- increased blood sugar (glucose)
- blood clot in your veins (deep vein thrombosis) - pain, swelling, warmth & redness, usually occurring in lower leg or thigh
- fluid in your lungs - difficulty breathing or cough
- feeling sleepy or confused

Allergic reactions

Talk to a doctor straight away if you notice any allergic reactions, including:

- 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

Inflamed pancreas ('pancreatitis'):

Talk to a doctor straight away if you notice any signs of an inflamed pancreas, including:

- sudden severe pain in your stomach (abdomen)
- feeling sick (nausea) or being sick (vomiting)
- diarrhoea

Other side effects

Tell your doctor if you notice any of the following side effects.

Very common (may affect more than 1 in 10 people):

- weight loss

Common (may affect up to 1 in 10 people):

- loss of interest in food

- headache
- hair loss
- unusually heavy or long menstrual bleeding
- feeling tired
- bruising, reddening, itching or hives where the injection is given
- your body producing antibodies to metreleptin which may increase the risk of developing serious or severe infections. You may notice you develop a high temperature, accompanied by increasing tiredness

Not known (frequency cannot be estimated from the available data):

- flu
- chest infection
- diabetes
- a higher than normal desire for food or excessive eating
- a faster than normal heart rate
- cough
- breathlessness
- muscle pain ('myalgia')
- joint pain
- swelling in your hands and feet
- increase in fatty tissue
- swelling or bleeding under the skin, where you injected
- a feeling of general discomfort, uneasiness or pain ('malaise')
- increased fat in the blood ('triglycerides')
- an increase in 'HbA1c' in your blood, shown in tests
- weight gain
- swelling or bleeding under the skin ('haemorrhage')
- high blood sugar levels
- having a high temperature
- chills
- shaking.

Tell your doctor if you notice any of the above side effects.

Signs of high and low blood sugar

Symptoms of **low blood sugar** levels 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

If you notice any of the symptoms above, or you are not sure, talk to your doctor straight away. Your doctor might need to change your treatment.

Symptoms of **high blood sugar** levels include:

- feeling very thirsty or hungry
- going to the toilet to pass urine more often
- feeling more sleepy
- feeling sick or being sick
- blurred vision
- pain in the chest or back
- feeling out of breath

Signs of high fat

Symptoms of **high fat** levels include:

- pain in the chest
- pain below the ribs like heartburn or indigestion
- feeling sick or being sick

Tell your doctor if you notice any of the above side effects.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via :

UK:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland:

HPRA Pharmacovigilance.

Earlsfort Terrace, IRL – Dublin 2;

Tel: +353 1 6764971, Fax: +353 1 6762517.

Website: www.hpra.ie; e-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Myalepta

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and carton. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C-8 °C). Keep the vial in the outer carton in order to protect from light.

After reconstitution, the solution must be administered immediately and cannot be stored for later use. Dispose of any unused medicine.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Myalepta contains

- The active substance is metreleptin.
- Each vial contains 11.3 milligrams of metreleptin. After dissolving the vial contents in 2.2 millilitres of water for injections, each millilitre contains 5 milligrams of metreleptin.
- The other ingredients are: glycine, sucrose, polysorbate 20, glutamic acid, sodium hydroxide (for pH adjustment).

What Myalepta looks like and contents of the pack

Myalepta is presented as a powder for solution for injection (powder for injection). It is a white powder supplied in a glass vial with a rubber stopper and an aluminium seal with a white plastic flip-off cap.

Myalepta is available in packs containing 1 or 30 vials.

Not all pack sizes may be marketed in your country.

Your doctor, nurse or pharmacist should provide you separately with the appropriate syringes and needles, wipes and water for injections to enable you to prepare and inject Myalepta. They will provide a 'sharps disposal container' for you to put your used vials, syringes and needles in.

Marketing Authorisation Holder

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This leaflet was last revised in October 2018.

This medicine has been authorised under 'exceptional circumstances'. This means that because of the rarity of this disease it has been impossible to get complete information on this medicine.

The European Medicines Agency will review any new information on this medicine every year and this leaflet will be updated as necessary.

Other sources of information

Detailed information on this medicine is available on the European

Medicines Agency web site: <http://www.ema.europa.eu>.

There are also links to other websites about rare diseases and treatments.

7. Instructions for Use

Before using Myalepta, you must first read Sections 1 – 6 of this package leaflet, and then read Section 7 Instructions for Use.

Before you begin self-administering this medicine at home, your doctor, nurse or pharmacist will train you how to prepare and inject Myalepta. Contact them if you are unclear about anything or if you need more information or help. Take your time to carefully prepare and inject your medicine, which when including the period of the vial warming up after being taken out of the fridge, can be approximately 20 minutes in total.

Additional training information

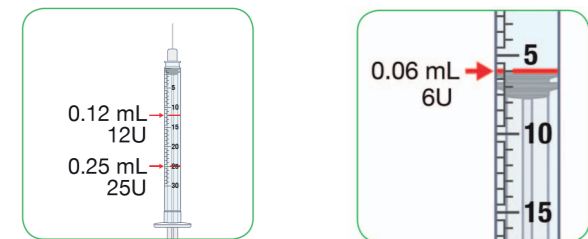
There are additional education training information and videos to help you understand how to use Myalepta correctly. Details on how to access these are available from your doctor.

Reading the syringe

Line up the top rim of the plunger with the line for the prescribed dose. An example is given below for the different syringe sizes. If your syringe looks different or has different dose markings, talk to your doctor, nurse or pharmacist for more information.

Using the 0.3 mL syringe

- The 0.3 mL syringe shows the injection amount in 'U' instead of 'mL'.
- 'U' means 'Units'.
- 1 U is the same as 0.01 mL.
- Each 5 U is shown as a number with a big line. This is the same as 0.05 mL.
- Each 1 U is shown as a smaller line between the big lines. This is the same as 0.01 mL.
- Each 0.5 U is shown as a small line between two 1 U lines. This is the same as 0.005 mL.



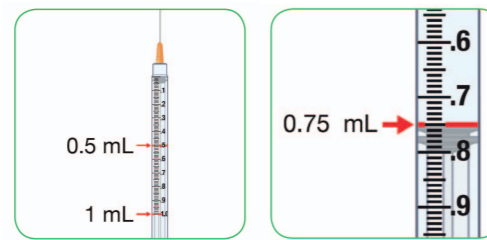
- To help with injecting Myalepta solution using the small 0.3 mL syringe, the last column in the table below shows the 'Unit' measurement on the syringe that relates to the different potential doses of the medicine prescribed by your doctor, nurse, or pharmacist.

Converting dose from 'mL' to 'Units' when using the 0.3 mL syringe

Weight of child	Dose of Myalepta	Amount of mixed Myalepta solution	Amount of mixed Myalepta solution to inject in 'Unit' measurements on your 0.3 mL syringe
9 kg	0.54 mg	0.10 mL	10
10 kg	0.60 mg	0.12 mL	12
11 kg	0.66 mg	0.13 mL	13
12 kg	0.72 mg	0.14 mL	14
13 kg	0.78 mg	0.15 mL	15
14 kg	0.84 mg	0.16 mL	16
15 kg	0.90 mg	0.18 mL	18
16 kg	0.96 mg	0.19 mL	19
17 kg	1.02 mg	0.20 mL	20
18 kg	1.08 mg	0.21 mL	21
19 kg	1.14 mg	0.22 mL	22
20 kg	1.20 mg	0.24 mL	24
21 kg	1.26 mg	0.25 mL	25
22 kg	1.32 mg	0.26 mL	26
23 kg	1.38 mg	0.27 mL	27
24 kg	1.44 mg	0.28 mL	28
25 kg	1.50 mg	0.30 mL	30

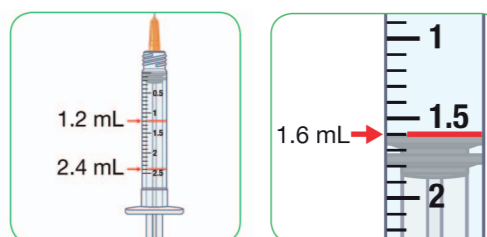
Using the 1 mL syringe

- This syringe shows the injection amount in mL, so you should inject the amount your doctor, nurse, or pharmacist has told you to. You do not need to convert the amount from mL to Units.
- You will be given the 1 mL syringe to use if your daily dose is more than 1.5 mg up to 5 mg, which as a volume is greater than 0.3 mL up to 1.0 mL of Myalepta solution.
- Each 0.1 mL is shown as a number with a big line.
- Each 0.05 mL is shown as a medium size line.
- Each 0.01 mL is shown as a smaller line.



Using the 2.5 mL syringe

- This syringe shows the injection amount in mL, so you should inject the amount your doctor, nurse, or pharmacist has told you to. You do not need to convert the amount from mL to Units.
- You will be given the 2.5 mL syringe to use if your daily dose is more than 5 mg up to 10 mg, which as a volume is greater than 1.0 mL of Myalepta solution.
- Each 0.5 mL is shown as a number next to a big line.
- Each 0.1 mL is shown as a smaller line between the big lines.



Step A: Setting up

1) Get together all the materials you will need for your injection. These will have been given to you by your doctor, nurse, or pharmacist.

- On a clean, well-lit work surface, place the following items:
 - a glass vial of Myalepta powder
 - a container of water for dissolving the Myalepta powder
 - The water for injections might come in glass or plastic ampoules, or glass vials with a rubber stopper.
 - alcohol wipes (to clean your skin where you will inject and to clean the tops of the vials)
 - sharps disposal container (to safely dispose of the injection equipment afterwards)

You will also need 2 syringes:

- One 3 mL syringe with a 21 gauge, 40mm needle for dissolving the powder
- One injection syringe with a much shorter needle for injecting the solution under your skin

The size of this syringe will be chosen by your doctor, nurse or pharmacist for your dose of Myalepta.

- If your dose is 1.5 mg or less, you will use a 0.3 mL syringe.
- If your dose is more than 1.5 mg up to 5 mg, you will use a 1 mL syringe.
- If your dose is more than 5 mg, you will use a 2.5 mL syringe.

If your dose is more than 5 mg, your doctor, nurse or pharmacist might tell you to give the dose as two separate injections. See section 3 "How much to inject" for more information.



2) Before preparing Myalepta solution, allow the powder vial to reach room temperature for about 10 minutes.



3) Wash your hands before preparing the medicine.

Step B: Filling the 3 mL syringe with 2.2 mL of water for injections

- Take the 3 mL syringe out of the plastic wrapper. Always use a new syringe.
 - The 3 mL syringe and needle will be provided separately.
 - How you connect the needle to the syringe will be depend on if you have been provided your water for injection in a plastic ampoule, a glass ampoule, or a glass vial (see below for specific instructions).

5) Withdraw 2.2 mL of water for injection into the 3 mL syringe.

Your doctor, nurse or pharmacist will give you 'water for injection' with the medicine vial and syringes. This is mixed with the Myalepta powder to dissolve the powder to make the liquid medicine that you inject. The water for injection will come in either:

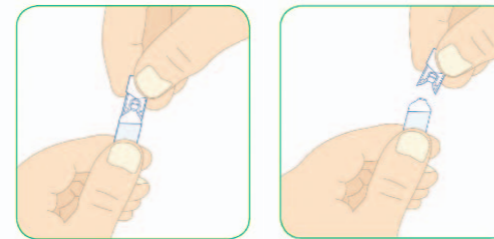
- a plastic ampoule
- a glass ampoule
- a glass vial (with rubber stopper)

Always use a new ampoule or vial of water for injection. Never use remaining water for injection left over from a previous day's preparation of Myalepta solution.

Plastic ampoule of water for injection



The plastic ampoule is a sealed container with a twist-off top.



To remove the water for injection, break open the ampoule.

- Hold the ampoule so that the top is facing up.
- Hold the bottom of the ampoule in one hand and the top of the ampoule in your other hand.
- Keeping the bottom of the ampoule still, gently twist the top of the ampoule until it is removed.

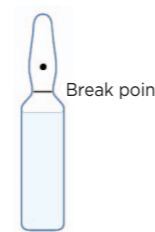
- Do not attach the needle to the syringe.
- Without the needle attached, insert the 3 mL syringe tip into the top of the plastic ampoule as far as possible.

With the syringe still in the ampoule, turn the ampoule and syringe upside down. The syringe will now be facing up.

- With the syringe still in the ampoule, pull the plunger down carefully.
 - Pull down until the top rim of the plunger lines up with the black 2.2 mL line.
- You must check for air pockets or air bubbles in your 3 mL syringe. See steps 6-8 below on removal of air pockets and air bubbles from the syringe.
- Remove the syringe from the plastic ampoule.

- Attach the needle to the syringe.
 - Do not over-tighten the needle.
 - Do not remove the needle guard.
 - Do not touch the needle.

Glass ampoule of water for injection



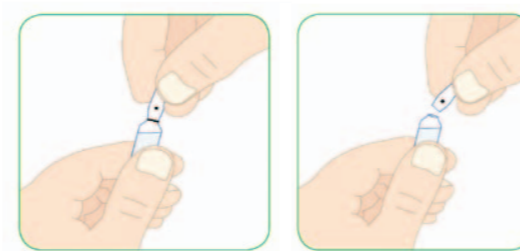
The glass ampoule is a sealed container.

Before opening the water for injection ampoule, prepare the 3 mL syringe by attaching the needle to it. Do not over-tighten the needle.

- Remove the needle guard.
- Do not touch the needle.

To remove the water for injection, break open the ampoule at the break-point as shown in the picture above.

- Hold the ampoule so that the tip is facing up.
- Use the alcohol swab to clean the break point on the ampoule.
- Hold the bottom of the ampoule in one hand and the top of the ampoule in your other hand.
- Keeping the bottom of the ampoule still, snap the tip off.

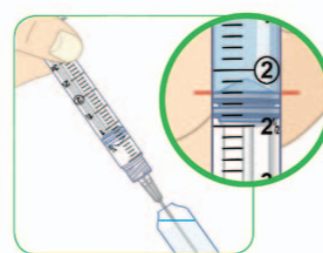


Insert the 3 mL syringe into the glass ampoule.

- The glass ampoule should be at a 45 degree angle to the ground.
- The needle should go as far into the ampoule as possible.

With the needle still in the ampoule, pull the plunger up carefully.

- Pull up until the top rim of the plunger lines up with the black 2.2 mL line.
- You must check for air pockets or air bubbles in your 3 mL syringe. See steps 6-8 below on removal of air pockets and air bubbles from the syringe.



Glass vial of water for injection



The glass vial will have a plastic cap that you should remove, revealing a rubber seal below.

- Do not remove the rubber seal.

Attach the needle to the 3 mL syringe. Do not over-tighten the needle.

- Remove the needle cover.
- Do not touch the needle.
- Pull the plunger down to the 2.2 mL line to draw air into the syringe.

Place the vial on a hard, flat surface.

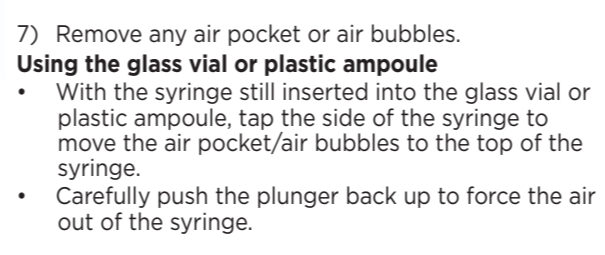
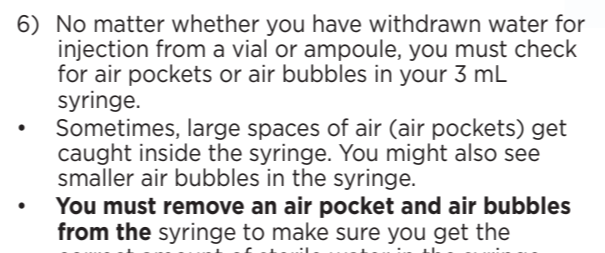
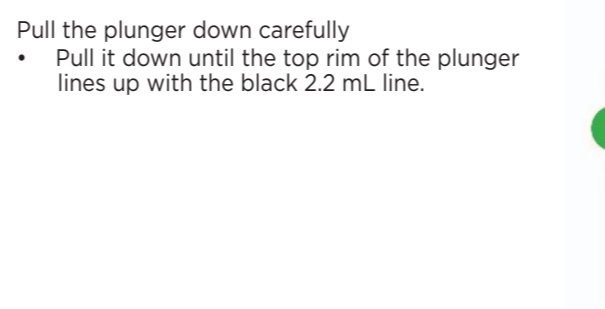
- Insert the 3 mL syringe needle into the vial, through the rubber seal.
- The needle should be facing down.
- The needle should go all the way into the vial.

Push the plunger all the way down.



With the needle still in the vial, turn the vial and syringe upside down. The needle will now be facing up.

- Do not remove the needle from the vial.



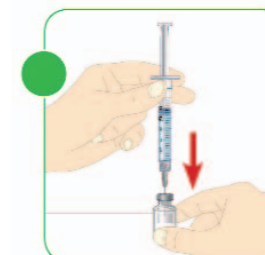
Using the glass ampoule

- Remove the syringe from the ampoule and hold it so that the needle faces up.
- Tap the side of the syringe to move the air pocket/air bubbles to the top of the syringe.
- Carefully push the plunger back up to force the air out of the syringe.
- Check the amount of water for injection.
 - If there is less than 2.2 mL of water for injection in the syringe, draw more water for injection into the syringe and repeat the steps 6 and 7 until you have 2.2 mL in the syringe.
- With 2.2 mL of water for injection in the syringe, remove the syringe from the vial or ampoule.
 - Do not move the plunger.
 - Do not touch the exposed needle on your syringe as it is sterile, and you may damage the needle or injure yourself.

Step C: Dissolving Myalepta

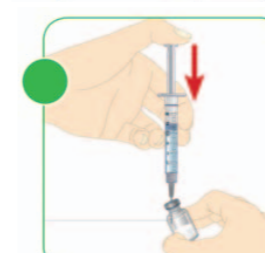
- Make sure the vial of Myalepta powder has been out of the refrigerator for at least 10 minutes to reach room temperature.
 - Do not remove the plastic cap from the vial of Myalepta powder.
 - Place the vial on a flat, hard surface.
 - Clean the top of the vial with the alcohol wipe.

12) Insert the needle of the 3 mL syringe containing the 2.2 mL of water for injection all the way into the Myalepta vial containing the powder.

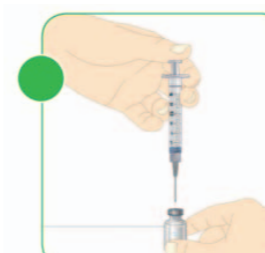


13) Hold the vial at 45 degree angle to the table and slowly push the plunger all the way down with your thumb.

- The water for injection should go down the inside wall of the vial.
- All of the water for injection should be injected into the vial.



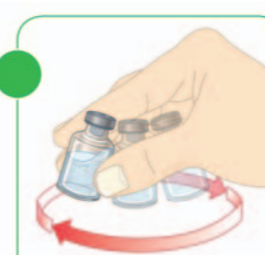
14) Take the needle out of the vial and throw away the syringe into a sharps disposal container.



15) Mix the powder and water for injection

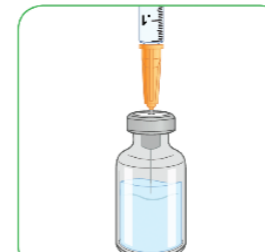
- Move the vial gently in a circle (swirling motion)
- Until the powder dissolves and the liquid is clear. **Do not shake or vigorously mix.**
- The solution will take less than 5 minutes to become clear.

When properly mixed, the Myalepta solution should be clear and free of lumps of dry powder, bubbles or foam. Do not use the solution if it is not clear or has bits or lumps in it. Throw it away and start again from step 1.



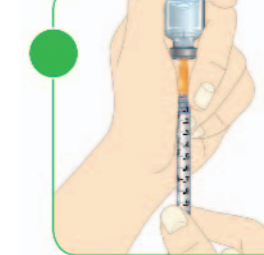
Step D: Filling the syringe with Myalepta for injection

- To inject the Myalepta solution, you will use a new injection syringe, which will either be the 0.3 mL, 1.0 mL, or 2.5 mL syringe that was provided to you by your doctor, nurse or pharmacist. Remove the needle cover.
 - Do not** touch the needle.
 - Do not** move the plunger.



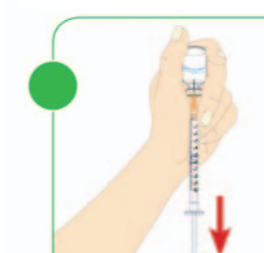
17) Insert the needle through the centre of the rubber bung, all the way into the vial containing the dissolved Myalepta solution.

18) With the needle in the vial, turn the vial and syringe upside down.



19) Keeping the needle inside the vial, pull the plunger down.

- The top rim of the plunger should line up with the black line on the syringe that matches the amount of Myalepta solution you are going to inject.

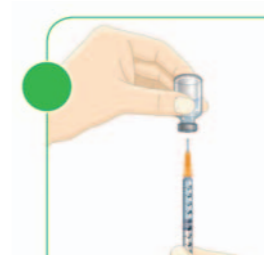


20) Check for air pockets and air bubbles.

- If you see an air pocket or any air bubbles, **follow the same instructions** described in step 7 to **remove the air from the syringe.**

21) If the syringe contains your correct dose amount of Myalepta solution, remove the needle from the vial.

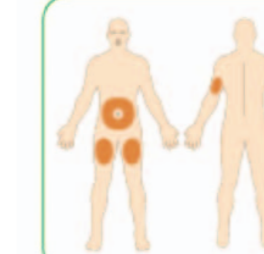
- Do not** move the plunger.
- Do not** touch the needle.



Step E: Choose and preparing where to inject

22) Carefully choose where you want to inject Myalepta. You can inject this medicine into the following areas:

- stomach area (abdomen), except for a 5 cm area directly around the belly button
- thigh
- back of the upper arm



If you want to use the same area of the body for each injection, do not use the same spot that you used for your last injection.

- If you inject other medicines, do not inject Myalepta in the same site as you have done for those other medicines.

- Clean the area where you will inject yourself with a clean alcohol swab and let the skin dry.
 - Do not touch the area you have cleaned until you are injecting Myalepta.

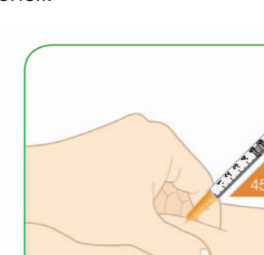
Step F: Injecting Myalepta

Important: Myalepta must be injected under the skin ('subcutaneous'). **Do not** inject into a muscle.

24) To inject under the skin, pinch the skin with one hand where you are going to inject.

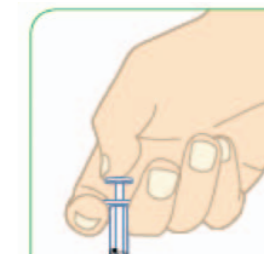


25) With the other hand, hold the syringe like a pencil.



26) Gently insert the needle into the skin at approximately a 45 degree angle to the body.

- Do not** insert the needle into a muscle.
- The needle is short in length, and all of the needle should go into the skin at a 45 degree angle.



27) Gently use your thumb to push the plunger all the way down.

- Inject all of the medicine.
- If there is medicine left in the syringe, you have not had your full dose.

28) Remove the syringe from the skin.

Step G: Throwing away used materials

29) Throw away the two used syringes and all caps, vials, or ampoules in the sharps disposal container straight away.

- Talk to your doctor, nurse or pharmacist about correct disposal of your sharps disposal container once it becomes full. There might be local regulations for this.



Important

- Do not use the syringes more than once. Use new syringes each time.
- The vials may remain almost completely filled with product after withdrawal of the required dose. Remaining solution should be discarded after use.
- Do not dissolve another dose of Myalepta powder with any ampoule or vial containing unused remaining water for injection. This unused water for injection should be disposed of in your sharps container. Always use a new ampoule or vial of water for injection each time when preparing to dissolve Myalepta powder.
- Do not recycle the syringes, caps, or sharps disposal container, or throw them into household waste.
- Always keep the sharps disposal container out of reach of children.