

MYALEPTA[®] ▼

(metreleptin powder for
solution for injection)

INSTRUCTIONS FOR USE

5.8 mg Vial

▼ This medicinal product 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 doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Side effects should also be reported to Aegerion by calling **00800 23437466**.

myalepta[®]
metreleptin

Aegerion[®]
Pharmaceuticals
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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 will take about 20 minutes (this includes the time for the vial to warm up after being taken out of the fridge).

Additional training information

There are additional educational materials including a video to help you understand how to use Myalepta correctly, which can be found at www.myalepta.info.eu. The video is also available via the following QR code:

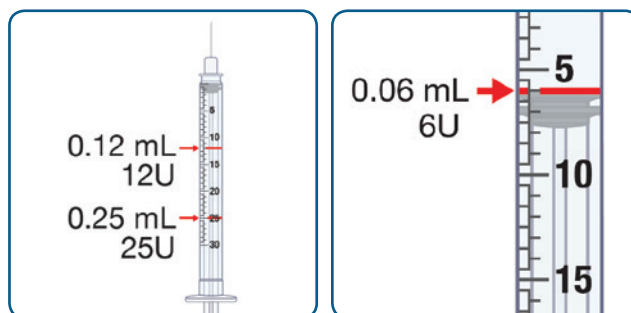


Reading the syringe

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'
- Your doctor has worked out the correct amount of Myalepta solution for your dose and it is marked on the syringe with a red line



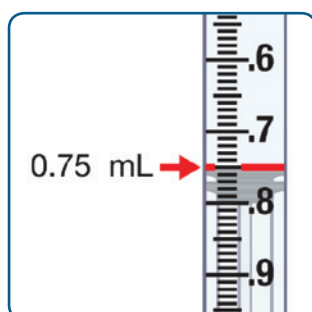
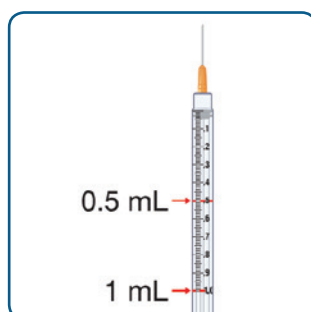
- Your doctor or nurse has worked out the correct amount of Myalepta solution for your child using the table below

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

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

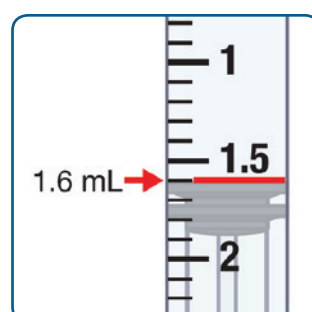
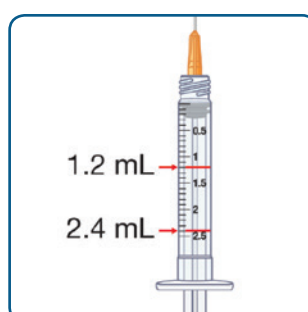
Using the 1 mL syringe

- 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 up to 1.0 mL (5 mg), but not less than 0.3 mL (1.5 mg)
- 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 1.0 mL (5 mg) 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 injection for dissolving the Myalepta powder
 - The water for injection 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:

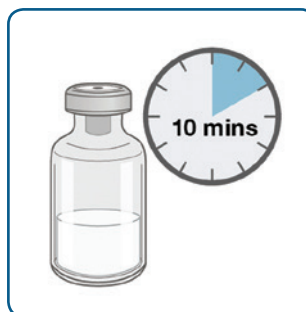
- One 3 mL syringe with a 21 gauge, 40 mm needle for dissolving the powder
- One injection syringe with a much shorter needle for injecting the solution under your skin

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 and 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 Step F “Injecting Myalepta” 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 1.1 mL of water for injection

4 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 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)

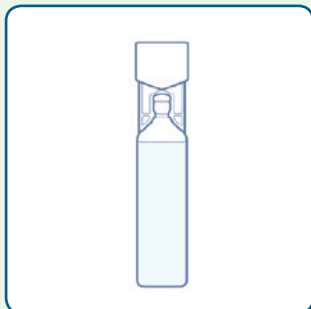
5 Withdraw 1.1 mL of water for injection into the 3 mL syringe.

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 days preparation of Myalepta solution.

Plastic ampoule of water for injection

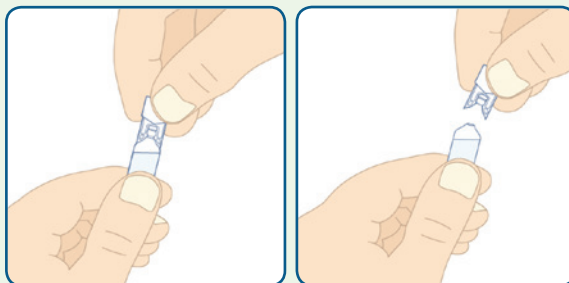


The plastic ampoule is a sealed container with a twist-off top.

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

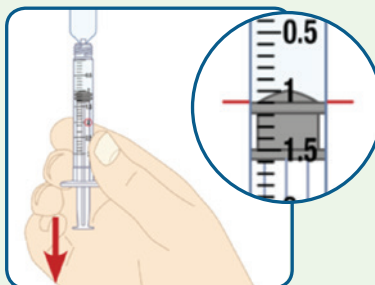


- Do not attach the needle to the syringe
- Without the needle attached, insert the 3 mL syringe tip into the top of the plastic ampoule as far as possible

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 1.1 mL line

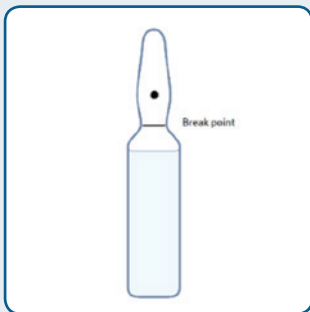


- You must check for air pockets or air bubbles in your 3 mL syringe. See steps 6-8 below on removal of air pockets and air bubbles from the syringe
- Remove the syringe from the plastic ampoule

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



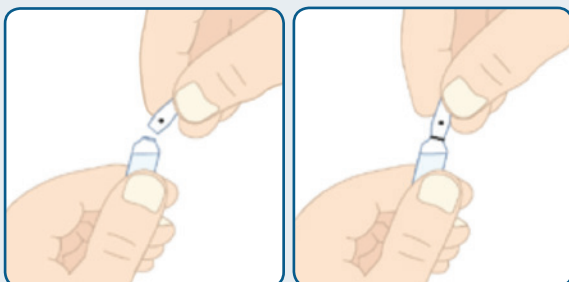
The glass ampoule is a sealed container.

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

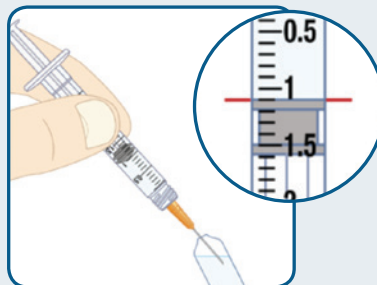


Insert the 3 mL syringe into the glass ampoule.

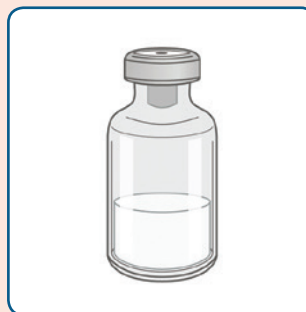
- The glass ampoule should be at a 45 degree angle to the ground
- The needle should go as far into the ampoule as possible

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 1.1 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

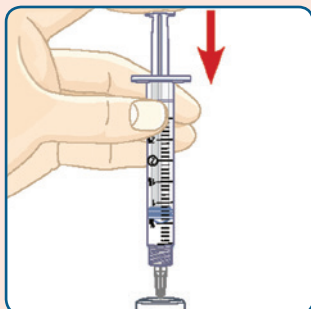
Attach the needle to the 3 mL syringe. Do not over-tighten the needle.

- Remove the needle cover
- Do not touch the needle
- Pull the plunger down to the 1.1 mL line to draw air into the syringe

Place the vial on a hard, flat surface.

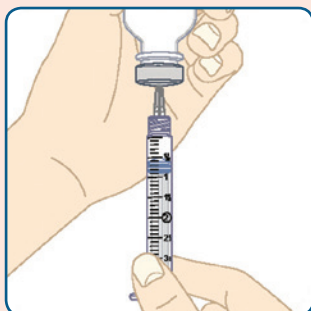
- Insert the 3 mL syringe needle into the vial, through the rubber seal
- The needle should be facing down
- The needle should go all the way into the vial

Push the plunger all the way down.



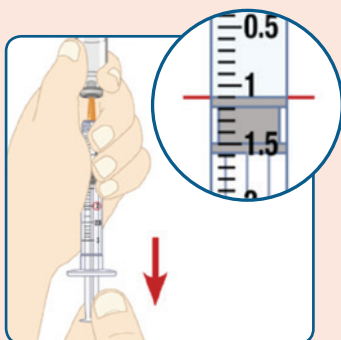
With the needle still in the vial, turn the vial and syringe upside down. The needle will now be facing up.

- Do not remove the needle from the vial



Pull the plunger down carefully

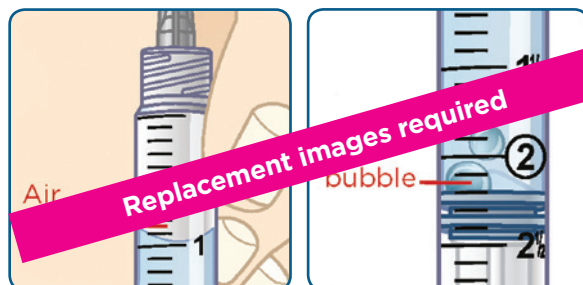
- Pull it down until the top rim of the plunger lines up with the black 1.1 mL line



6 No matter whether you have withdrawn water for injection from a vial or ampoule, you must check for air pockets or air bubbles in your 3 mL syringe.

- Sometimes, large spaces of air (air pockets) get caught inside the syringe. You might also see smaller air bubbles in the syringe

- **You must remove any air pocket and air bubbles from the syringe** to make sure you get the correct amount of sterile water in the syringe

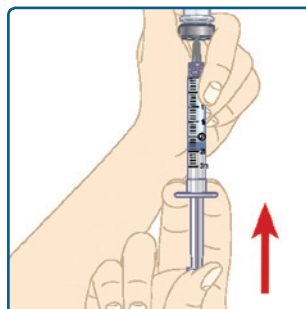


7 Remove any air pocket or air bubbles.

Using the glass vial or plastic ampoule

With the syringe still inserted into the glass vial or plastic ampoule, 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



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

8 Check the amount of water for injection.

- If there is less than 1.1 mL of water for injection in the syringe, draw more water for injection into the syringe and repeat steps 6 and 7 until you have 1.1 mL in the syringe

9 With 1.1 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

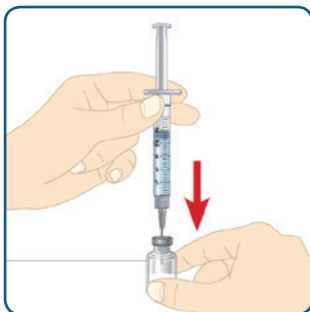
STEP C: Dissolving Myalepta

10 Make sure the vial of Myalepta powder has been out of the refrigerator for at least 10 minutes to reach room temperature.

11 Remove the plastic cap from the vial of Myalepta powder.

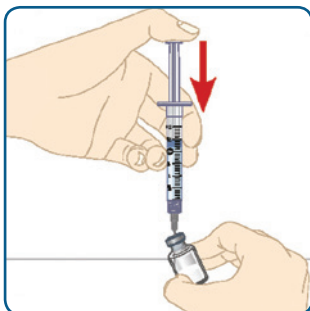
- Place the vial on a flat, hard surface
- Clean the top of the vial with the alcohol wipe

12 Insert the needle of the 3 mL syringe containing the 1.1 mL of water for injection all the way into the Myalepta vial containing the powder.

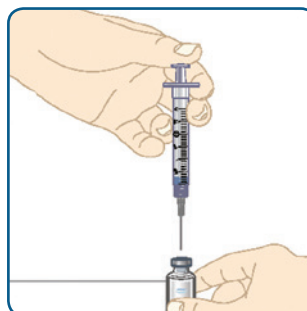


13 Hold the vial at a 45 degree angle to the table and slowly push the plunger all the way down with your thumb.

- 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



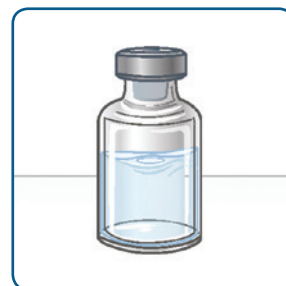
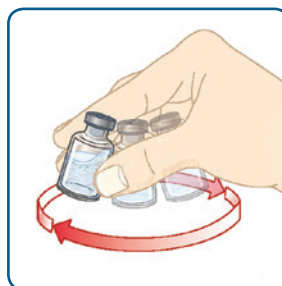
14 Take the needle out of the vial and throw away the empty syringe and needle into a sharps disposal container.



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.

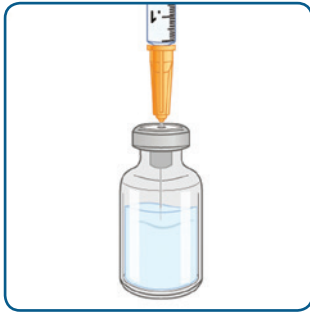


STEP D: Filling the syringe with Myalepta for injection

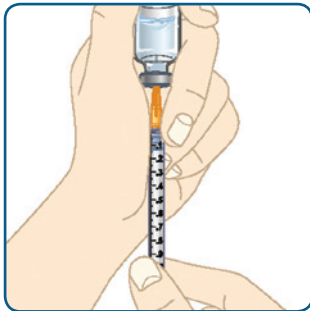
16 To inject the Myalepta solution, you will use a new injection syringe, which will either be the 0.3 mL, 1.0 mL, or 2.5 mL syringe that was provided to you by your doctor, nurse or pharmacist. Remove the needle cover.

- **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.

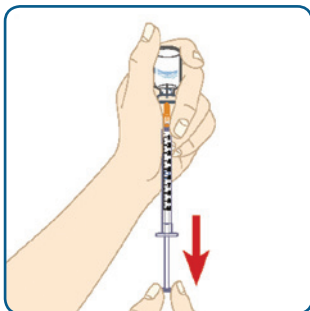


18 With the needle in the vial, turn the vial and syringe upside down.



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

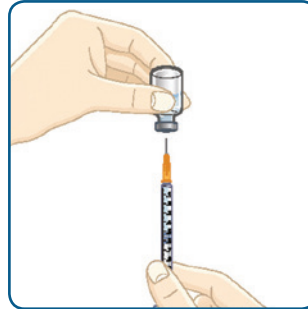


20 Check for any air pockets and air bubbles.

- 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.

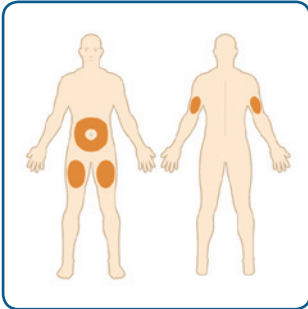
- **Do not** move the plunger
- **Do not** touch the needle



STEP E: Choosing 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

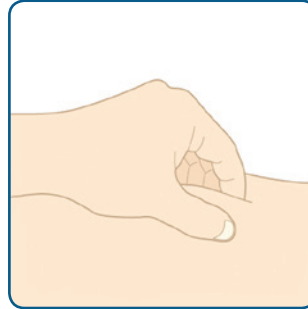
23 Clean the area where you will inject yourself with a clean alcohol swab and let the skin dry.

- 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

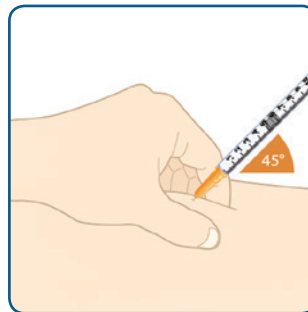
24 To inject under the skin, pinch the skin with one hand where you are going to inject.



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

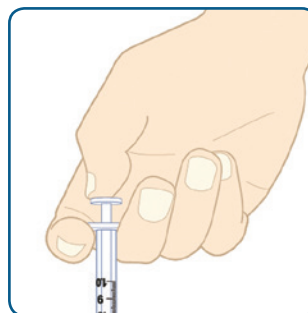
26 Gently insert the needle into the skin at approximately a 45 degree angle to the body.

- **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 of dissolved Myalepta may be still almost completely full of solution after you have withdrawn your dose for injection. 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

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Pharmaceuticals
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Aegerion Pharmaceuticals B.V.
Atrium Building
8th Floor
Strawinskylaan 3127
1077 ZX Amsterdam
The Netherlands

Aegerion UK Ltd,
Lakeside House,
1 Furzeground Way,
Stockley Park,
Uxbridge
UB11 1BD

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