

INSTRUCTIONS FOR USE

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

MYALEPTA

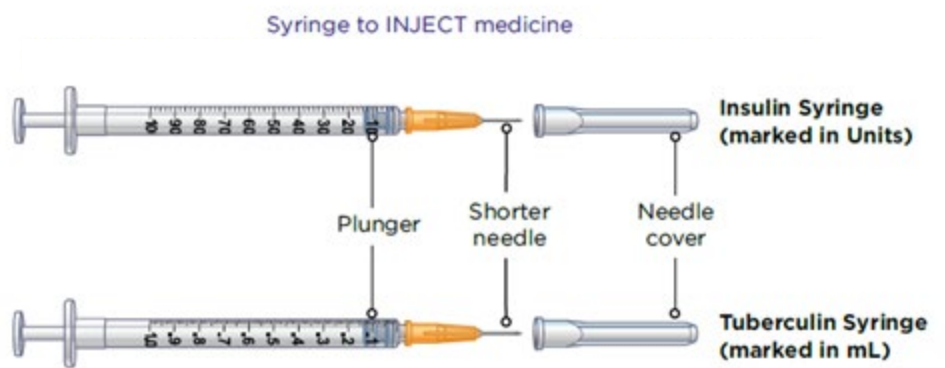
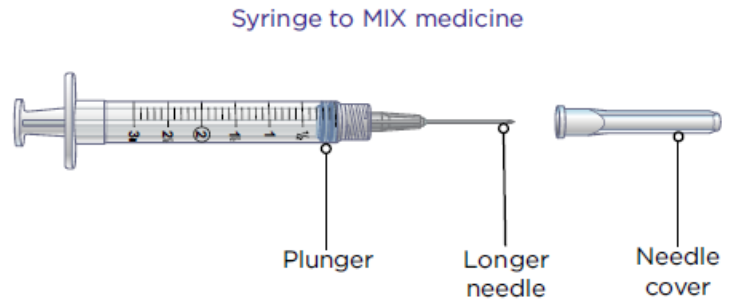
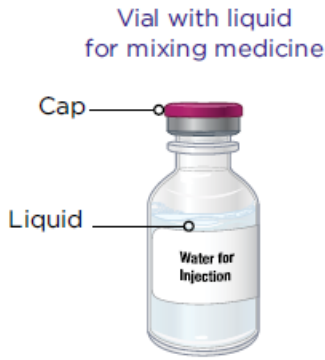
Metreleptin for injection

Read this carefully before you start taking Myalepta and each time you get a refill. 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.

Make sure you have all the supplies listed below BEFORE using Myalepta.

You can get these supplies with a prescription from your healthcare provider, from a retail or hospital pharmacy, or the specialty pharmacy that distributes Myalepta.

- a vial with liquid for mixing Myalepta
 - 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
- a 3 mL syringe with a longer needle for mixing Myalepta
- a vial with Myalepta powder
 - 3 mg and 5.8 mg vial are for single use reconstituted with SWFI. Should be used immediately and any remaining reconstituted solution should be discarded.
 - 11.3 mg vial is for multi use reconstituted with BWFI. Should be used within 3 days of reconstitution when stored at 2°C to 8°C and protected from light.
- a syringe for injecting the Myalepta medicine under your skin – this syringe has a much shorter needle.
 - The size of this second syringe will be chosen by your doctor or pharmacist for your dose of Myalepta.
 - If your dose is 1.25 mg or less - you will use a 0.3 mL syringe.
 - If your dose is more than 1.25 mg up to 5 mg - you will use a 1 mL syringe.
 - If your dose is more than 5 mg - you will use a 3.0 mL syringe.
- 2 alcohol wipes
- 1 sharps container for throwing away used needles and syringes. See "**Disposing of used needles and syringes**" at the end of these instructions.
- Stickers to note discard date for mixed medicine



Stickers to note the last day you can use the mixed medicine

Date Opened _____
Discard After _____

Pen to write on the stickers



Figure A

How to read your syringes:

0.3 mL syringe (Figure B)

- The 0.3 mL syringe shows the injection amount in 'U' instead of 'mL'
- 1 U is the same as 0.01 mL. See section 3, "How much to inject" for more information.
- Each 0.05 mL is shown as a number with a big line. This is the same as 5 U.

- Each 0.005 mL is shown as a smaller line between the big lines. This is the same as 0.5 U.

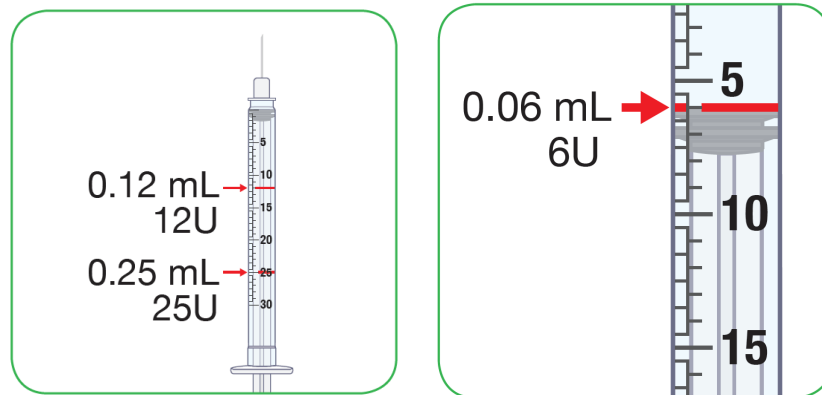


Figure B

1 mL syringe (Figure C)

- 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.

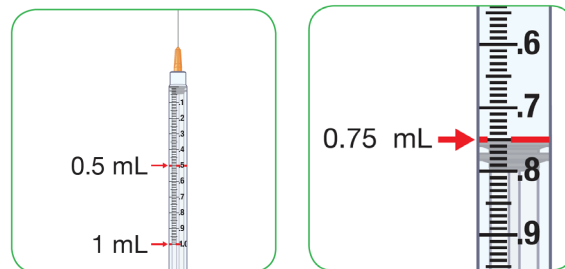


Figure C

3.0 mL syringe (Figure D)

- 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.

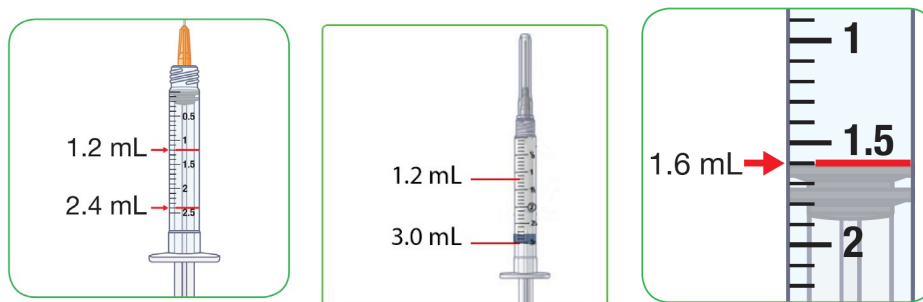


Figure D

The 3 mL syringe has a longer needle (see Figure B).

The 3 mL syringe is the syringe you will use to mix Myalepta. Always fill the 3 mL syringe with 2.2 mL of liquid. **Do not** inject yourself with the 3 mL syringe.

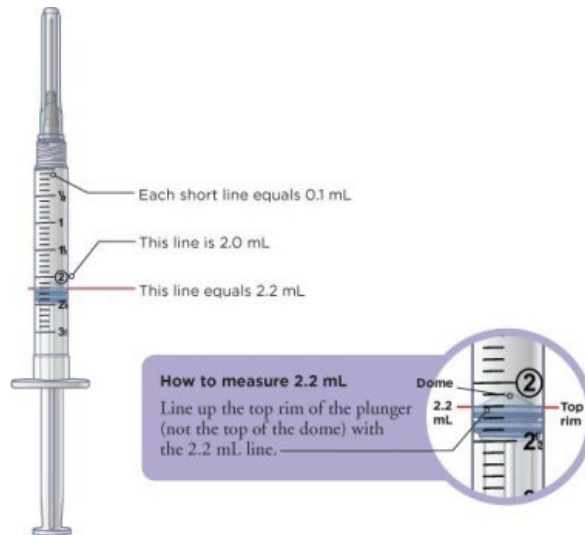


Figure E

The injection syringes have a shorter needle (see Figures B-D).

- The size of this injection syringe will be chosen by your doctor or pharmacist for your dose of Myalepta.
 - If your dose is 1.25 mg or less - you will use a 0.3 mL syringe.
 - If your dose is more than 1.25 mg up to 5 mg - you will use a 1 mL syringe.
 - If your dose is more than 5 mg - you will use a 3.0 mL syringe.

STEP 1: Getting Started

Your dose of Myalepta may change over time, depending on how Myalepta works for you. So it is important to keep track of your dose. On the line below, write down your dose in mL and the date. Be sure to keep this up-to-date if your dose changes:

_____ mL _____ Date
Dose you will take each day

Take 1 Myalepta vial out of the refrigerator 10 minutes before you plan to inject to allow it to reach room temperature.

Set 1 vial with the liquid you will need to mix Myalepta on your work surface.

Check the powder in the Myalepta vial. It should be white. **Do not** use Myalepta if the powder is discolored. Throw it away and get a new one.

Check the expiration date printed on the Myalepta vial. **Do not** use Myalepta past the expiration date printed on the vial (see Figure F).



Figure F

For this step, you will need:

Vial with liquid for mixing
a dose of Myalepta



Vial with powder
(Myalepta)



Alcohol wipes



1a Wash your hands
with soap and water.



1b Remove 2 alcohol
wipes from their
wrappers. Place the
wipes on their
wrappers to keep
them clean.



1c Use your thumb to
remove the caps
from the vials



1d Clean the tops of the
vials with one of the
alcohol wipes.

STEP 2: Filling the 3 mL syringe (used to mix Myalepta) with 2.2 mL of liquid

For this step, you will need:

A 3 mL syringe (with longer needle) used to mix
Myalepta



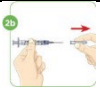
Vial with
liquid
(from Step 1)



Sharps disposal
container



2a Take the 3 mL syringe out of the plastic wrapper. Always use a new syringe.

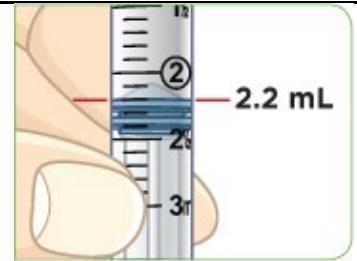


Pull the needle cover straight off. **Do not** twist the needle when removing the cover.

Put the needle cover in the sharps disposal container.



Pull down the plunger to fill the syringe with air.



Line up the top rim of the plunger with the black 2.2 mL line.

You **must first** fill the syringe with air and put that air into the vial to make it easier to later fill the syringe with liquid.



Set the vial with the liquid on the work surface. Insert the needle into the top of the vial.

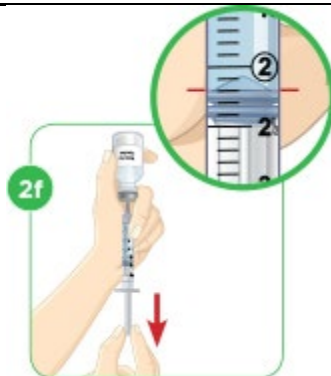


Push the plunger down all the way to fill the vial with air.



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

Keep the whole needle in the liquid.



Pull down the plunger until the top rim of the plunger lines up with the black 2.2 mL line.



Check to see if there is an air pocket in the syringe.

If you see an air pocket, tap the side of the syringe to move the air pocket to the top of the syringe.



Push the plunger up to remove the air pocket.

You must remove the air pocket to be able to fill the syringe with 2.2 mL of liquid.

Tip: You will always fill the 3 mL syringe with 2.2 mL of liquid.



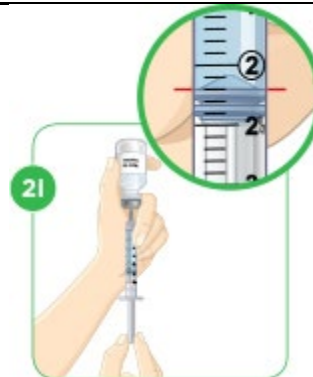
Check to see if there are large air bubbles in the syringe.

If you see large air bubbles in the syringe, tap the syringe to move the air bubbles to the top.

If there are a few small bubbles left, that is okay.



Push the plunger up to remove as many large air bubbles as you can.



Pull down the plunger so the top rim of the plunger lines up with the black 2.2 mL line. Keep the whole needle in the liquid.



Remove the needle from the vial. Be careful not to move the plunger.

Keep the syringe in your hand. **Do not** set it down.

For instructions on how to discard the used vial of liquid, read the carton that contained those vials.

STEP 3: Preparing Myalepta

Note: If you already mixed your Myalepta before today, go to “Using a vial of mixed Myalepta” at the end of this step.

Option 1: Mixing a new vial of Myalepta:

For this step, you will need:

The 3 mL syringe filled with 2.2 mL of



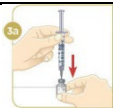
liquid (from Step 2)

Vial with powder (from Step 1)



Sharps disposal container

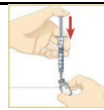




Set the vial with the Myalepta powder on the work surface. Insert the needle straight down into the center of the vial.



Then tilt the vial so that the tip of the needle is pointing toward the inside wall of the vial.



With your thumb, slowly push the plunger down all the way.

The liquid should go down the inside wall of the vial.



Make sure you add the liquid slowly so that bubbles do not form in the vial.

No liquid should be left in the syringe.



While keeping the plunger all the way down, take the needle out of the vial.

Throw away the syringe with the needle still attached into your sharps disposal container.

Do not recap the needle. Recapping the needle can lead to a needlestick injury.



To mix the powder and liquid, **move the vial gently in a circle** (swirl) until the liquid is clear. **Do not** shake the vial.



When the medicine is mixed well, the liquid should be clear. You should not see any clumps, powder, bubbles, or foam.

Tip: If your vial of Myalepta is not mixed well, go back to Step 3c.

Note: Go to Step 4 if you just mixed a new vial of Myalepta.

Option 2: Using a vial of mixed Myalepta:

Note: For **newborns or infants** using Myalepta, **throw away any unused mixed Myalepta right away**. Do not store it for reuse.

For this step, you will need:

Vial of mixed Myalepta Alcohol wipes



Choose a **clean, flat work surface** large enough to let you prepare the medicine.



Take 1 vial of mixed Myalepta out of the refrigerator.

Only Myalepta mixed with bacteriostatic water for injection can be stored for reuse.

You must use the vial within 2 days after the day the medicine was mixed.



Set the vial of mixed Myalepta on the work surface for 10 to 15 minutes so that it comes to room temperature.



Wash your hands with soap and water.



Remove 2 alcohol wipes from their wrappers.

Place the wipes on their wrappers to keep them clean.



Clean the top of the vial with the alcohol wipe.



Check that the Myalepta is mixed well and is clear. You should not see any clumps, powder, bubbles, or foam.

If you see clumps, powder, bubbles, or foam, throw away the vial in the sharps disposal container.

Important: Do not mix any liquid or mixed medicine from another vial with the vial you just cleaned.

STEP 4: Filling the syringe used for injecting Myalepta

Ensure the proper size syringe is selected.

For this step, you will need:

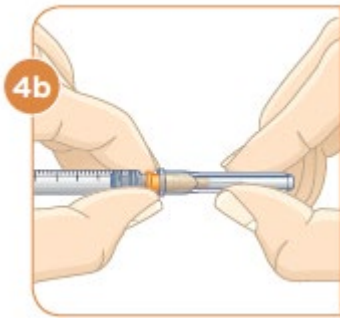
A syringe (with shorter needle) used to inject Myalepta (see Figure B-D)

Vial of mixed Myalepta (from Step 3)

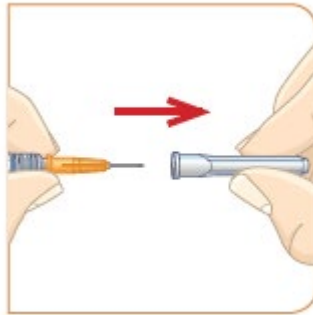
Sharps disposal container



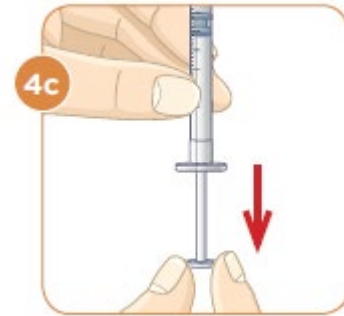
4a Remove the injection syringe from the plastic wrapper. Always use a new syringe.



Firmly grip the needle base.

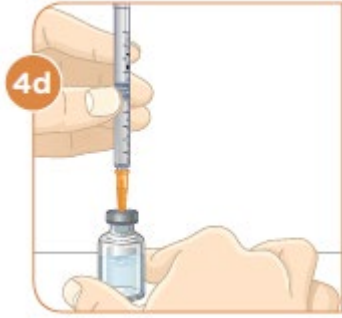


Pull the needle cover straight off.
Throw away the needle cover in the sharps disposal container.



Pull down the plunger until the top rim of the plunger lines up with the black line of the dose prescribed by your healthcare provider.

You **must first** fill the syringe with air and put that air into the vial to make it easier to later fill the syringe with liquid.



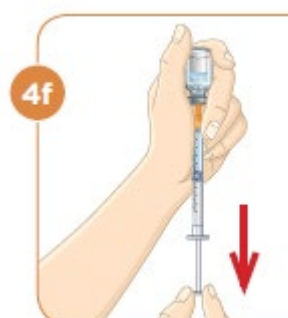
4d Hold the vial with the mixed Myalepta. Insert the needle into the top of the Myalepta vial.



Push the plunger down all the way, to fill the vial with air.



4e With the needle still in the vial, turn the vial and syringe upside down. Keep the whole needle in the liquid. It is okay if the plunger moves down.



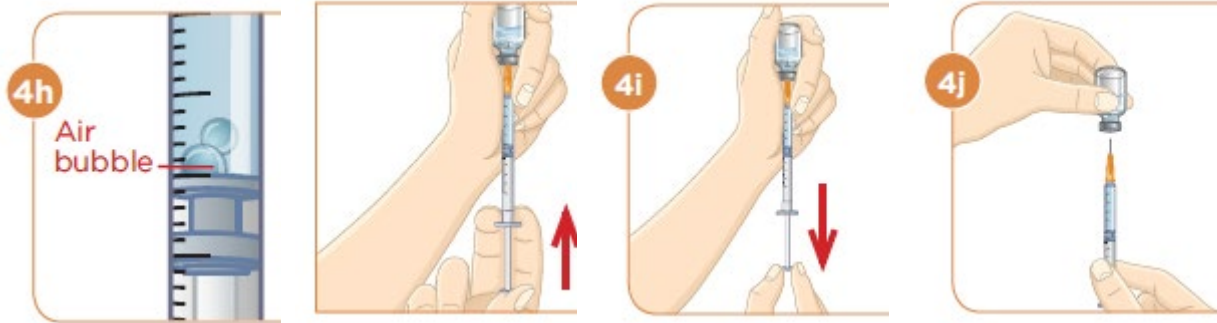
4f Pull down the plunger until the top rim of the plunger lines up with the black line of the dose prescribed by your healthcare provider.



4g Check to see if there is an air pocket in the syringe. If you see an air pocket, tap the side of the syringe to move the air pocket to the top of the syringe.



Push the plunger up to remove the air pocket. You must remove the air pocket to be able to fill the syringe with a full dose of Myalepta.



Check to see if there are large air bubbles in the syringe.

If you see large air bubbles in the syringe, tap the side of the syringe to move the air bubbles to the top.

If there are a few small bubbles left, that is okay.

Push the plunger up to remove as many large air bubbles as you can.

Pull down the plunger again until the top rim of the plunger lines up with the black line of the dose prescribed by your healthcare provider.

Remove the needle from the vial.

Set the vial down. **Do not** set the syringe down.

STEP 5: Injecting Myalepta

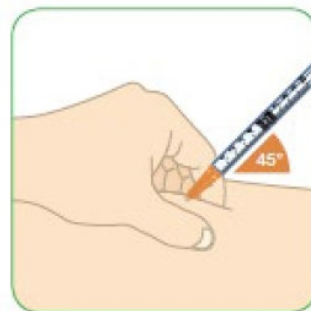
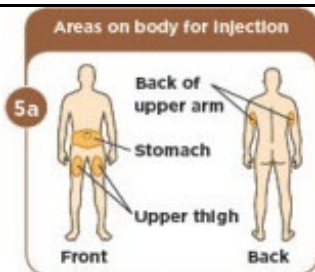
For this step, you will need:

Syringe filled with your Myalepta dose (from Step 4)

Alcohol wipe (from Step 1)

Sharps disposal container for used syringes and needles





Choose an injection site that you will use to inject your Myalepta.

The recommended injection sites are an area of your body that has the most fat, such as the stomach (abdomen), thigh, or the back of your upper arm.

You can use the same area of the body for each injection. But be sure to choose a

Use an alcohol wipe to clean the injection site.

Let the alcohol dry before you move on to 5c.

Pinch the skin with one hand.

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

Insert the needle into the skin at an angle.

Do not insert the needle straight up and down.

Let go of the skin.

Use your thumb to push the plunger down until it stops.

Take the needle out of your skin.

different injection site in that area.

If you inject other medicines you should choose a different site from where you inject Myalepta. **Do not** inject Myalepta in the same site as your other medicines.

Important:

Inject Myalepta under the skin (subcutaneous). **Do not** inject Myalepta into a muscle or vein.



Throw away the used syringe with the needle still attached in your sharps disposal container. See “**Disposing of used needles and syringes**” at the end of this document.

Do not recap the needle. Recapping the needle can lead to a needlestick injury.

Important:

Unused Myalepta mixed with sterile water for injection (for infants less than 3 years of age, or adults with a known hypersensitivity to benzyl alcohol), **must be thrown away**.

Do not store it for reuse.

Myalepta mixed with bacteriostatic water for injection can be stored for reuse.



Store only if mixed with bacteriostatic water for injection.

Store the vial of mixed Myalepta in the refrigerator as soon as you are done.



Looking at a calendar, count 2 days after the day you mixed the Myalepta.



Write that date on the stickers found to the right.



Place the sticker on the vial of mixed Myalepta.

For example, if you mixed Myalepta on Monday, January 2, you would throw it away **after your dose** on Wednesday, January 4.

Important:

Stickers to Note the Last Day You Can Use Myalepta When Mixed with Bacteriostatic Water for Injection

Date Opened _____ Discard After _____	Date Opened _____ Discard After _____
Date Opened _____ Discard After _____	Date Opened _____ Discard After _____
Date Opened _____ Discard After _____	Date Opened _____ Discard After _____
Date Opened _____ Discard After _____	Date Opened _____ Discard After _____
Date Opened _____ Discard After _____	Date Opened _____ Discard After _____
Date Opened _____ Discard After _____	Date Opened _____ Discard After _____
Date Opened _____ Discard After _____	Date Opened _____ Discard After _____
Date Opened _____ Discard After _____	Date Opened _____ Discard After _____
Date Opened _____ Discard After _____	Date Opened _____ Discard After _____

STEP 6: Disposing of used needles and syringes:

Put your used needles and syringes in a sharps disposal container right away after use. **Do not** throw away (dispose of) loose needles and syringes in your household trash.

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.

This Instructions For Use was prepared by Chiesi Farmaceutici S.p.A.

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