

Instructions for Use
MYALEPT[®] (MAI-uh-lept)
(metreleptin) for injection, for subcutaneous use
Vial

- **A healthcare provider should show you how to inject MYALEPT before you use it for the first time. A healthcare provider should also watch you inject your MYALEPT dose the first time you inject it.**
- **Do not** inject MYALEPT until your healthcare provider has shown you the right way to inject it. If you have questions or do not understand the instructions, talk to your healthcare provider or pharmacist.
- MYALEPT is **only** for use under the skin (subcutaneous).
- **Do not** share your MYALEPT needles with another person. You may give an infection to them, or get an infection from them.

This Instructions for Use is divided into 6 steps:

Step 1: Getting started

Step 2: Filling the 3 mL syringe with 2.2 mL of liquid

Step 3: Preparing MYALEPT

Step 4: Filling the syringe used for injecting MYALEPT

Step 5: Injecting MYALEPT

Step 6: Disposing of used needles and syringes

If at any time during these steps you have questions:

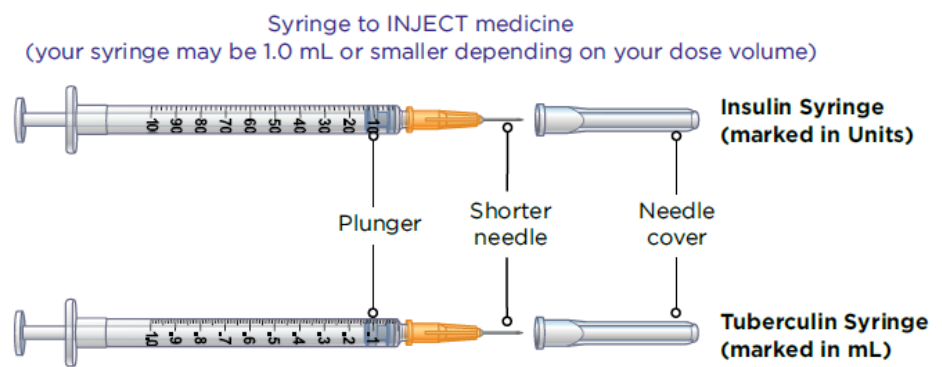
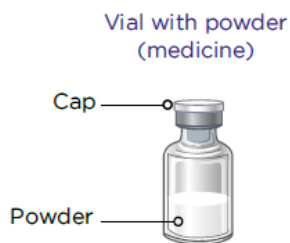
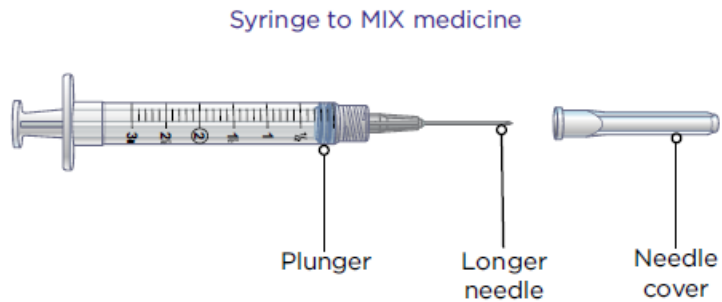
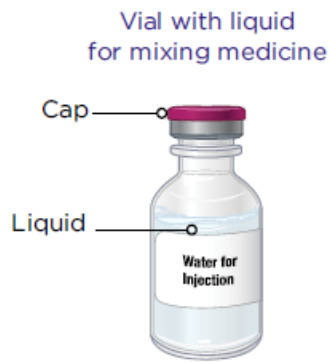
- See the "Common Questions" tab
- Call 1-855-669-2537
- **Visit www.MYALEPT.com**

Supplies you will need to give your MYALEPT (see Figure A).

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

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

- a vial with liquid for mixing MYALEPT
 - Sterile water for injection should be used in newborns and infants
 - Bacteriostatic water for injection should be used for older children and adults
- a 3 mL syringe with a longer needle for mixing MYALEPT
- a vial with MYALEPT powder
- a 1 mL syringe (or smaller) with a shorter needle for injecting MYALEPT
- 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



Sharps disposal container



Stickers to note the last day you can use
the mixed medicine (page 14)

Discard vial
after dose on: _____

Pen to write on the stickers



Figure A

How to read your syringes:

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

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

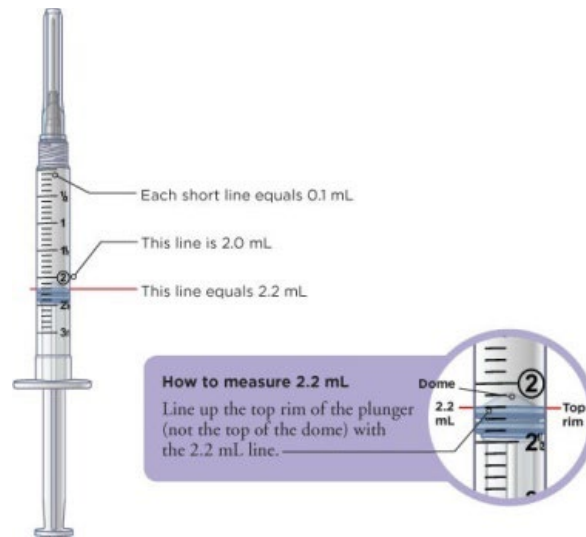


Figure B

The injection syringes have a shorter needle (see Figure C).

- People who weigh more than 88 pounds (lbs) (40 kg) should use a 1 mL syringe to administer their injection of MYALEPT. People who weigh 88 lbs (40 kg) or less should use either a 1 mL or smaller syringe because smaller amounts of MYALEPT are needed for injection. Using the wrong size syringe can cause you to measure the wrong amount of MYALEPT.

The 1 mL (or smaller) syringe is the syringe you will use to inject MYALEPT. **Only use the 1 mL (or smaller) syringe to inject your dose of MYALEPT.**

How to measure your dose
Line the top rim of the plunger with the unit line for the prescribed dose.

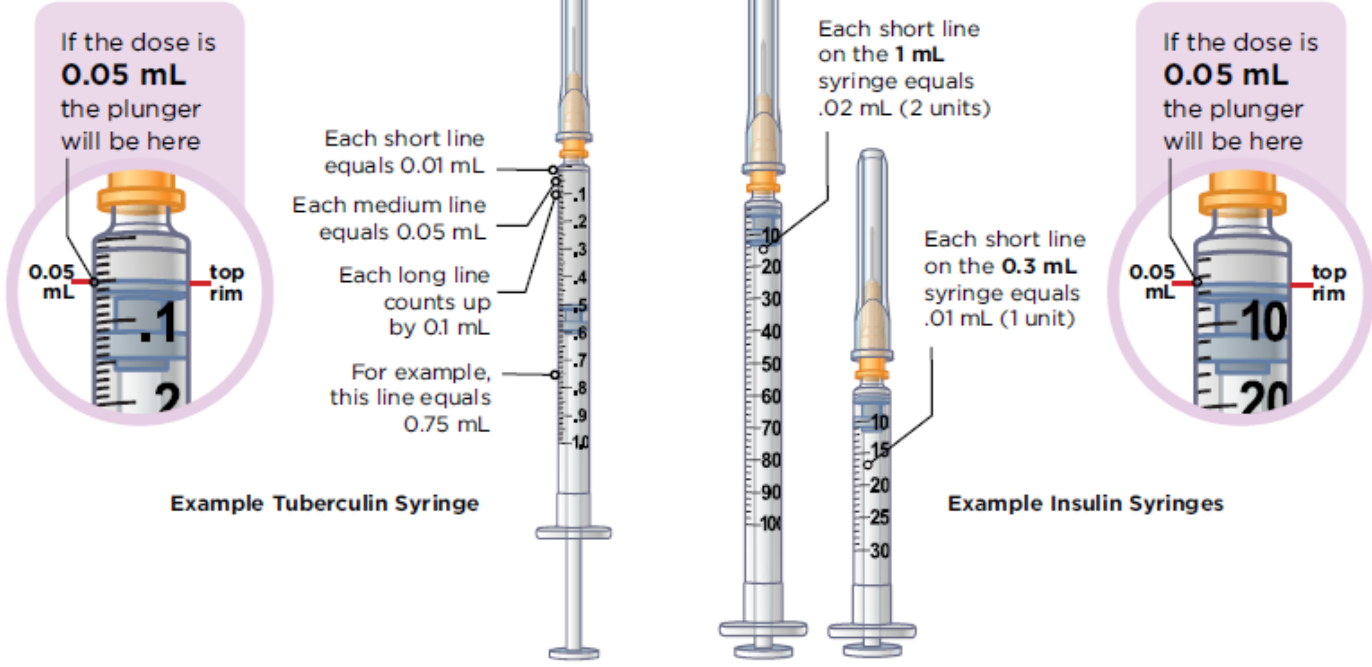


Figure C

Step 1: Getting Started

Your dose of MYALEPT may change over time, depending on how MYALEPT 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 MYALEPT 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 MYALEPT on your work surface.
- Check the powder in the MYALEPT vial. It should be white. **Do not** use MYALEPT if the powder is discolored. Throw it away and get a new one.
- Check the expiration date printed on the MYALEPT vial. **Do not** use MYALEPT past the expiration date printed on the vial (see **Figure D**).



Figure D

For this step, you will need:

Vial with liquid for mixing a dose of MYALEPT



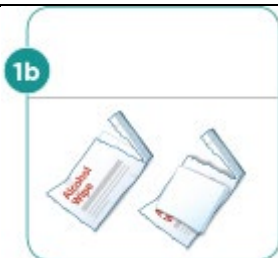
Vial with powder (MYALEPT)



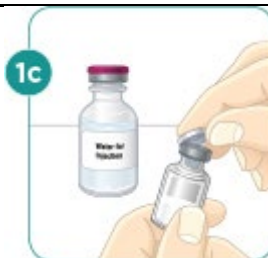
Alcohol wipes



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 MYALEPT) with 2.2 mL of liquid

For this step, you will need:

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



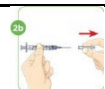
Vial with liquid (from Step 1)



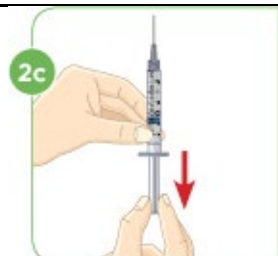
Sharps disposal container



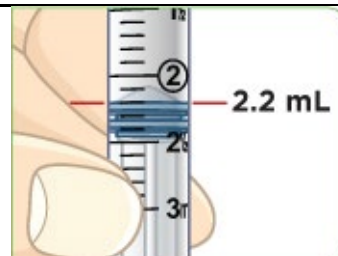
2a Take the 3 mL syringe out of the plastic wrapper. Always use a new syringe.



Pull the needle cover straight off. **Do not** twist the needle when removing the cover. Put the needle cover in the sharps disposal container.



2c 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.

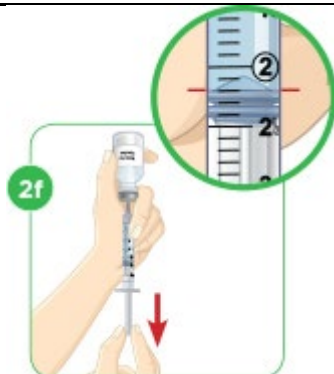


Push the plunger down all the way to fill the vial with air.



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.

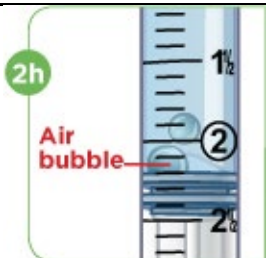
If you see an air pocket, tap the side of the syringe to move the air pocket to the top of the syringe.



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 MYALEPT

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

Option 1: Mixing a new vial of MYALEPT:

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)



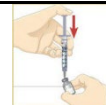
Sharps disposal container



Set the vial with the MYALEPT 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 MYALEPT is not mixed well, go back to Step 3c.

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

Option 2: Using a vial of mixed MYALEPT:

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

For this step, you will need:

Vial of mixed MYALEPT Alcohol wipes



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

3e



Take 1 vial of mixed MYALEPT out of the refrigerator.

Only MYALEPT 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.

3f



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

3g



Wash your hands with soap and water.

3h



Remove 2 alcohol wipes from their wrappers.

Place the wipes on their wrappers to keep them clean.

3i



Clean the top of the vial with the alcohol wipe.

3j



Check that the MYALEPT 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 MYALEPT

Patients greater than 40 kg should use a 1 mL syringe for administration. In pediatric patients, small volumes for administration can result in medication errors when measured incorrectly. Smaller syringe sizes may be more appropriate for pediatric patients weighing less than or equal to 25 kg. Ensure the proper size syringe is selected.

The table below shows how a dose of MYALEPT (mg) is converted to solution volume (mL) and the injection syringe marks (units) that correspond with the dose.

Conversion of MYALEPT Dose to Unit Measurement for Injection

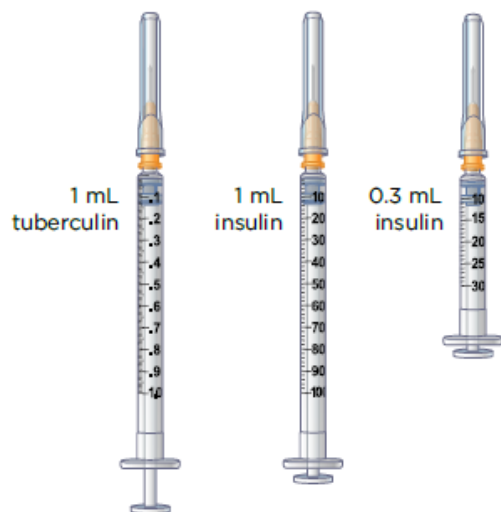
DOSE OF MYALEPT	AMOUNT OF MIXED MYALEPT SOLUTION TO INJECT (TUBERCULIN SYRINGE USERS)	AMOUNT OF MIXED MYALEPT SOLUTION TO INJECT (INSULIN SYRINGE USERS)
0.30 mg	0.06 mL	6 units
0.36 mg	0.07 mL	7 units
0.42 mg	0.08 mL	8 units
0.48 mg	0.09 mL	9 units
0.54 mg	0.10 mL	10 units
0.60 mg	0.12 mL	12 units
0.66 mg	0.13 mL	13 units
0.72 mg	0.14 mL	14 units
0.78 mg	0.15 mL	15 units
0.84 mg	0.16 mL	16 units
0.90 mg	0.18 mL	18 units
0.96 mg	0.19 mL	19 units
1.02 mg	0.20 mL	20 units
1.08 mg	0.21 mL	21 units
1.14 mg	0.22 mL	22 units
1.20 mg	0.24 mL	24 units
1.26 mg	0.25 mL	25 units
1.32 mg	0.26 mL	26 units
1.38 mg	0.27 mL	27 units
1.44 mg	0.28 mL	28 units
1.50 mg	0.30 mL	30 units
1.56 mg	0.31 mL	31 units
1.62 mg	0.32 mL	32 units
1.68 mg	0.33 mL	33 units
1.74 mg	0.34 mL	34 units
1.80 mg	0.36 mL	36 units
1.86 mg	0.37 mL	37 units
1.92 mg	0.38 mL	38 units
1.98 mg	0.39 mL	39 units
2.04 mg	0.40 mL	40 units
2.10 mg	0.42 mL	42 units
2.16 mg	0.43 mL	43 units
2.22 mg	0.44 mL	44 units
2.28 mg	0.45 mL	45 units
2.34 mg	0.46 mL	46 units

DOSE OF MYALEPT	AMOUNT OF MIXED MYALEPT SOLUTION TO INJECT (TUBERCULIN SYRINGE USERS)	AMOUNT OF MIXED MYALEPT SOLUTION TO INJECT (INSULIN SYRINGE USERS)
2.40 mg	0.48 mL	48 units
2.5 mg	0.50 mL	50 units
3.75 mg	0.75 mL	75 units
5.00 mg	1.00 mL	100 units
6.25 mg	1.25 mL	125 units
7.50 mg	1.5 mL	150 units
8.75 mg	1.75 mL	175 units
10.00 mg	2.00 mL	200 units

For this step, you will need:

A (1 mL or smaller) syringe (with shorter needle) used to inject MYALEPT

Examples:



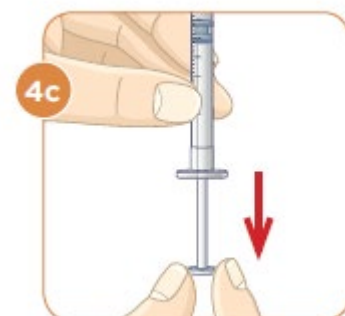
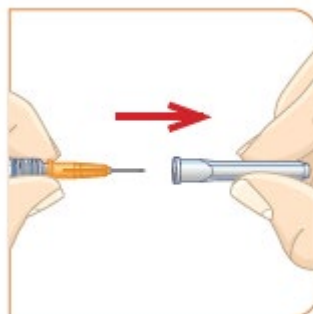
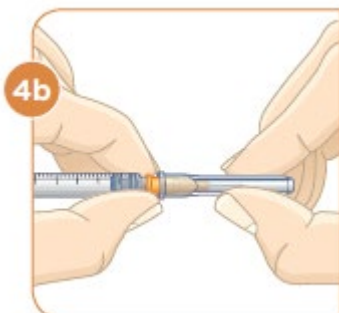
Vial of mixed MYALEPT (from Step 3)



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.



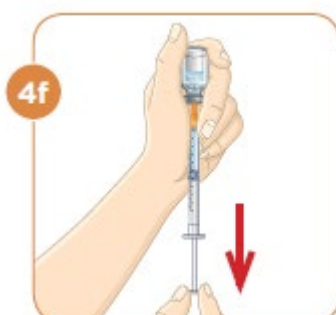
Hold the vial with the mixed MYALEPT. Insert the needle into the top of the MYALEPT vial.



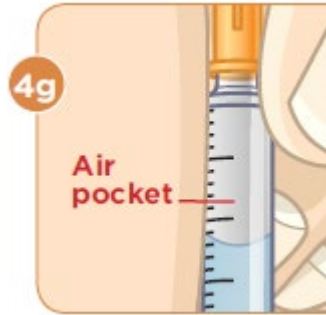
Push the plunger down all the way, to fill the vial with air.



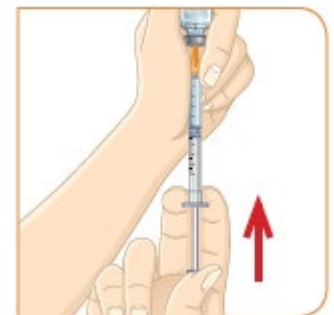
With the needle still in the vial, turn the vial and syringe upside down. Keep the whole needle in the liquid. It is okay if the plunger moves down.



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.



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 MYALEPT.

Tip: If your prescribed dose is more than 1 mL, you will need to use 2 separate injections to take your full daily dose. Repeat Step 4 to fill the second syringe.



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.

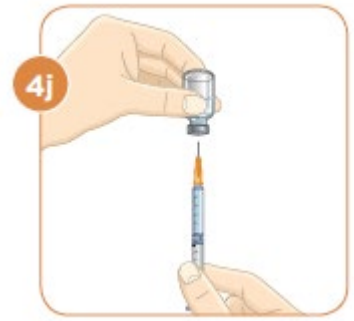
If there are a few small bubbles left, that is okay.



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 MYALEPT

For this step, you will need:

Syringe filled with your MYALEPT dose (from Step 4)

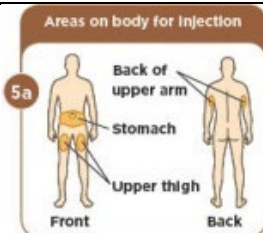


Alcohol wipe (from Step 1)



Sharps disposal container for used syringes and needles





Choose an injection site that you will use to inject your MYALEPT. 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 different injection site in that area. If you inject other medicines you should choose a different site from where you inject MYALEPT. **Do not** inject MYALEPT in the same site as your other medicines.



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.

Important:

Inject MYALEPT under the skin (subcutaneous). **Do not** inject MYALEPT 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 IFU.

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

Important:

Unused MYALEPT mixed with sterile water for injection (newborns or infants), **must be thrown away**.

Do not store it for reuse.

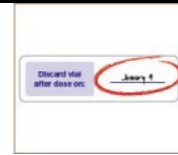
MYALEPT mixed with bacteriostatic water for injection can be stored for reuse.



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



Looking at a calendar, count 2 days after the day you mixed the MYALEPT. For example, if you mixed MYALEPT on Monday, January 2, you would throw it away **after your dose** on Wednesday, January 4.



Write that date on the stickers found to the right.



Place the sticker on the vial of mixed MYALEPT.

Important:

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

Discard vial after dose on: _____	Discard vial after dose on: _____
Discard vial after dose on: _____	Discard vial after dose on: _____
Discard vial after dose on: _____	Discard vial after dose on: _____
Discard vial after dose on: _____	Discard vial after dose on: _____
Discard vial after dose on: _____	Discard vial after dose on: _____
Discard vial after dose on: _____	Discard vial after dose on: _____
Discard vial after dose on: _____	Discard vial after dose on: _____
Discard vial after dose on: _____	Discard vial after dose on: _____
Discard vial after dose on: _____	Discard vial after dose on: _____

STEP 6: Disposing of used needles and syringes:

- Put your used needles and syringes in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) loose needles and syringes in your household trash.
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container

- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA’s website at: <http://www.fda.gov/safesharpsdisposal>.

Common questions

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Questions about preparing and mixing your dose of MYALEPT	pages 15-16
Questions about injecting MYALEPT	page 16
Questions about MYALEPT supplies	page 16

Common questions

Questions about storing and traveling with MYALEPT

1Q How do I store a vial of powder (MYALEPT) and mixed MYALEPT?

A The vial of powder has a white cap. The vial of mixed medicine is the vial to which you applied the sticker.



- These vials should be kept in their carton in the refrigerator until you are ready to use them
- Store these vials in their carton so they can be protected from light
- Do not freeze or heat these vials

2Q How long can I leave a vial of powder or mixed MYALEPT at room temperature?

A A vial of powder or MYALEPT mixed with bacteriostatic water for injection can be left at room temperature for up to 4 hours. MYALEPT mixed with sterile water for injection should be used right away. Throw away any unused mixed MYALEPT. If you are unsure about whether you can use a vial of powder or mixed MYALEPT, call 1-855-6MYALEPT.

3Q What do I do with a vial of powder or mixed MYALEPT if it has been frozen or heated?

A If a vial of powder or mixed MYALEPT has been frozen or heated, throw it away in the sharps disposal container.

4Q What do I do with a vial of mixed MYALEPT if there is not a full dose left?

A Ask your healthcare provider how to use or store a vial of mixed MYALEPT that contains less than a full dose.

5Q How do I take MYALEPT if I am away from home or traveling?

A To take a dose of MYALEPT if you are away from home or traveling, you must take all of your supplies with you. Do not fill a syringe or prepare a dose ahead of time and take it with you.

Questions about preparing and mixing your dose of MYALEPT

6Q What should I do if I touch the top of a vial after I have cleaned it?

A Clean the top of the vial again with a new alcohol wipe.

7Q What should I do if my dose is written in mg (milligrams), not mL (milliliters)?

A If your dose of MYALEPT is written in mg and not mL, call your pharmacist. Your pharmacist can give you your dose in mL. Do not try to prepare a dose of MYALEPT if your dose is in mg.

8Q What should I do if there are air bubbles or air pockets in the syringe?

A Follow steps 2g (page 5) and 2h (page 6) to remove air bubbles or an air pocket from the syringe when filling it with liquid. Follow steps 4g and 4h (page 11) to remove air bubbles or an air pocket from the syringe when filling it with MYALEPT.

Check to see if there are large air bubbles in the syringe. If so, tap the syringe to move the air bubbles to the top. If there are still a few small air bubbles left in the syringe after these steps, that is okay. The air bubbles will not harm you.



9Q What if the needle comes off the syringe used to mix MYALEPT when I am trying to remove the needle cover?

A With the needle cover still on the needle, twist the needle back onto the syringe. Firmly grip the syringe and pull the needle cover straight off. Do not twist the syringe or needle when pulling off the needle cover.

10Q What if the needle comes off the syringe used to inject MYALEPT when I am trying to remove the needle cover?

A With the needle cover still on the needle, firmly push the needle back onto the syringe. Grip the base of the needle as firmly as you can between your index finger and thumb while pulling on the needle cover.

11Q What do I do if I see foam in a vial of medicine I am mixing?

A If foam forms in the vial of medicine as you swirl it, let the vial sit on the work surface until the foam is gone.

12Q Can I fill a syringe with a dose of mixed MYALEPT and save it to use later?

A A dose of MYALEPT should be taken right after it is mixed. Do not fill a syringe or prepare a dose for later use.

Questions about injecting MYALEPT

13Q What are some tips for injecting MYALEPT?

A Try these tips to help you prepare for your injection with MYALEPT:

- **Know the steps in the process.** To get to know the steps, read this booklet ahead of time. It may help to read the steps out loud. If you have questions about how to inject, make sure to ask your healthcare provider
- **Find a place that is clean and well lit in which you can do the injection**
- **Ask for help.** You may feel more comfortable if a care partner does the injection for you
- **Put ice on the injection site.** You may want to use ice at the injection site, after your injection, to help lessen some of the pain you might feel
- **Make sure the vial with powder (MYALEPT) is at room temperature before you mix and inject it.** To do this, take a vial with powder out of the refrigerator and set it out for 10 to 15 minutes

Questions about MYALEPT supplies

14Q How do I obtain the supplies needed to inject MYALEPT?

A The standard supplies needed to inject MYALEPT include needles, syringes, liquid for mixing and a disposal container. Your healthcare provider will give you a prescription for these supplies which can be filled by a retail or hospital pharmacy, or the specialty pharmacy who distributes MYALEPT.

15Q How do I store the other supplies that are needed to prepare and inject a dose of MYALEPT?

A Store syringes, vials of liquid with colored caps, alcohol wipes, and sharps disposal container at room temperature or at the temperature that is written on the package they came in. Be sure to check the expiration date on the packages of your supplies before use. Do not use expired supplies.

To learn more about MYALEPT

- **Talk with your healthcare provider**
- **Read the Medication Guide that came with MYALEPT. The Medication Guide can help answer your questions about MYALEPT, such as what it is used for, possible side effects, and when to take it**
- **Visit www.MYALEPT.com or call 1-855-6MYALEPT for FREE ongoing support and services**

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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