

LEROCHOL[®] (lerodalcibep-liga) Injection 300 mg/1.2 mL

INSTRUCTIONS FOR USE



LEROCHOL[®] [leer-O-call]

(lerodalcibep-liga)

injection, for subcutaneous use only
 Single-use Prefilled Syringe

This Instructions for Use contains information on how to inject LEROCHOL.

Read and follow these instructions before you start using the LEROCHOL prefilled syringe and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

Do not use the LEROCHOL prefilled syringe until your healthcare provider has given you instructions on the right way to give an injection.

Parts of the Prefilled Syringe (see Figure A)

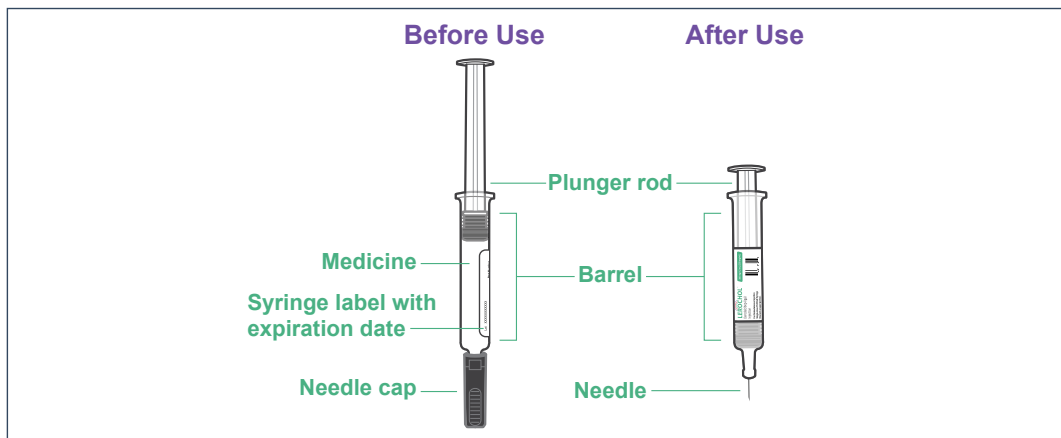


Figure A

Important Information You Need to Know Before Injecting LEROCHOL

- For subcutaneous injection only (inject under the skin).
- **Do not** use LEROCHOL if the seals on the sides of the carton have already been broken. If seals have already been broken, LEROCHOL may have been tampered with, get a new carton.
- **Do not** use LEROCHOL if the prefilled syringe is dropped or damaged. Get a new carton.
- **Do not** re-cap the prefilled syringe as you may stick yourself or damage the needle.
- **Do not** freeze.
- Safely throw away (dispose of) the used prefilled syringe after the injection is completed (see **Step 15. Dispose of used prefilled syringe**).

Preparing to Inject LEROCHOL

Step 1. Gather the supplies needed to give the injection.

- a. Choose a clean, flat surface in a well-lit area.
- b. Gather the following supplies and place them on the surface (see **Figure B**):
 - Carton containing prefilled syringe

Items not included in the carton:

- Alcohol wipe
- Cotton ball or gauze
- Adhesive bandage
- FDA-cleared Sharps disposal container

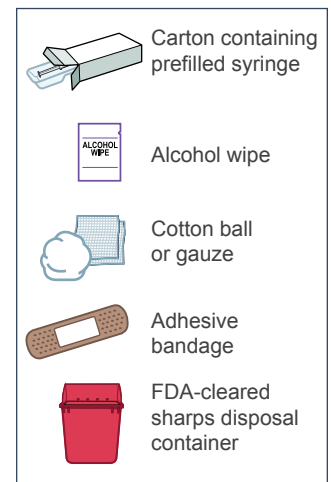


Figure B

Step 2. If refrigerated, let the prefilled syringe warm to room temperature for 30 minutes.

- a. Let the carton sit at room temperature for 30 minutes before use (see **Figure C**).
- b. Keep the prefilled syringe in the carton during warm-up to protect from light.
 - Letting the prefilled syringe warm to room temperature will make the injection more comfortable.
 - **Do not** use a heat source such as a microwave or warm the carton containing the prefilled syringe any other way.
 - **Do not** shake the carton.

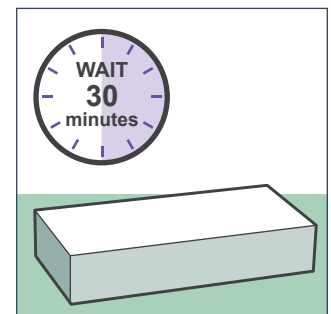


Figure C

Step 3.

Remove the plastic tray from the carton.

- a. Break the seal and open the side of the carton.
 - **Do not** use LEROCHOL if the seals on the sides of the carton have already been broken. If seals have already been broken, LEROCHOL may have been tampered with, get a new carton.
- b. Gently slide the plastic tray containing the prefilled syringe from the carton into the palm of your hand (**Figure D**).

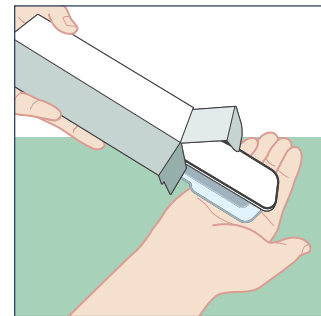


Figure D

Step 4.

Remove the prefilled syringe from the plastic tray.

- a. Place the plastic tray on your hand and peel off the paper seal with your other hand (see **Figure E**).
- b. Turn the plastic tray over and gently press the middle of the tray's back to release the prefilled syringe into the palm of your hand (see **Figures F, G and H**).
 - **Do not** pick up or pull the prefilled syringe by the plunger rod or gray needle cap. This could damage the syringe.
 - **Do not** remove the gray needle cap from the prefilled syringe until you are ready to inject.
 - Always hold the prefilled syringe by the syringe barrel.

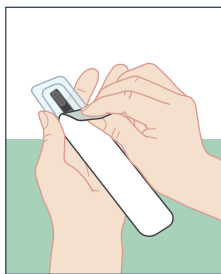


Figure E

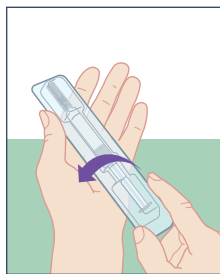


Figure F

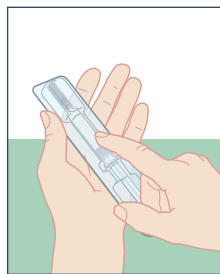


Figure G

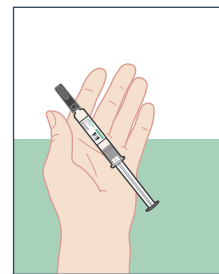


Figure H

Step 5.

Inspect the prefilled syringe.

- a. Make sure LEROCHOL appears on the prefilled syringe label.
- b. Check the expiration (EXP) date (see **Figure I**).
- c. Check the prefilled syringe for damage.
 - **Do not** use and get a new carton if LEROCHOL does not appear on the label, the expiration date has passed, or there are signs of damage.

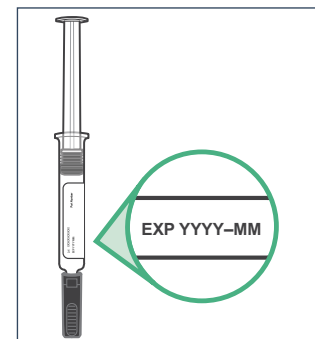


Figure I

Step 6.

Inspect the medicine.

- a. Check the medicine to make sure the liquid is clear to brownish-yellow or amber (see **Figure J**).
 - **Do not** use the prefilled syringe if the liquid is cloudy or contains visible particles. Get a new carton.

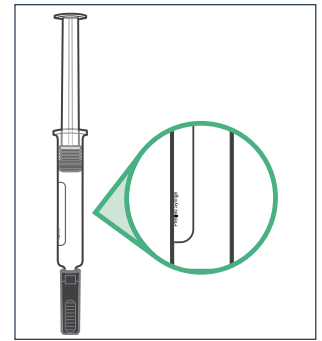


Figure J

Step 7.

Wash your hands.

- a. Wash your hands with soap and water and dry them thoroughly (see **Figure K**).



Figure K

Step 8.

Choose an injection site.

- a. Choose an injection site from the following areas (see **Figure L**):
 - Stomach area (abdomen) except for the 2-inch (5 cm) area right around your navel (belly button)
 - Front of upper legs (thighs)
 - Back of upper arms (injection by caregiver or healthcare provider only)
- **Do not** inject LEROCHOL together with other injectable drugs at the same site.
- **Do not** select an area of the skin that is tender, bruised, red, or hard. Avoid areas with scars or stretch marks.
- **Do not** inject through clothing.
- Choose a different site each time you give yourself an injection. If you need to use the same injection site, make sure it is not the same spot on the site you used last time.

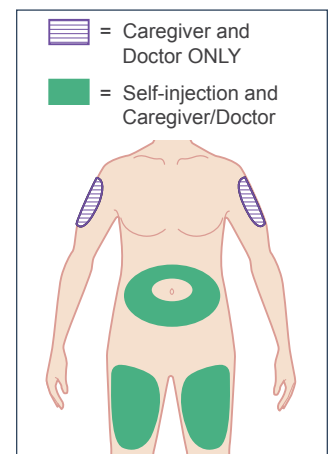


Figure L

Step 9.

Clean the injection site.

- a. Clean the skin of the injection site with an alcohol wipe (see **Figure M**).
 - **Do not** touch or blow on the injection site again before giving the injection. Let the skin dry before injecting.

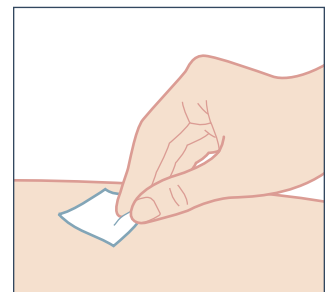


Figure M

Injecting LEROCHOL

Step 10.

Remove the needle cap.

- Hold the barrel of the prefilled syringe with the needle facing away from you.
- Firmly grip the needle cap and pull it straight off (see **Figure N**).
 - Do not** twist the needle cap.
 - Do not** touch the plunger rod as this may cause the prefilled syringe to release medicine prior to injection.
 - You may see a drop of liquid at the tip of the needle. This is normal.
 - Do not** remove any air bubbles in the prefilled syringe.
- Dispose of the needle cap right away in an FDA-cleared sharps disposal container (see **Figure N**).
 - Do not** re-cap the prefilled syringe as you may stick yourself or damage the needle.

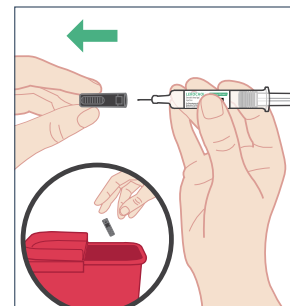


Figure N

Step 11.

Pinch the skin and insert the needle.

- Hold the barrel of the prefilled syringe in one hand between the thumb and index fingers.
- Gently pinch a fold of skin at the injection site with one hand.
- With a quick and dart-like motion, insert the needle completely into the pinched skin at a 45 to 90-degree angle (see **Figure O**).

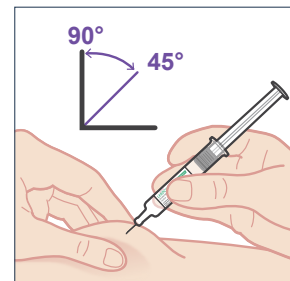


Figure O

Step 12.

Give the injection.

- Hold the pinch.
- Slowly push the plunger rod all the way down until the prefilled syringe is empty (see **Figure P**).

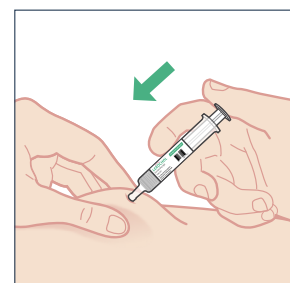


Figure P

Step 13.

Remove the prefilled syringe.

- When the prefilled syringe is empty, gently remove the needle from the injection site (see **Figure Q**).

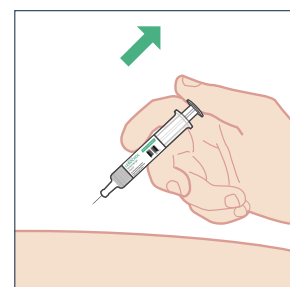


Figure Q

Step 14.

Care for the injection site.

- If any bleeding happens, gently press a cotton ball or gauze on the injection site and hold for several seconds (see **Figure R**). Apply an adhesive bandage if needed.

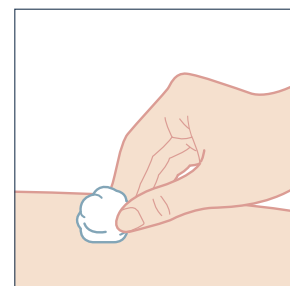


Figure R

Storing LEROCHOL

- Store LEROCHOL in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton until ready to use and to protect from light.
- If needed, LEROCHOL may be kept at room temperature between 68°F to 77°F (20°C to 25°C) in the original carton for up to 3 months after being removed from the refrigerator. Throw away LEROCHOL that has been stored at room temperature for more than 3 months.
- Do not freeze.
- Do not shake.

Keep LEROCHOL and all medicines out of reach of children.

Disposing of LEROCHOL

Step 15. Dispose of used syringe.

- a. Put the used syringe in an FDA-cleared sharps disposal container right away after injection (see **Figure S**).
 - **Do not** re-cap the syringe as you may stick yourself.
 - **Do not** reuse the syringe.
 - **Do not** throw away your syringe in your household trash.
 - **Do not** recycle your used FDA-cleared sharps disposal container.



Figure S

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.

Disposing of sharps disposal containers:

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your FDA-cleared sharps disposal container.

There may be state or local laws about how you should throw away used needles and syringes.

Additional information about your FDA-cleared sharps disposal container.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at:

<http://www.fda.gov/safesharpsdisposal>



A novel, third-generation, PCSK9 inhibitor

LEROCHOL® [lee-ro-cal] (lerodalcibep-liga)

injection, for subcutaneous use only
Single-use Prefilled Syringe

PATIENT INFORMATION

What is LEROCHOL?

LEROCHOL is an injectable prescription medicine used along with diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C), or bad cholesterol, in adults with high blood cholesterol levels called hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

It is not known if LEROCHOL is safe and effective in children.

What should I tell my healthcare provider before using LEROCHOL?

Before you start using LEROCHOL, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if LEROCHOL will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking LEROCHOL.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take LEROCHOL or breastfeed. You should not do both without talking to your healthcare provider first.

Tell your healthcare provider or pharmacist about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use LEROCHOL?

- **See the detailed Instructions for Use that comes with this Patient Information about the right way to prepare and give your LEROCHOL injections.**
- Use LEROCHOL exactly as your healthcare provider tells you to use it.
- LEROCHOL comes as a single-dose (1 time) prefilled syringe.
- If your healthcare provider decides that you or a caregiver can give the injections of LEROCHOL, you or your caregiver should receive training on the right way to prepare and give LEROCHOL. Do not try to inject LEROCHOL until you have been shown the right way by your healthcare provider or nurse.
- LEROCHOL is injected under the skin (subcutaneously) 1 time every month.
- LEROCHOL can be self-injected in the stomach area, at least 2 inches away from the belly button or upper front of the legs (thighs).
- LEROCHOL can be injected by a caregiver or healthcare provider in the back of the upper arm.
- **Do not** choose an area where the skin is tender, bruised, red, or hard.
- **Do not** inject LEROCHOL together with other injectable medicines at the same injection site.
- Always check the label of your syringe to make sure you have the correct medicine.
- If you forget to use LEROCHOL or are not able to take the dose on your regular schedule, inject your missed dose as soon as you remember if it has been less than 7 days of the missed dose and continue the original monthly dosage schedule.

PATIENT INFORMATION (continued)

- If it is 7 or more days from the missed dose, inject the dose and start a new monthly schedule using the date LEROCHOL was taken. If you are not sure when to re-start LEROCHOL, ask your healthcare provider or pharmacist.
- If you use more LEROCHOL than you should, talk to your healthcare provider or pharmacist.
- **Do not** stop using LEROCHOL without talking with your healthcare provider. If you stop using LEROCHOL, your cholesterol levels can increase.

What are the possible side effects of LEROCHOL?

The common side effects of LEROCHOL include:

- redness, itching, swelling, pain, bruising or tenderness at the injection site
- runny or stuffy nose, sore throat (nasopharyngitis)
- diarrhea
- nausea
- swelling in arms, hands, legs, or feet (peripheral edema)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. Ask your healthcare provider or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LEROCHOL?

Store LEROCHOL in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton until ready to use and protect from light.

If needed, LEROCHOL may be kept at room temperature between 68°F to 77°F (20°C to 25°C) in the original carton for up to 3 months after being removed from the refrigerator. Throw away LEROCHOL that has been stored at room temperature for more than 3 months.

Do not freeze.

Do not shake.

Keep LEROCHOL and all medicines out of reach of children.

General information about the safe and effective use of LEROCHOL.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

Do not use LEROCHOL for a condition for which it was not prescribed. **Do not** give LEROCHOL to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about LEROCHOL that is written for health professionals.

What are the ingredients in LEROCHOL?

- **Active ingredient:** lerodalcibep-liga
- **Inactive ingredients:** histidine, L-histidine monohydrochloride, polysorbate 80, sodium chloride, and Water for Injection, USP.

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For more information about LEROCHOL, go to www.LEROCHOL.com or call 1-877-2-LEROCHOL (1-877-253-7624).

This Patient Package Insert has been approved by the U.S. Food and Drug Administration. 12/2025

