



GETTING STARTED WITH Repatha® (EVOLOCUMAB) SINGLE-USE PRE-FILLED AUTOINJECTOR

- What is Repatha®
- What you need to know before you use Repatha®
- How to use Repatha®
- Possible side effects
- Step-by-step instructions

REPATHA® (evolocumab) is used:

- Along with diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL) or atherosclerotic heart or blood vessel problems, who need additional lowering of LDL cholesterol.
- Along with diet and other LDL lowering therapies in people with homozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL), who need additional lowering of LDL cholesterol.

This booklet is specifically written for patients prescribed REPATHA® and must be distributed by physicians. The information provided in this booklet is for your reference only. It cannot be used in place of a consultation with a medical professional nor as a basis of self-diagnosis or for treatment option. Only your physician can provide you with accurate diagnosis and appropriate treatment.

AMGEN®

LDL=low-density lipoprotein



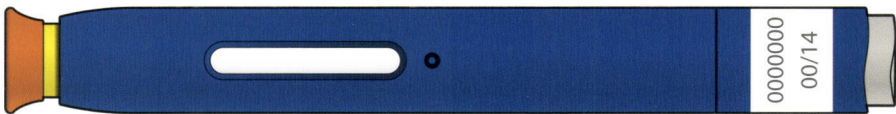
What is REPATHA®?

REPATHA® is an injectable prescription medicine called a PCSK9 inhibitor. REPATHA® is used:

- along with diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL) or atherosclerotic heart or blood vessel problems, who need additional lowering of LDL cholesterol.
- along with diet and other LDL lowering therapies in people with homozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL), who need additional lowering of LDL cholesterol.

The effect of REPATHA® on heart problems such as heart attacks, stroke, or death is not known.

It is not known if REPATHA® is safe and effective in children with homozygous familial hypercholesterolemia (HoFH) who are younger than 13 years of age or in children who do not have HoFH.



Who should not use REPATHA®?

Do not use REPATHA® if you are allergic to evolocumab or to any of the ingredients in REPATHA®.

What should I tell my healthcare provider before using REPATHA®?

Before you start using REPATHA®, tell your healthcare provider about all your medical conditions, including allergies, and if you:

- are allergic to rubber or latex. The needle covers within the needle caps on the single-use pre-filled autoinjectors contain dry natural rubber.
- are pregnant or plan to become pregnant. It is not known if REPATHA® will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking REPATHA®.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take REPATHA® or breastfeed. You should not do both without talking to your healthcare provider first.

Tell your healthcare provider or pharmacist about any prescription and over-the-counter medicines you are taking or plan to take, including natural or herbal remedies.

How should I use REPATHA®?

See the detailed “Instructions for Use” about the right way to prepare and administer REPATHA®.



Use REPATHA® exactly as your healthcare provider tells you to use it. REPATHA® is administered under the skin (subcutaneously), every 2 weeks or 1 time each month.



If your healthcare provider prescribes you the monthly dose, you may use 3 separate injections in a row, using a different single-use pre-filled autoinjector for each injection. Give all of these injections within 30 minutes.

If your healthcare provider decides that you or a caregiver can administer REPATHA®, you or your caregiver should receive training on the right way to prepare and administer REPATHA®. Do not try to administer REPATHA® until you have been shown the right way by your healthcare provider or nurse.

Do not administer REPATHA® together with other injectable medicines at the same injection site.

Always check the label of your single-use pre-filled autoinjector to make sure you have the correct medicine and the correct dose of REPATHA® before each administration.

If you forget to use REPATHA® or are not able to take the dose at the regular time, administer your missed dose as soon as you remember, as long as there are more than 7 days until the next scheduled dose. If there are 7 days or less until your next scheduled dose, administer the next dose according to the original schedule. This will put you back on your original schedule. If you are not sure when to take REPATHA® after a missed dose, ask your healthcare provider or pharmacist.

If you use more REPATHA® than you should, talk to your healthcare provider or pharmacist.

Do not stop using REPATHA® without talking with your healthcare provider. If you stop using REPATHA®, your cholesterol levels can increase.

POSSIBLE SIDE EFFECTS

REPATHA® can cause side effects including:

- Allergic reactions. REPATHA® may cause allergic reactions. Call your healthcare provider or go to the nearest hospital emergency room right away if you have any symptoms of an allergic reaction including a severe rash, redness, severe itching, a swollen face, or trouble breathing.

The most common side effects of REPATHA® include: runny nose, sore throat, symptoms of the common cold, flu or flu-like symptoms, back pain, and redness, pain, or bruising at the injection site.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of REPATHA®. Ask your healthcare provider or pharmacist for more information.

Call your healthcare provider for medical advice about side effects.

Contents of pack

Contents of the pack and other information

The active substance in REPATHA® is evolocumab. Each REPATHA® pre-filled autoinjector contains 140 mg of evolocumab in 1 ml of solution. The other ingredients are proline, glacial acetic acid, polysorbate 80, sodium hydroxide and water for injections.

REPATHA® is a solution which is clear to opalescent and colourless to yellowish, and practically free from particles. Do not use this medicine if you notice it is discoloured or contains large lumps, flakes or coloured particles.

Each pack contains one single-use REPATHA® pre-filled autoinjector.

INSTRUCTIONS FOR USE

GUIDE TO PARTS

Before use

Grey start
button

00/00
0000000

Window

Medicine

Orange
cap on

After use

00/00
0000000

Yellow
window
(injection
complete)

Yellow safety
guard

Orange
cap off



NEEDLE IS INSIDE

INSTRUCTIONS FOR USE

Important

Before you use a REPATHA® autoinjector, read this important information:

- It is important that you do not try to give yourself or someone else the injection unless you have received training from your healthcare provider.
- The orange cap on the REPATHA® autoinjector contains a needle cover (located inside the cap) that contains dry natural rubber, which is made from latex. Tell your healthcare provider if you are allergic to latex.

Storage of REPATHA®:

- Keep the REPATHA® autoinjector in the original carton to protect from light during storage.
- Keep the REPATHA® autoinjector in the refrigerator between 2°C to 8°C.
- If removed from the refrigerator, the REPATHA® autoinjector should be kept at room temperature up to 25°C in the original carton and must be used within 30 days.
- Do not freeze the REPATHA® autoinjector or use a REPATHA® autoinjector that has been frozen.

DO NOT:

- ✗ shake the REPATHA® autoinjector.
- ✗ remove the orange cap from the REPATHA® autoinjector until you are ready to inject.
- ✗ use the REPATHA® autoinjector if it has been dropped on a hard surface. Part of the REPATHA® autoinjector may be broken even if you cannot see the break. Use a new REPATHA® autoinjector.
- ✗ use the REPATHA® autoinjector after the expiration date.

- A healthcare provider who knows how to use the REPATHA® autoinjector should be able to answer your questions.
- Keep the REPATHA® autoinjector out of the sight and reach of children.

Step 1: Prepare

A Remove one REPATHA[®] autoinjector from the package.

Carefully lift the autoinjector straight up out of the box.

Wait at least 30 minutes for the autoinjector to reach room temperature before injecting.

This is important for administering the entire dose and helps minimize discomfort. REPATHA[®] may take longer to inject if it has not reached room temperature.

Do NOT heat the autoinjector. Let it warm up on its own.

DO NOT:

- ✗ try to warm the autoinjector by using a heat source such as hot water or microwave.
- ✗ leave the autoinjector in direct sunlight.
- ✗ shake the autoinjector.
- ✗ remove the orange cap from the autoinjector yet.

B Inspect the REPATHA[®] autoinjector.



Check the expiration date. **DO NOT** use the REPATHA[®] autoinjector past the expiration date printed on the label.

Make sure the medicine in the window is clear and colorless to slightly yellow.

 **DO NOT** use autoinjector if:

- ✗ the medicine is cloudy or discolored or contains particles.
- ✗ any part appears cracked or broken.
- ✗ the autoinjector has been dropped.
- ✗ the orange cap is missing or not securely attached.

In all cases, use a new pre-filled autoinjector.

INSTRUCTIONS FOR USE

Step 1: Prepare, continued

C Gather all materials needed for your injection.

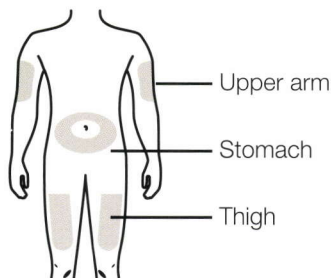
Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the:

- new autoinjector
- alcohol wipes
- cotton ball or gauze pad
- adhesive bandage
- sharps disposal container (see Step 4: Finish)




D Prepare and clean your injection site.



You can use:

- thigh
- stomach, except for a 2-inch area around your belly button
- outer area of upper arm (only if someone else is giving you the injection)

Clean the injection site with an alcohol wipe. Let your skin dry.

 **DO NOT** touch this area again before injecting.

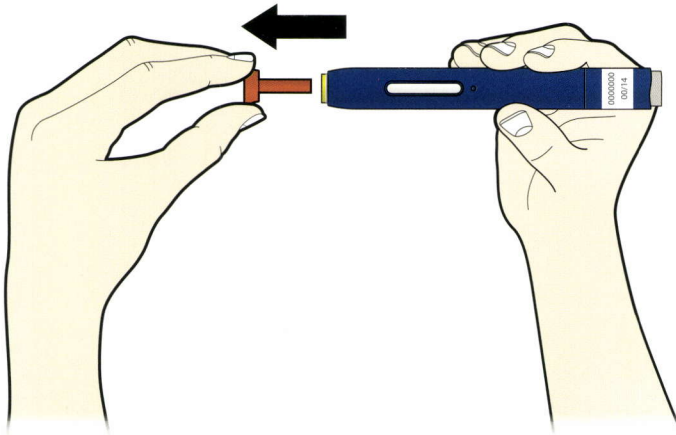
 Choose a different site each time you give yourself an injection. If you need to use the same injection site, just make sure it is not the same spot on that site you used last time.

DO NOT inject into areas where the skin is tender, bruised, red, or hard.

Step 2: Get ready

A

Pull the orange cap off only when you are ready to inject. DO NOT leave the orange cap off for more than 5 MINUTES. This can dry out the medicine.



It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

DO NOT:

- ✗ twist, bend or wiggle the orange cap.
- ✗ put the orange cap back onto the autoinjector.
- ✗ put fingers into the yellow safety guard.

! **DO NOT** remove the orange cap from the pre-filled autoinjector until you are ready to inject.

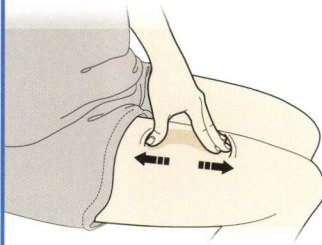
If you are unable to inject, please contact your healthcare provider.

INSTRUCTIONS FOR USE

Step 2: Get ready, continued

B

Stretch or pinch your injection site to create a firm surface.

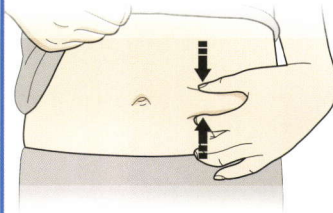


Thigh:

Stretch method

Stretch skin firmly by moving your thumb and fingers in opposite directions, creating an area about 2 inches wide.

OR



Stomach or upper arm:

Pinch method

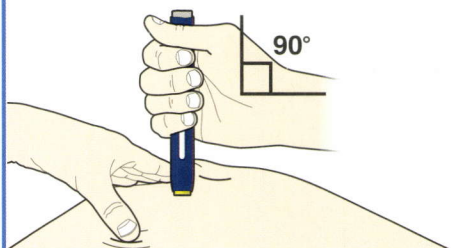
Pinch skin firmly between your thumb and fingers, creating an area about 2 inches wide.



IT IS IMPORTANT TO KEEP SKIN STRETCHED OR PINCHED WHILE INJECTING.

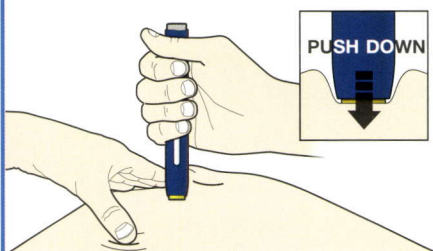
Step 3: Inject

A Hold the stretched or pinched skin. With the orange cap off, **PLACE** the yellow end of the autoinjector on the skin at 90 degrees.



! **DO NOT** touch the grey start button yet.

B Firmly **PUSH** down the autoinjector onto the skin until it stops moving

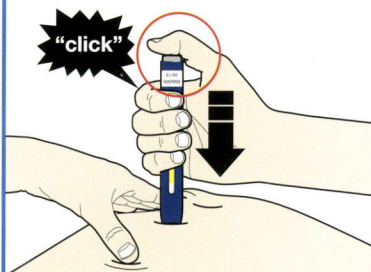


! You must push all the way down but **DO NOT** touch the grey start button until you are ready to inject.

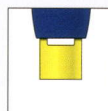
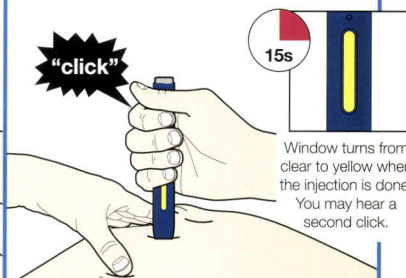
INSTRUCTIONS FOR USE

Step 3: Inject, continued

C When you are ready to inject, **PRESS** the grey start button. You will hear a click.



D Keep **PUSHING** the autoinjector down on your skin. Then **LIFT** your thumb while still holding the autoinjector on your skin. Your injection could take about 15 seconds.



NOTE: When you remove the autoinjector, if the window has not turned yellow, or if it looks like the medicine is still injecting, this means you have not received a full dose. Call your healthcare provider immediately.

Step 4: Finish

A

Throw away the used autoinjector and orange needle cap.



B

Check the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. Apply an adhesive bandage if needed.

 **Do not** rub the injection site.

Put the used autoinjector and orange needle cap in a sharps disposal container right away after use. Do not throw away (dispose of) the autoinjector or orange cap in your household trash.


If you do not have a sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- stomach, except for a 2-inch area around your belly button
- 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.

DO NOT:

- ✗ dispose of your used sharps disposal container in your household trash unless
- ✗ your community guidelines permit this.
- ✗ recycle your used sharps disposal container.
- ✗ reuse the autoinjector.
- ✗ recap the autoinjector or put fingers into the yellow safety guard.

 **Important: Always keep the sharps disposal container out of reach of children.**

FREQUENTLY ASKED QUESTIONS

What will happen if I press the grey start button before I am ready to do the injection on my skin?

You can lift your finger up off the grey start button and place the pre-filled autoinjector back on your injection site. Then, you can push the grey start button again.

Can I move the autoinjector around on my skin while I am choosing an injection site?

It is okay to move the autoinjector around on the injection site as long as you do not press the grey start button. However, if you press the grey start button and the yellow safety guard is pushed into the autoinjector, the injection will begin.

Can I release the grey start button after I start my injection?

You can release the grey start button, but continue to hold the autoinjector firmly against your skin during the injection.

Will the grey start button pop up after I release my thumb?

The grey start button may not pop up after you release your thumb if you held your thumb down during the injection. This is okay.

What do I do if I did not hear a second click?

If you did not hear a second click, you can confirm a complete injection by checking that the window has turned yellow.

Whom do I contact if I need help with the autoinjector or my injection?

A healthcare provider familiar with REPATHA® should be able to answer your questions.

NOTES

Page No. _____

Date: ____/____/____

NOTES



You can find complete information and a step-by-step guide for using the Repatha® pre-filled autoinjector in the instructions that come with your box.



References:

1. Repatha® Hong Kong prescribing information.
2. Repatha® Hong Kong instructions for use.
3. Data on file.
4. Repatha® patient information.

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