

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrRepatha®

evolocumab injection

Single-use Prefilled SureClick® Autoinjector

Read this carefully before you or your child start taking **REPATHA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **REPATHA**. Keep this leaflet, as you may need to read it again.

#### What is REPATHA used for?

REPATHA is used:

- along with diet and in combination with usual therapy, including cholesterol-lowering medications called statins, to reduce the risk of heart attack, stroke, and certain heart procedures (to restore blood flow to the heart) in adult patients who have cardiovascular disease by further lowering low-density lipoprotein (LDL) cholesterol.
- along with diet, alone or together with other cholesterol-lowering therapies, in adults with primary hyperlipidemia (high LDL cholesterol level in your blood) to reduce LDL cholesterol.
- along with diet and other cholesterol-lowering therapies, to reduce LDL cholesterol in people 10 years and older who need additional lowering of the high LDL cholesterol in their blood because of a condition that runs in their family (heterozygous familial hypercholesterolemia [HeFH]).
- along with diet and other cholesterol-lowering therapies, to reduce LDL cholesterol in people 10 years and older who need additional lowering of the high LDL cholesterol in their blood because of a condition that runs in their family (homozygous familial hypercholesterolemia [HoFH]).

#### How does REPATHA work?

REPATHA is a medicine used to lower levels of cholesterol. REPATHA lowers levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, REPATHA raises levels of “good” cholesterol (HDL cholesterol).

Evolocumab, the active ingredient of REPATHA, works by helping the liver’s ability to remove bad cholesterol from the blood. Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol. LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke and can cause other health problems. HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease. Triglycerides are another form of fat in your blood that may increase your risk of heart disease.

## What are the ingredients in REPATHA?

Medicinal ingredients: evolocumab

Non-medicinal ingredients: glacial acetic acid, polysorbate 80, proline, sodium hydroxide and water for injection. The autoinjector is not made with natural rubber latex.

## REPATHA comes in the following dosage forms:

REPATHA is available in the presentations listed below. Your doctor will prescribe the type that is best for you or your child.

- 1 mL single-use prefilled autoinjector (SureClick®). Each 1 mL prefilled autoinjector contains 140 mg of evolocumab (140 mg/mL).
- 3.5 mL prefilled cartridge with an automated mini-doser (AMD). Each 3.5 mL prefilled cartridge contains 420 mg of evolocumab (120 mg/mL).
- 1 mL single-use prefilled syringe\*. Each 1 mL prefilled syringe\* contains 140 mg of evolocumab (140 mg/mL).

## Do not use REPATHA if:

- You or your child have ever had an allergic reaction to REPATHA or any of the ingredients in REPATHA.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you or your child take REPATHA. Talk about any health conditions or problems you or your child may have, including if you or your child:**

- Use REPATHA together with a statin and other cholesterol lowering medicines, please read the package leaflet of that particular medicine.

## Other warnings you should know about:

### Children and adolescents

The use of REPATHA has been studied in children 10 years of age and older being treated for heterozygous or homozygous familial hypercholesterolemia.

The use of REPATHA has not been studied in children under 10 years of age or in children with other types of hypercholesterolemia.

### Pregnancy and Breastfeeding

REPATHA has not been tested in pregnant women. It is not known if REPATHA will harm your unborn baby.

If you are trying to get pregnant or think you may be pregnant when taking REPATHA:

- Inform your doctor
- If you are also taking a statin along with REPATHA, stop taking REPATHA and read the package leaflet of the statin that you are taking with REPATHA

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\* Prefilled syringes are not available in Canada

Women who become pregnant during REPATHA treatment, or their healthcare provider, are encouraged to call Amgen at 1-866-502-6436 to report the pregnancy.

It is not known whether REPATHA is found in breast milk. It is important to tell your doctor if you are breastfeeding or plan to do so. Your doctor will then help you decide whether to stop breastfeeding, or whether to stop taking REPATHA, considering the benefit of breastfeeding to the baby and the benefit of REPATHA to the mother.

**Tell your healthcare professional about all the medicines you or your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with REPATHA:**

No important drug interactions have been identified for REPATHA. No drug-drug interaction studies have been carried out for REPATHA.

**How to take REPATHA:**

REPATHA is given as an injection under the skin (subcutaneous or SC). REPATHA is available in the presentations listed below. Your doctor will prescribe the type that is best for you or your child.

- Single-use prefilled autoinjector (SureClick®)
- Single-use automated mini-doser
- Single-use prefilled syringe\*

If your doctor decides that you or your child or a caregiver (e.g. parent) can give the injections of REPATHA, you or your child or your caregiver should receive training on the right way to prepare and inject REPATHA. Do not try to inject REPATHA until you or your child have been shown the right way by your healthcare provider.

- When using the prefilled autoinjector (SureClick®), place the correct (yellow) end of the autoinjector on the skin before injecting (Please see the detailed Instructions for Use below).

Always take REPATHA exactly as your doctor has told you or your child. Check with your doctor if you are not sure.

- Before starting REPATHA, you or your child should be on a diet to lower cholesterol.
- You or your child should stay on this cholesterol lowering diet while taking REPATHA.

If your doctor has prescribed REPATHA along with a statin or other cholesterol lowering medicine for you or your child, follow your doctor's instructions on how to take these medicines together. In this case, please read the dosage instructions in the package leaflet of the other medicines.

Ask your doctor if you or your child have any further questions on how to use REPATHA.

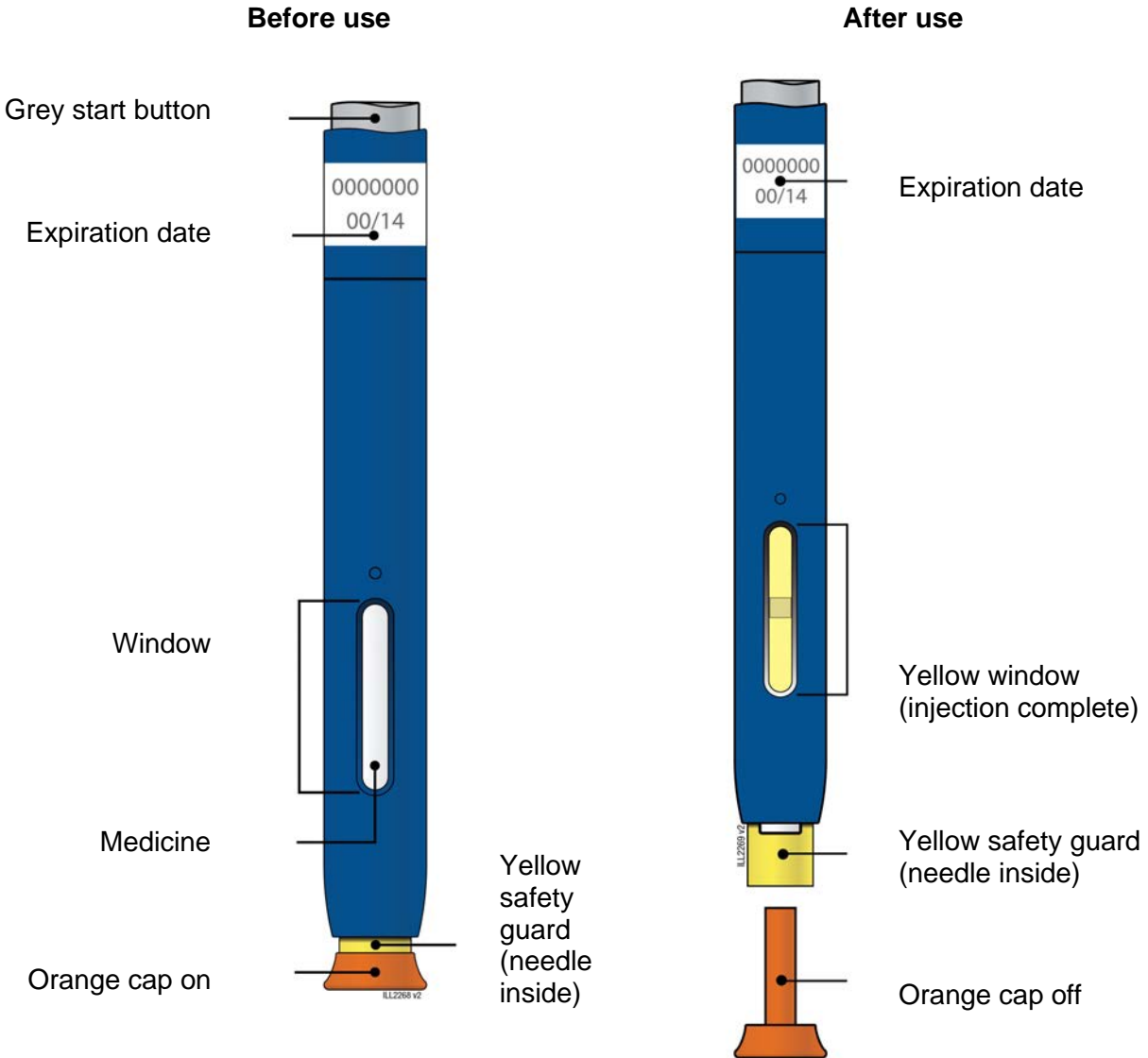
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## REPATHA Single-Use Prefilled SureClick® Autoinjector

The following instructions are for preparing and giving an injection of REPATHA using a single-use prefilled SureClick® autoinjector.

### Guide to Parts



**Important: Needle is inside the yellow safety guard**

## Important

### Important Information You Need to Know Before Injecting Repatha:

- It is important that you **do not** try to give the injection until you have fully read and understood these instructions for use.
- 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 REPATHA SureClick® autoinjector is not made with natural rubber latex.

### Storing your REPATHA SureClick® autoinjector:

- Keep the autoinjector and all medicines out of the reach of children.
- Keep the autoinjector in the original carton to protect from light.
- Keep the autoinjector in the refrigerator at 2°C to 8°C.
- After removing from the refrigerator, the autoinjector should be kept at controlled room temperature (up to 25°C) in the original carton and must be used within 30 days.
- Throw away REPATHA that has been stored at room temperature for more than 30 days.
- **Do not** store the autoinjector in extreme heat or cold. For example, avoid storing the autoinjector in your vehicle's glove box or trunk.
- **Do not** freeze or use the autoinjector if it has been frozen.

### Using your REPATHA SureClick® autoinjector:

- **Do not** use the autoinjector after the expiration date on the label.
- **Do not** shake the autoinjector.
- **Do not** remove the orange cap from the autoinjector until you are ready to inject. Leaving the cap off for more than 5 minutes can dry out the medicine.
- **Do not** use the autoinjector if it has been dropped on a hard surface. Part of the autoinjector may be broken even if you cannot see the break. Use a new autoinjector.

For more information or help, contact your healthcare provider, the RepathaREADY® Support Program at 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

### Step 1: Preparing to inject REPATHA

- A.** Remove the autoinjector from the carton.

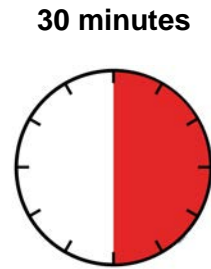
Carefully lift the autoinjector straight up out of the carton.

Before you inject, always check the label of the autoinjector to make sure you have the correct medicine and the correct dose of REPATHA.

Put the original carton with any unused autoinjectors back in the refrigerator.

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

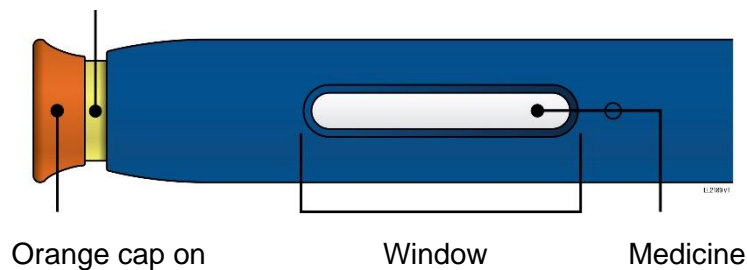
This is important for administering the entire dose and helps minimize discomfort. REPATHA may take longer to inject if it has not reached room temperature. **Do not** heat the autoinjector. Let it come to room temperature naturally.



- **Do not** try to warm the autoinjector by using a heat source such as hot water or microwave.
- **Do not** leave the autoinjector in direct sunlight.
- **Do not** shake the autoinjector.
- **Do not** remove the orange cap from the autoinjector yet.

**B.** Inspect the REPATHA SureClick® autoinjector.

Yellow safety guard (needle inside)



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

- **Do not** use the autoinjector if the medicine is cloudy or discoloured or contains large lumps, flakes, or particles.
- **Do not** use the autoinjector if any part appears cracked or broken.
- **Do not** use the autoinjector if the autoinjector has been dropped.
- **Do not** use the autoinjector if the orange cap is missing or not securely attached.
- **Do not** use the autoinjector if the expiration date printed on the label has passed.

In all cases, use a new autoinjector, and contact the RepathaREADY® Support Program at 1-888-Repatha (1-888-737-2842).

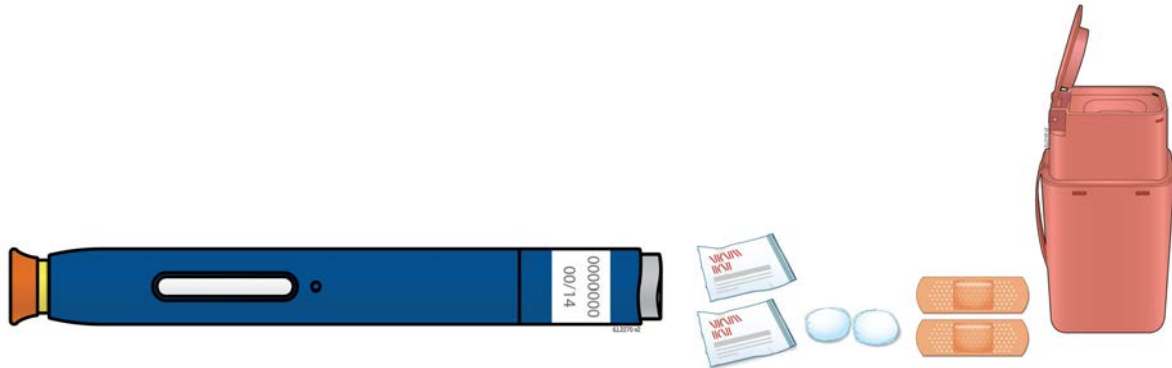
**C.** Gather all materials needed for your injection.

Wash your hands thoroughly with soap and water.

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

- New autoinjector
- Alcohol wipes
- Cotton balls or gauze pads

- Adhesive bandages
- Sharps disposal container (see **Step 4: Finish**)



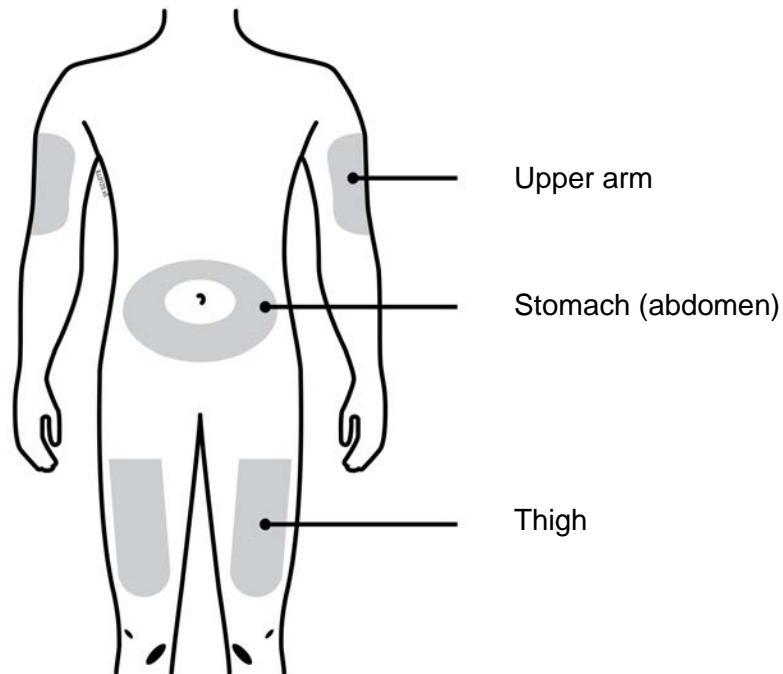
**D.** Prepare and clean your injection site.

**Only use these injection sites:**

- Thigh
- Stomach (abdomen), except for a **5** centimetre (2 inch) area around your navel (belly button)
- Outer area of upper arm (only if someone else is giving you the injection)

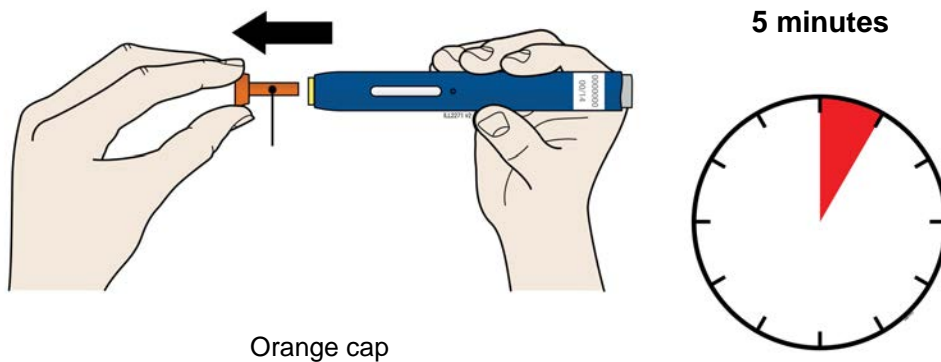
Clean the injection site with an alcohol wipe. Let your skin dry.

- **Do not** touch this area again before injecting.
- Choose a different site each time you give yourself an injection. If you want to use the same injection site, make sure it is not the same spot you used for the last injection.
- **Do not** inject into areas where skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.
- Avoid injecting directly into raised, thick, red, or scaly skin patch or lesion.



## Step 2: Get ready

- E. Pull the orange cap straight 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 and may clog the needle when you take the injection.



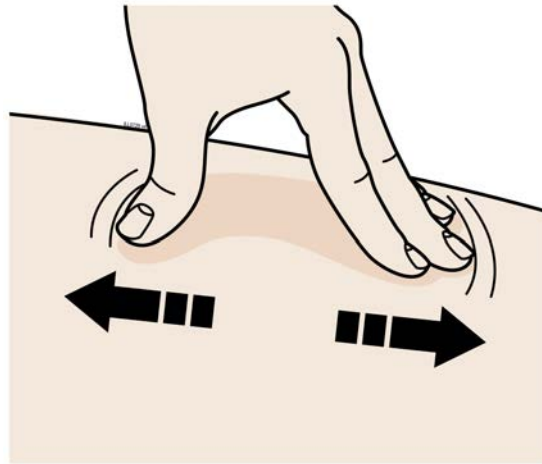
It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

- **Do not** twist, bend, or wiggle the orange cap.
- **Do not** put the orange cap back onto the autoinjector.
- **Do not** put fingers into the yellow safety guard.
- **Do not** remove the orange cap from the autoinjector until you are ready to inject.

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

- F. Create a firm surface at the selected injection site (thigh, stomach, or outer areas of the upper arm), by using **either** the Stretch method **or** the Pinch method.

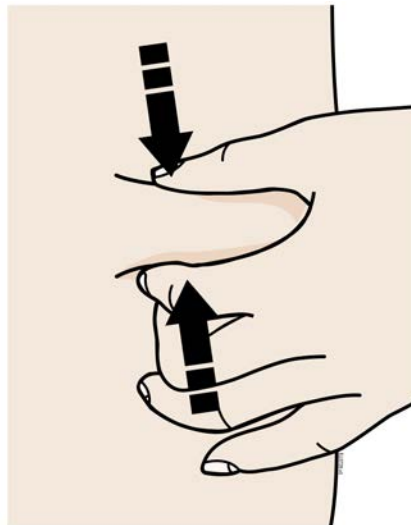
**Stretch Method:**



Stretch the skin firmly by moving your thumb and fingers in opposite directions, creating an area about **5** centimetres (**2** inches) wide.

**OR**

**Pinch Method:**

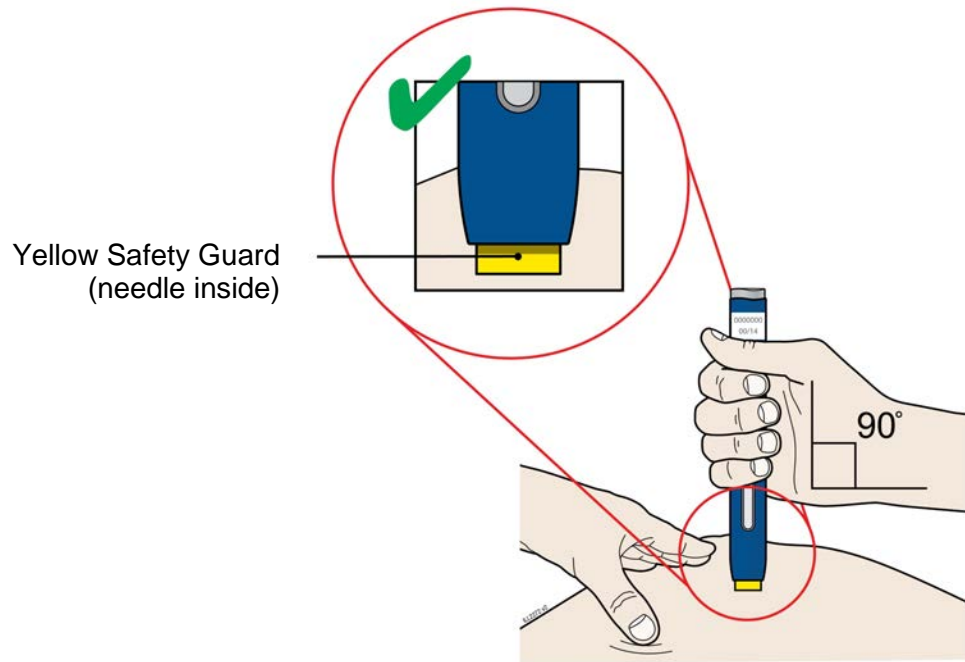


Pinch the skin firmly between your thumb and fingers, creating an area about **5** centimetres (**2** inches) wide.

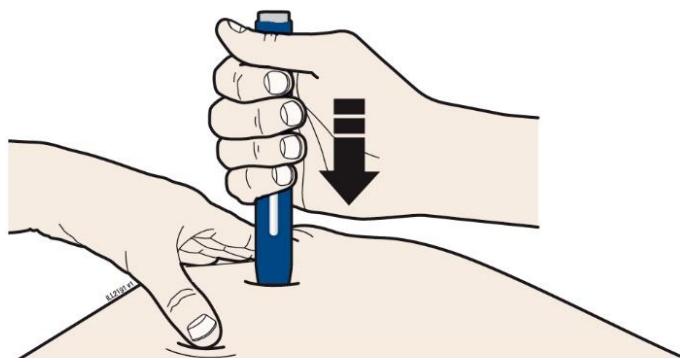
**Important:** Keep skin stretched or pinched while injecting.

### Step 3: Inject

- G.** Keep holding the stretched or pinched skin. With the orange cap off, **put** the yellow safety guard on your skin at 90 degrees. The **needle is inside** the yellow safety guard. Do not touch the grey start button yet.

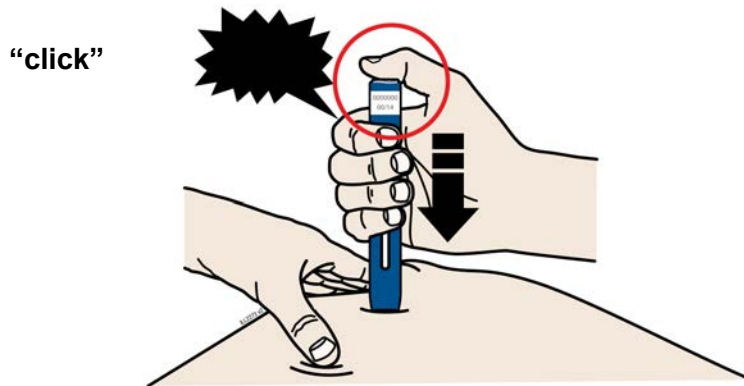


- H.** Firmly **push** down autoinjector onto the skin until it stops moving.

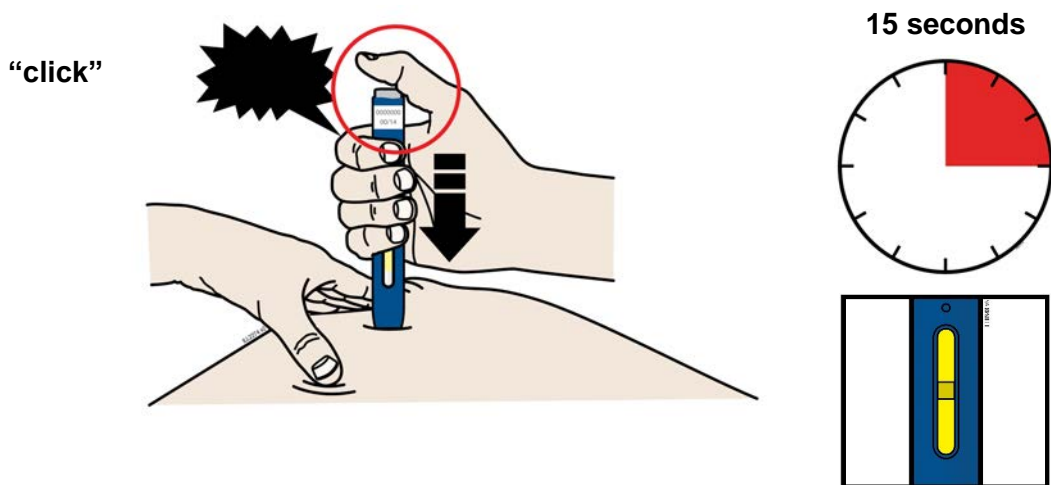


**Important:** You must push all the way down but **do not** touch the grey start button until you are ready to inject.

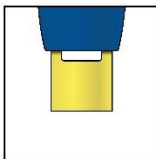
- I. When you are ready to inject, **press** the grey start button. You will hear a click.



- J. Keep **pushing** the autoinjector down on the skin. Then **lift** your thumb while still holding the autoinjector on your skin. The injection may take up to **15** seconds to complete.



Window turns from clear to yellow when the injection is done. You may hear a second click.



**NOTE:** After you remove the autoinjector from your skin, the needle will be automatically covered.

**Important:** 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.

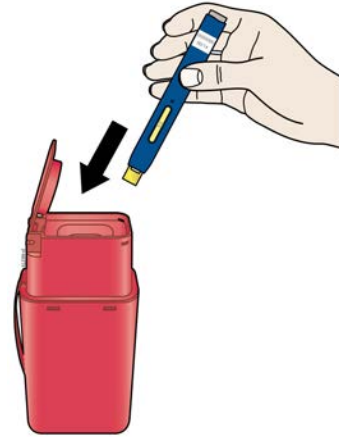
#### Step 4: Finish

**K.** Throw away the used autoinjector and orange needle cap.

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,
- 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 local laws about how you should throw away used needles and syringes.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

- **Do not** reuse the autoinjector
- **Do not** recap the autoinjector or put fingers into the yellow safety guard

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

**L.** Check the injection site.

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

**Do not** rub the injection site.

## Commonly Asked Questions:

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

The injection will only happen when the grey start button is pressed and the autoinjector is pushed into the injection site. Release the grey start button and push the autoinjector down until the yellow safety guard stops moving. 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. For more information, contact the RepathaREADY® Support Program at 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

## Usual dose:

*Prevention of Cardiovascular Events and Primary Hyperlipidemia in Adult Patients (including HeFH and atherosclerotic cardiovascular disease) and HeFH in Pediatric Patients (aged 10 years and older)*

The usual dose for REPATHA is 140 mg every 2 weeks or 420 mg once monthly. If you or your child and your doctor have decided that you should switch from one dosing regimen to the other, take the first dose of the new regimen on the day you were scheduled to take the previous one.

*Homozygous Familial Hypercholesterolemia*

Adult and Pediatric Patients (aged 10 years and older): The usual dose for REPATHA is 420 mg, either once monthly or every 2 weeks. If you or your child are on apheresis you may initiate treatment with 420 mg every 2 weeks to correspond with your apheresis schedule.

**Overdose:**

If you think you, or a person you are caring for, have taken too much REPATHA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you or your child forget to take your every 2 week or once monthly dose of 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 your 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 or your child are not sure when to take REPATHA after a missed dose, ask your healthcare provider or pharmacist.

**What are possible side effects from using REPATHA?**

Like all medicines, REPATHA can cause side effects, although not everybody gets them. REPATHA may cause allergic reactions. Call your healthcare provider or go to the nearest hospital emergency room right away if you or your child have any symptoms of an allergic reaction including a severe rash, redness, severe itching, a swollen face or trouble breathing.

The following are not all the possible side effects you or your child may have when taking REPATHA. If you or your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

- Flu or flu-like symptoms (high temperature, sore throat, runny nose, cough and chills)
- Common cold, such as runny nose, sore throat or sinus infections (nasopharyngitis or upper respiratory tract infections)
- Nausea
- Back pain
- Joint pain (arthralgia)
- Muscle pain (myalgia), with or without associated muscle weakness
- Injection site reactions (redness, bruising, pain, swelling, or bleeding)
- Allergic reactions including rash, hives, red itchy bumps on your skin (urticaria), and in rare cases, swelling of face, mouth, tongue or throat (angioedema)

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store in a refrigerator at 2°C to 8°C in the original carton. When removed from the refrigerator, REPATHA should be kept at controlled room temperature (up to 25°C) in the original carton and must be used within 30 days. Protect REPATHA from direct light and do not expose to temperatures above 25°C. Do not freeze. Do not shake.

Keep REPATHA and all medicines out of the reach and sight of children.

Do not throw away any medicines via wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use.

### **If you want more information about REPATHA:**

- 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>; the RepathaREADY® Support Program at 1-888-Repatha (1-888-737-2842) or by visiting [www.repatha.ca](http://www.repatha.ca).

This leaflet was prepared by Amgen Canada Inc.

Last Revised: May 16, 2025

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrRepatha®

evolocumab injection

#### Single-use Prefilled Cartridge with Automated Mini-Doser (AMD)

Read this carefully before you or your child start taking **REPATHA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **REPATHA**. Keep this leaflet, as you may need to read it again.

#### What is REPATHA used for?

REPATHA is used:

- along with diet and in combination with usual therapy, including cholesterol-lowering medications called statins, to reduce the risk of heart attack, stroke, and certain heart procedures (to restore blood flow to the heart) in adult patients who have cardiovascular disease by further lowering low-density lipoprotein (LDL) cholesterol.
- along with diet, alone or together with other cholesterol-lowering therapies, in adults with primary hyperlipidemia (high LDL cholesterol level in your blood) to reduce LDL cholesterol.
- along with diet and other cholesterol-lowering therapies, to reduce LDL cholesterol in people 10 years and older who need additional lowering of the high LDL cholesterol in their blood because of a condition that runs in their family (heterozygous familial hypercholesterolemia [HeFH]).
- along with diet and other cholesterol-lowering therapies, to reduce LDL cholesterol in people 10 years and older who need additional lowering of the high LDL cholesterol in their blood because of a condition that runs in their family (homozygous familial hypercholesterolemia [HoFH]).

#### How does REPATHA work?

REPATHA is a medicine used to lower levels of cholesterol. REPATHA lowers levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, REPATHA raises levels of “good” cholesterol (HDL cholesterol).

Evolocumab, the active ingredient of REPATHA, works by helping the liver’s ability to remove bad cholesterol from the blood. Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol. LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke and can cause other health problems. HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease. Triglycerides are another form of fat in your blood that may increase your risk of heart disease.

## What are the ingredients in REPATHA?

Medicinal ingredients: evolocumab

Non-medicinal ingredients: glacial acetic acid, polysorbate 80, proline, sodium hydroxide and water for injection. The automated mini-doser is not made with natural rubber latex.

## REPATHA comes in the following dosage forms:

REPATHA is available in the presentations listed below. Your doctor will prescribe the type that is best for you or your child.

- 1 mL single-use prefilled autoinjector (SureClick®). Each 1 mL prefilled autoinjector contains 140 mg of evolocumab (140 mg/mL).
- 3.5 mL prefilled cartridge with an automated mini-doser (AMD). Each 3.5 mL prefilled cartridge contains 420 mg of evolocumab (120 mg/mL).
- 1 mL single-use prefilled syringe\*. Each 1 mL prefilled syringe\* contains 140 mg of evolocumab (140 mg/mL).

## Do not use REPATHA if:

- You or your child have ever had an allergic reaction to REPATHA or any of the ingredients in REPATHA.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you or your child take REPATHA. Talk about any health conditions or problems you or your child may have, including if you or your child:**

- Use REPATHA together with a statin and other cholesterol lowering medicines, please read the package leaflet of that particular medicine.

## Other warnings you should know about:

### Children and adolescents

The use of REPATHA has been studied in children 10 years of age and older being treated for heterozygous or homozygous familial hypercholesterolemia.

The use of REPATHA has not been studied in children under 10 years of age or in children with other types of hypercholesterolemia.

### Pregnancy and Breastfeeding

REPATHA has not been tested in pregnant women. It is not known if REPATHA will harm your unborn baby.

If you are trying to get pregnant or think you may be pregnant when taking REPATHA:

- Inform your doctor
- If you are also taking a statin along with REPATHA, stop taking REPATHA and read the package leaflet of the statin that you are taking with REPATHA

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Women who become pregnant during REPATHA treatment, or their healthcare provider, are encouraged to call Amgen at 1-866-502-6436 to report the pregnancy.

It is not known whether REPATHA is found in breast milk. It is important to tell your doctor if you are breastfeeding or plan to do so. Your doctor will then help you decide whether to stop breastfeeding, or whether to stop taking REPATHA, considering the benefit of breastfeeding to the baby and the benefit of REPATHA to the mother.

**Tell your healthcare professional about all the medicines you or your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with REPATHA:**

No important drug interactions have been identified for REPATHA. No drug-drug interaction studies have been carried out for REPATHA.

**How to take REPATHA:**

REPATHA is given as an injection under the skin (subcutaneous or SC). REPATHA is available in the presentations listed below. Your doctor will prescribe the type that is best for you or your child.

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- Single-use automated mini-doser
- Single-use prefilled syringe\*

If your doctor decides that you or your child or a caregiver (e.g. parent) can give the injections of REPATHA, you or your child or your caregiver should receive training on the right way to prepare and inject REPATHA. Do not try to inject REPATHA until you or your child have been shown the right way by your healthcare provider.

Always take REPATHA exactly as your doctor has told you or your child. Check with your doctor if you are not sure.

- Before starting REPATHA, you or your child should be on a diet to lower cholesterol.
- You or your child should stay on this cholesterol lowering diet while taking REPATHA.

If your doctor has prescribed REPATHA along with a statin or other cholesterol lowering medicine for you or your child, follow your doctor's instructions on how to take these medicines together. In this case, please read the dosage instructions in the package leaflet of the other medicines.

Ask your doctor if you or your child have any further questions on how to use REPATHA.

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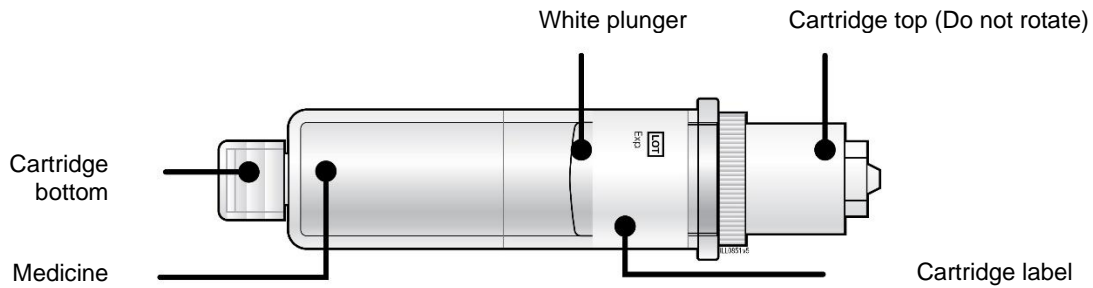
\* Prefilled syringes are not available in Canada

## REPATHA Automated Mini-Doser and Prefilled Cartridge

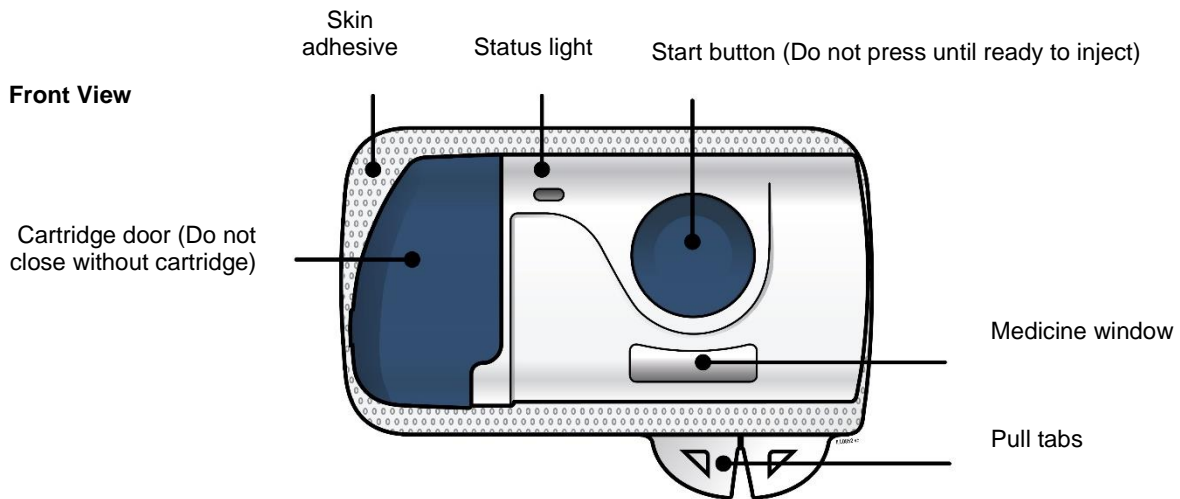
The following instructions are for preparing and giving an injection of REPATHA using an automated mini-doser and single-use prefilled cartridge.

### Guide to Parts

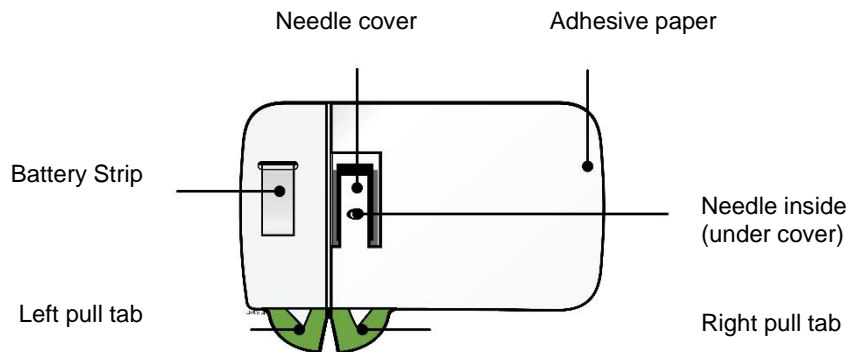
#### Prefilled Cartridge



#### Automated Mini-Doser



#### Back View



**Important:** Needle is inside.

**Important:** Before you use the automated mini-doser and prefilled cartridge for use with REPATHA, read this important information:

### **Storing your automated mini-doser and prefilled cartridge**

- Keep the automated mini-doser and prefilled cartridge out of the reach of children.
- Keep the automated mini-doser and prefilled cartridge in the original carton to protect from light or physical damage.
- The automated mini-doser and prefilled cartridge must be kept in the refrigerator at 2°C to 8°C.
- If removed from the refrigerator, the automated mini-doser and prefilled cartridge should be kept at room temperature at 20°C to 25°C in the original carton and must be used within 30 days.
- **Do not** store the automated mini-doser and prefilled cartridge in extreme heat (e.g., Above 25°C) or cold (e.g., avoid storing in your vehicle's glove box or trunk). **Do not** freeze.

### **Using your automated mini-doser and prefilled cartridge**

- It is important that you do not try to give yourself the injection unless you have received training from your healthcare provider.
- The automated mini-doser and prefilled cartridge are not made with natural rubber latex.
- Adult supervision is recommended for children aged 13 years and younger while using the automated mini-doser and prefilled cartridge.
- **Do not** use the automated mini-doser and prefilled cartridge after the expiration date on the carton.
- **Do not** shake the automated mini-doser or prefilled cartridge.
- **Do not** remove the automated mini-doser and prefilled cartridge from the carton or clear tray until you are ready to inject.
- **Do not** touch the start button until you place the loaded automated mini-doser and prefilled cartridge onto your skin and are ready to inject.
- You can only press the start button once. If an error occurs, the automated mini-doser cannot be used.
- **Do not** use the automated mini-doser and prefilled cartridge if either have been dropped onto a hard surface. Part of the automated mini-doser and prefilled cartridge may be broken even if you cannot see the break. Use a new automated mini-doser and prefilled cartridge.
- **Do not** reuse the automated mini-doser and prefilled cartridge. The automated mini-doser and prefilled cartridge are for single-use only.

- **Do not** let the automated mini-doser get wet from water or any other liquids. It contains electronics that should not get wet.
- The single-use automated mini-doser for subcutaneous injection is intended only for use with the prefilled cartridge.
- Moderate physical activities can be performed during the injection process, such as walking, reaching and bending.

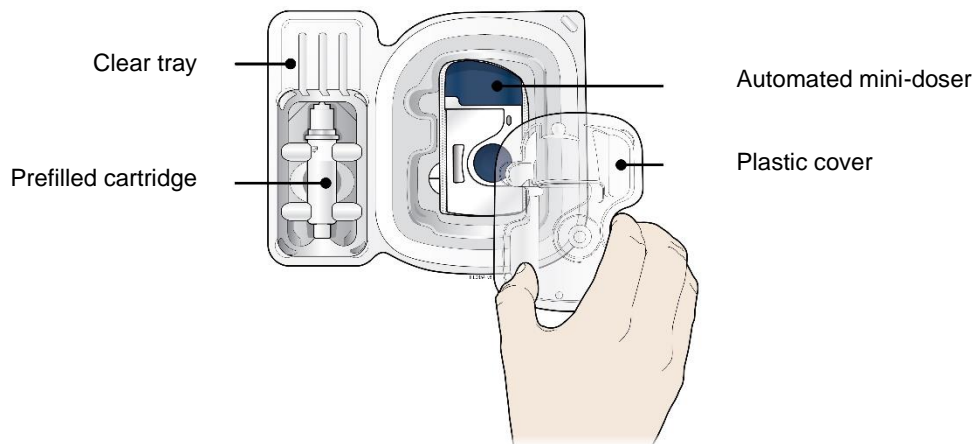
A healthcare provider who knows how to use the automated mini-doser should be able to answer your questions. For more information, contact the RepathaREADY® Support Program at 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

### Step 1: Prepare

- A.** Remove the automated mini-doser and prefilled cartridge carton from the refrigerator. Wait 45 minutes.

**Important: Wait at least 45 minutes for the automated mini-doser and prefilled cartridge to naturally reach room temperature in the carton, before you inject.**

- **Do not** try to warm the prefilled cartridge by using a heat source such as hot water or a microwave
- B.** Open the carton and peel away the white paper cover. Remove the automated mini-doser cover from the clear tray.



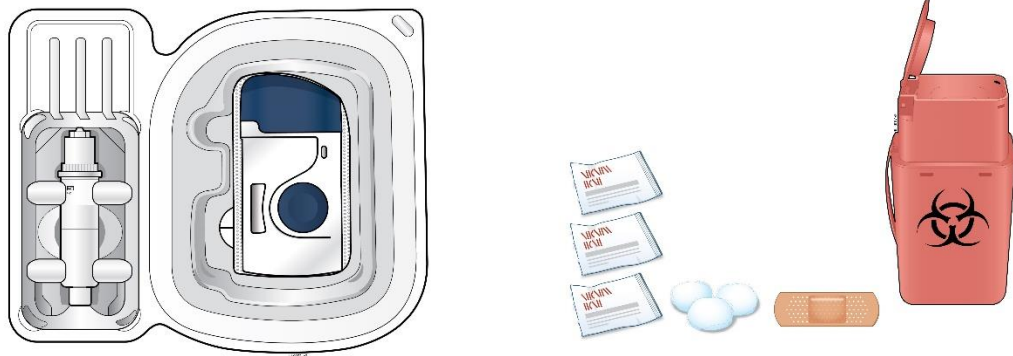
Leave the automated mini-doser and prefilled cartridge in the clear tray until you are ready to inject.

- **Do not** touch the start button until the automated mini-doser is on skin and you are ready to inject.
- **Do not** use if the white paper cover is missing or damaged.

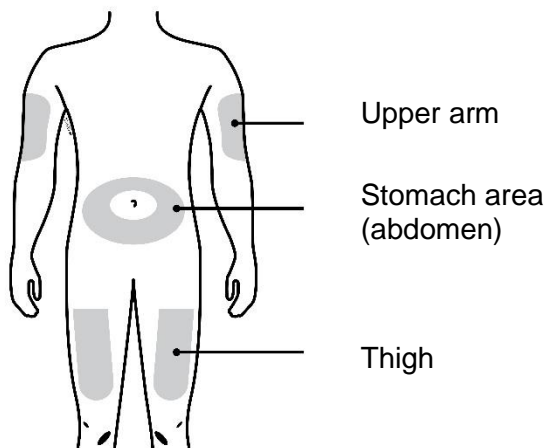
- C. Gather all materials needed for your injection and then wash your hands thoroughly with soap and water.

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

- Clear tray containing the automated mini-doser and prefilled cartridge
- Alcohol wipes
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



- D. To securely attach the automated mini-doser, prepare and clean an injection site that is less likely to have body hair, or you can trim the area. Use a firm and flat skin surface.



**You can use:**

- Thigh
- Stomach area (abdomen), except for a 5 centimetre (2 inch) area around your navel (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
- **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with wrinkles, skin folds, moles, excessive hair, scars or stretch marks

**Important: To attach the automated mini-doser securely, it is important to use a firm and flat skin surface.**

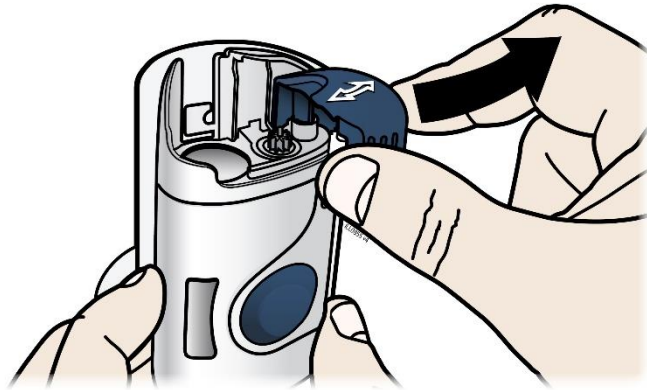
## Step 2: Get ready

- E. Open the automated mini-doser by swinging the cartridge door to the right. Then, **leave the door open**. **Do not** close the cartridge door before the cartridge is loaded.

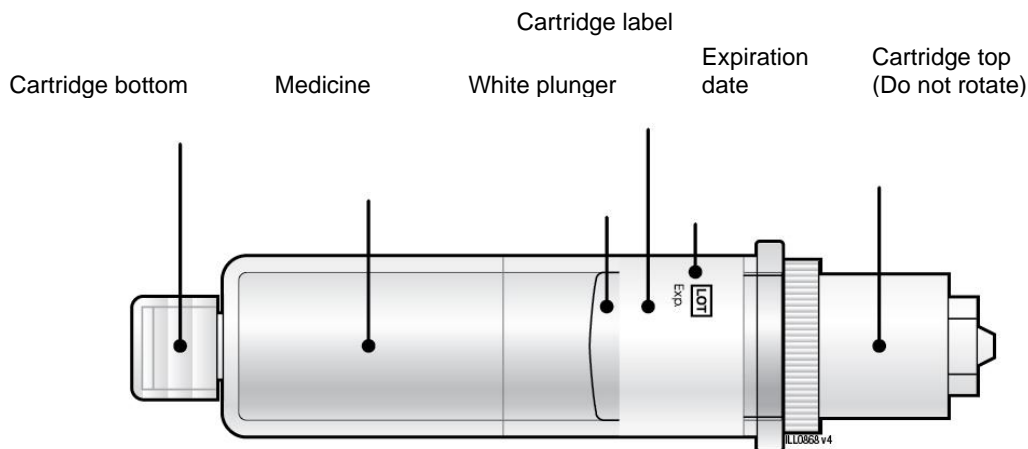
If you accidentally close the cartridge door, press on the left side of the door to release the door latch.

If you are still unable to open the door, call 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

**Do not** press the start button until you are ready to inject.



- F. Inspect the cartridge.



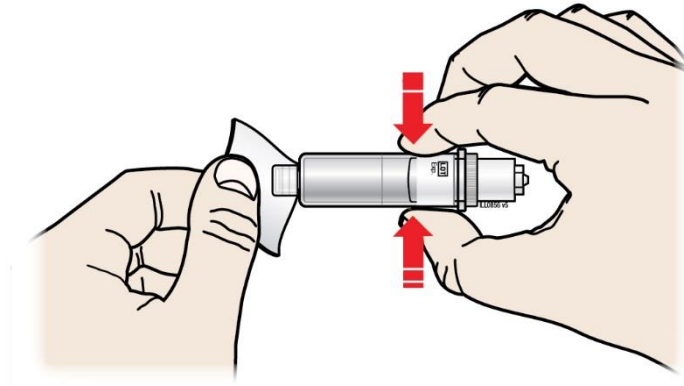
**Make sure the medicine in the cartridge is clear and colourless to slightly yellow.**

- **Do not** use if the medicine is cloudy or discoloured or contains flakes or particles
- **Do not** use if any part of the cartridge appears cracked or broken
- **Do not** use if pieces of the cartridge are missing or not securely attached

- **Do not** use if the expiration date on the cartridge has passed

In any above cases, use a new automated mini-doser and prefilled cartridge and call 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

**G.** Clean the cartridge bottom.

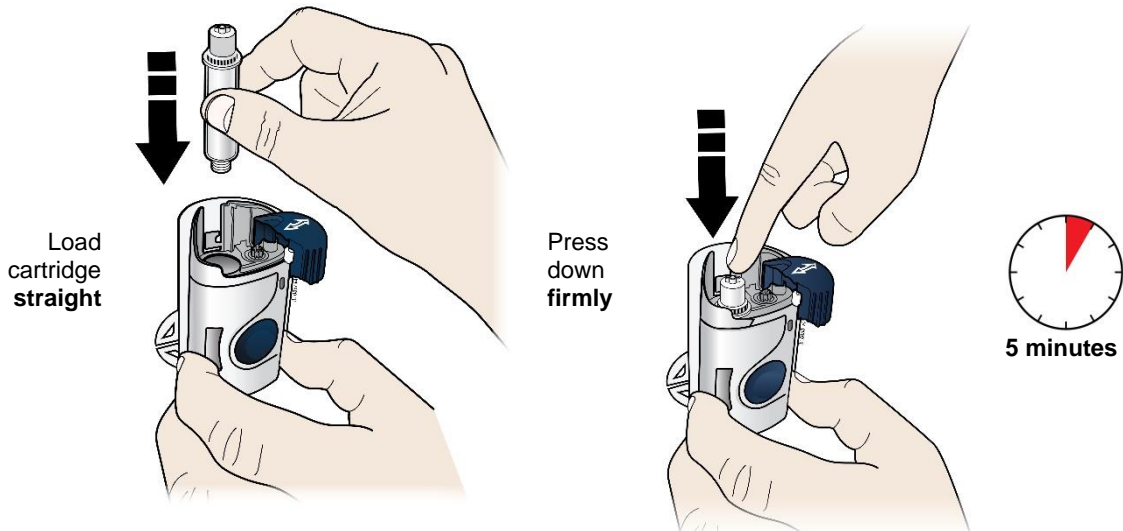


**Grab Here**

Hold the cartridge barrel and clean the cartridge bottom with an alcohol wipe.

- **Do not** touch the bottom of the cartridge after cleaning with alcohol wipe
- **Do not** remove or rotate the cartridge top or bottom

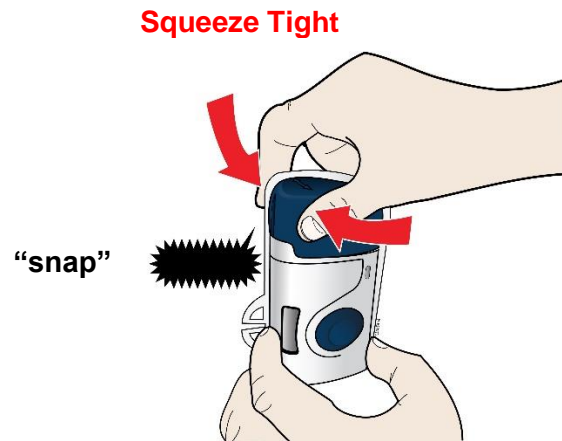
**H.** Load the cleaned cartridge into the automated mini-doser and firmly press on the top until it is secured in place. **Do not** insert the cartridge more than five minutes before injection. This can dry out the medicine.



Insert the cartridge bottom first.

- **Do not** touch the start button until you have placed the loaded automated mini-doser on your skin

- I. Swing the door to the left. Then, squeeze firmly until it snaps shut. Apply enough pressure when closing the door and make sure there is a “snap” before going to the next step.



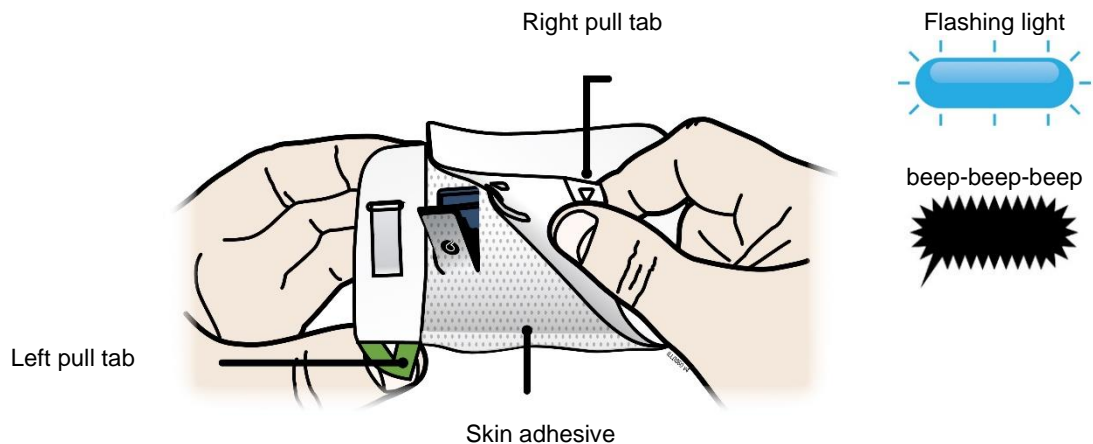
Make sure the cartridge fits securely in the automated mini-doser before you close the door.

- **Do not** close the door if the cartridge is missing or not fully inserted
- **Do not** touch the start button until you have placed the loaded automated mini-doser on your skin

**Important:** After you load the automated mini-doser, proceed to the next step without delay.

### Step 3: Inject

- J. **Peel away both** green pull tabs to show the adhesive. The automated mini-doser is on when the blue status light flashes.

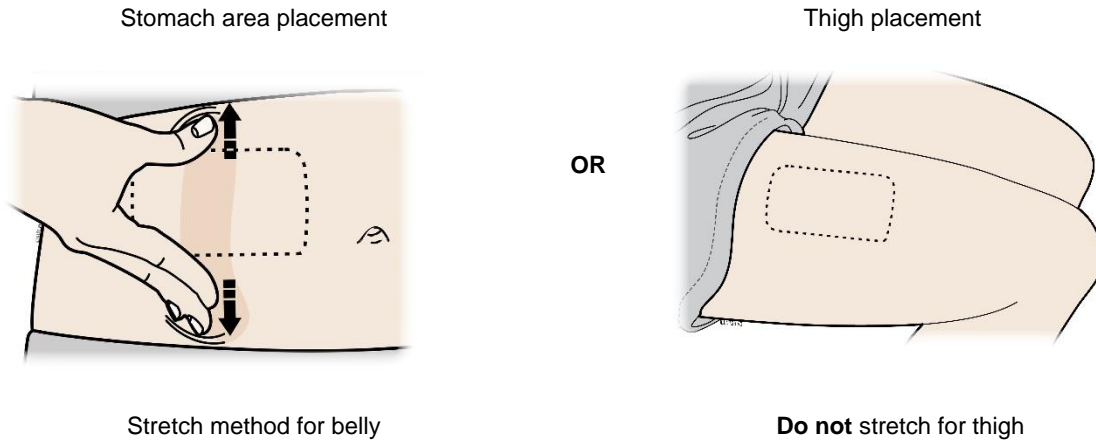


You must remove **both** green pull tabs to turn the loaded automated mini-doser on. You will hear beeping and see a flashing blue status light.

- **Do not** touch the skin adhesive
- **Do not** touch the start button until you have placed the loaded automated mini-doser on your skin

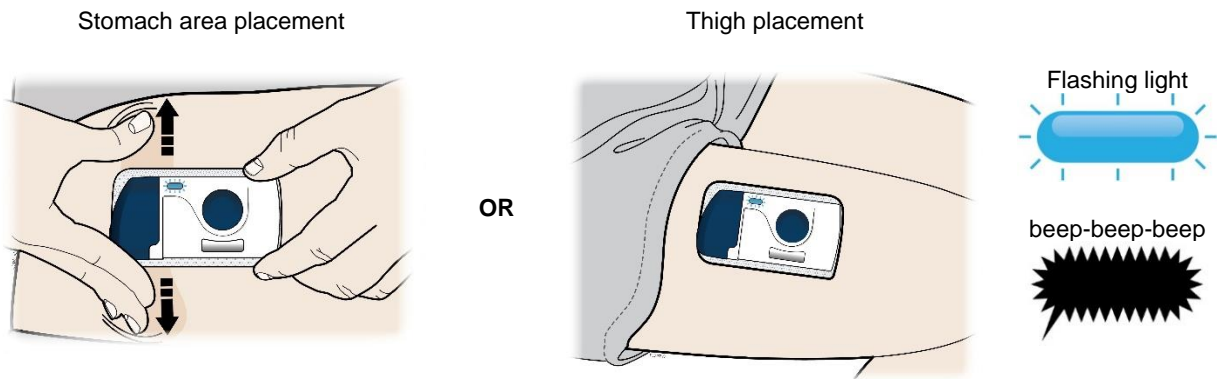
- **Do not** touch or contaminate the needle cover area
- **Do not** place the loaded automated mini-doser on your body if the red status light flashes continuously
- **Do not** pull the skin adhesive backing off of the automated mini-doser
- **Do not** fold the skin adhesive over onto itself

**K.** Choose your automated mini-doser injection site. Only use the outer arm if someone else is giving the injection.



**Important:** Adjust your body posture to avoid skin folds and bulges.

**L.** When the blue light flashes, the automated mini-doser is ready. **Keep the stretch** (stomach area method only). Hold the loaded automated mini-doser with the blue light visible, and place it on your skin. You may hear beeps.

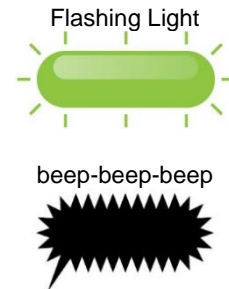
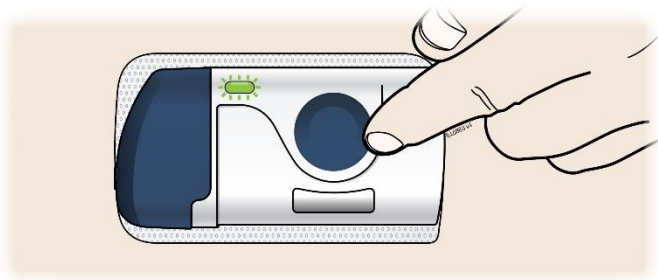


The loaded automated mini-doser will lay flat on your body. Make sure all of the adhesive is attached to your skin. Run a finger around the adhesive edges to secure it.

Make sure clothing does not get in the way of the loaded automated mini-doser, and you can see the blue light at all times.

- **Do not** try to reposition the loaded automatic mini-doser after it has been placed onto your skin.

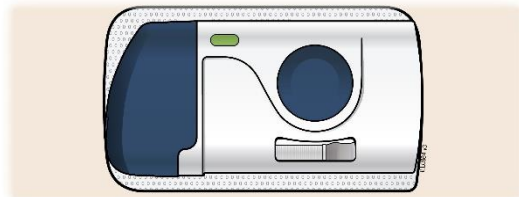
- M.** Firmly **press and release** the start button. A flashing green light and a click signal the injection has started.



- You may hear a pumping sound.
- You may feel a pinch.
- Make sure you see a green, flashing status light.
- You may hear beeps indicating your injection has started.

**Important:** If medication leaks from the loaded automated mini-doser, call 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

- N.** Injection takes about five minutes to finish. The status light turns **solid green**, and the device beeps, when done.



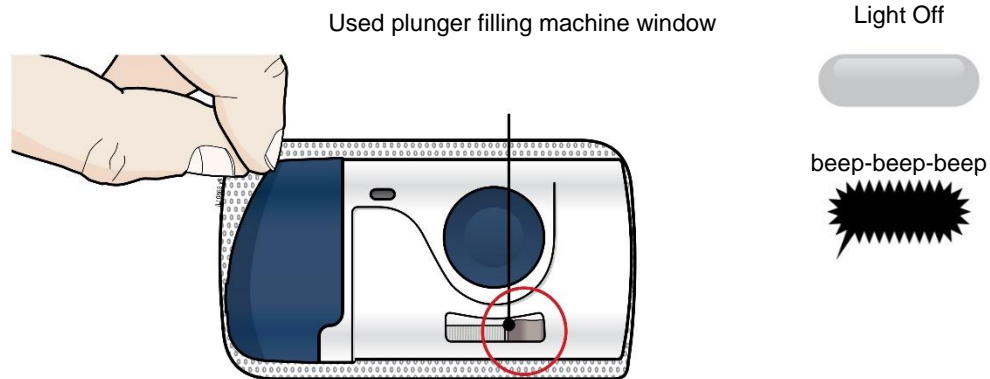
**It is okay to hear a pumping sound start and stop during injection.**

**Injection is finished when:**

- The status light changes to **solid green**.
- You hear several beeps.
- The plunger fills the medicine window.

#### Step 4: Finish

- O. When the injection is done, grab the skin adhesive to carefully peel the automated mini-doser off skin. After removal, check the medicine window. The green light should now be off.



Check to see that the used plunger completely fills the medicine window, and the green solid light is turned off, letting you know all medicine has been injected. If the plunger did not fill the window, call 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

- The used automated mini-doser will beep when removed from your skin.
  - It is normal to see a few drops of fluid on your skin after you remove the used automated mini-doser.
- P. Discard the used automated mini-doser in a sharps container.

The automated mini-doser contains batteries, electronics, and a needle.

Put the used automated mini-doser in a sharps disposal container right away after use. **Do not** throw away (dispose of) the automated mini-doser 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,
- 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 provincial or local laws about how you should throw away used needles and syringes.

- **Do not** remove the used cartridge from the automated mini-doser.
- **Do not** reuse the automated mini-doser.

**Do not** recycle the automated mini-doser or sharps disposal container or throw them into household trash.

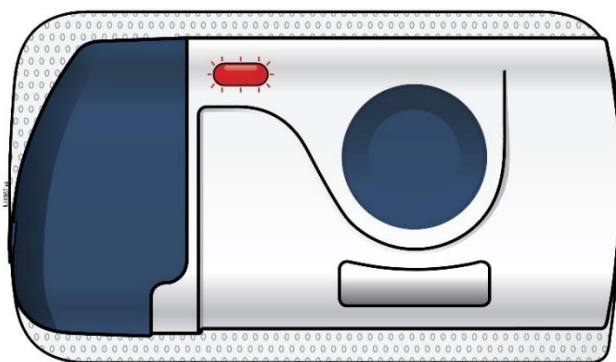
**Important:** Always keep the sharps disposal container out of the reach of children.

**Q.** Examine injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. **Do not** rub the injection site. Apply an adhesive bandage if needed.

### Troubleshooting:

What do I do if the loaded automated mini-doser status light continuously flashes red and I hear beeps?



Flashing Warning Light



beep-beep-beep-beep-beep



**Stop using** the loaded automated mini-doser. If the automated mini-doser is attached to your body, carefully remove it. Call 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

### Commonly Asked Questions:

**What if I hear the automated mini-doser beep and see a red blinking light when it is on my body?**

This means that an error has occurred. When this happens, the injection will automatically stop. Remove the automated mini-doser from your body by slowly and carefully peeling it off of your skin, call 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

**What should I do if the automated mini-doser comes off my body during the injection?**

Though unlikely, if the automated mini-doser comes off during the injection, the automated mini-doser will make a beeping sound, you will see the blinking red light, and the automated mini-doser will stop. The loaded automated mini-doser can no longer be used, and do not reapply to your body. Call 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

**What if I push the start button before I place the automated mini-doser on my skin?**

If you have removed the adhesive backing and pressed the start button, the automated mini-doser will make a beeping sound and you will see the blinking red light. The automated

mini-doser will not inject. Stop using the automated mini-doser, call 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

**What if the automated mini-doser does not beep and the blue status light does not blink when I remove the pull tabs?**

Check to see if both green pull tabs have been fully removed from the automated mini-doser, including the adhesive paper over the battery strip and needle cover. If both green pull tabs have been fully removed and the automated mini-doser still does not turn on, use a new automated mini-doser and prefilled cartridge. Call 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

**What if I push the start button and nothing happens?**

Remove the automated mini-doser by slowly and carefully peeling it away from your skin. Do not reapply the same automated mini-doser that you have already placed on your skin. Call 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

**What if I cannot open the cartridge door to insert the cartridge?**

To open the automated mini-doser door, press on the left side of the door to release the door latch. If you are still unable to open the door, call 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

**Additional environmental conditions:**

Relative humidity range is 15% to 85%.











Altitude range is -300 meters to 3500 meters.

During injection, keep the automated mini-doser a minimum of 30 cm (12 inches) away from other electronics such as cellular phones.

Warning: Do not modify the device.

Automated mini-doser operating temperature range is 15°C to 40°C.

[www.devicepatents.com](http://www.devicepatents.com)

SYMBOL TABLE				
 Do not re-use	 Serial number	 Type BF Applied Part	 Do not use if packaging is damaged	 Automated mini-doser containing 420 mg/3.5 mL (120 mg/mL)
 Sterilized using ethylene oxide	 Refer to Instructions for Use	 Lot number	 Keep dry	 Open here

**Usual dose:**

*Prevention of Cardiovascular Events and Primary Hyperlipidemia in Adult Patients (including HeFH and atherosclerotic cardiovascular disease) and HeFH in Pediatric Patients (aged 10 years and older).*

The usual dose for REPATHA is 140 mg every 2 weeks or 420 mg once monthly. If you or your child and your doctor have decided that you should switch from one dosing regimen to the other, take the first dose of the new regimen on the day you were scheduled to take the previous one.

***Homozygous Familial Hypercholesterolemia***

Adult and Pediatric Patients (aged 10 years and older): The usual dose for REPATHA is 420 mg, either once monthly or every 2 weeks. If you or your child are on apheresis you may initiate treatment with 420 mg every 2 weeks to correspond with your apheresis schedule.

**Overdose:**

If you think you, or a person you are caring for, have taken too much REPATHA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you or your child forget to take your every 2 week or once monthly dose of 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 your 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 or your child are not sure when to take REPATHA after a missed dose, ask your healthcare provider or pharmacist.

**What are possible side effects from using REPATHA?**

Like all medicines, REPATHA can cause side effects, although not everybody gets them. REPATHA may cause allergic reactions. Call your healthcare provider or go to the nearest hospital emergency room right away if you or your child have any symptoms of an allergic reaction including a severe rash, redness, severe itching, a swollen face or trouble breathing.

The following are not all the possible side effects you or your child may have when taking REPATHA. If you or your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

- Flu or flu-like symptoms (high temperature, sore throat, runny nose, cough and chills)
- Common cold, such as runny nose, sore throat or sinus infections (nasopharyngitis or upper respiratory tract infections)
- Nausea
- Back pain
- Joint pain (arthralgia)
- Muscle pain (myalgia), with or without associated muscle weakness

- Injection site reactions (redness, bruising, pain, swelling, or bleeding)
- Allergic reactions including rash, hives, red itchy bumps on your skin (urticaria), and in rare cases, swelling of face, mouth, tongue or throat (angioedema)

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

Store in a refrigerator at 2°C to 8°C in the original carton. When removed from the refrigerator, REPATHA should be kept at controlled room temperature (up to 25°C) in the original carton and must be used within 30 days. Protect REPATHA from direct light and do not expose to temperatures above 25°C. Do not freeze. Do not shake.

Keep REPATHA and all medicines out of the reach and sight of children.

Do not throw away any medicines via wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use.

### If you want more information about REPATHA:

- 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>; the RepathaREADY® Support Program at 1-888-Repatha (1-888-737-2842) or by visiting [www.repatha.ca](http://www.repatha.ca).

This leaflet was prepared by Amgen Canada Inc.

Last Revised: May 16, 2025

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

**PrRepatha<sup>®</sup>**

**evolocumab injection**

**Single-use Prefilled Syringe\***

Read this carefully before you or your child start taking **REPATHA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **REPATHA**. Keep this leaflet, as you may need to read it again.

#### **What is REPATHA used for?**

REPATHA is used:

- along with diet and in combination with usual therapy, including cholesterol-lowering medications called statins, to reduce the risk of heart attack, stroke, and certain heart procedures (to restore blood flow to the heart) in adult patients who have cardiovascular disease by further lowering low-density lipoprotein (LDL) cholesterol.
- along with diet, alone or together with other cholesterol-lowering therapies, in adults with primary hyperlipidemia (high LDL cholesterol level in your blood) to reduce LDL cholesterol.
- along with diet and other cholesterol-lowering therapies, to reduce LDL cholesterol in people 10 years and older who need additional lowering of the high LDL cholesterol in their blood because of a condition that runs in their family (heterozygous familial hypercholesterolemia [HeFH]).
- along with diet and other cholesterol-lowering therapies, to reduce LDL cholesterol in people 10 years and older who need additional lowering of the high LDL cholesterol in their blood because of a condition that runs in their family (homozygous familial hypercholesterolemia [HoFH]).

#### **How does REPATHA work?**

REPATHA is a medicine used to lower levels of cholesterol. REPATHA lowers levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, REPATHA raises levels of “good” cholesterol (HDL cholesterol).

Evolocumab, the active ingredient of REPATHA, works by helping the liver’s ability to remove bad cholesterol from the blood. Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol. LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke and can cause other health problems. HDL cholesterol is often called “good” cholesterol because it helps keep the bad

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\* Prefilled syringes are not available in Canada

cholesterol from building up in the arteries and protects against heart disease. Triglycerides are another form of fat in your blood that may increase your risk of heart disease.

### **What are the ingredients in REPATHA?**

Medicinal ingredients: evolocumab

Non-medicinal ingredients: glacial acetic acid, polysorbate 80, proline, sodium hydroxide and water for injection. The prefilled syringe\* is not made with natural rubber latex.

### **REPATHA comes in the following dosage forms:**

REPATHA is available in the presentations listed below. Your doctor will prescribe the type that is best for you or your child.

- 1 mL single-use prefilled autoinjector (SureClick®). Each 1 mL prefilled autoinjector contains 140 mg of evolocumab (140 mg/mL).
- 3.5 mL prefilled cartridge with an automated mini-doser (AMD). Each 3.5 mL prefilled cartridge contains 420 mg of evolocumab (120 mg/mL).
- 1 mL single-use prefilled syringe\*. Each 1 mL prefilled syringe\* contains 140 mg of evolocumab (140 mg/mL).

### **Do not use REPATHA if:**

- You or your child have ever had an allergic reaction to REPATHA or any of the ingredients in REPATHA.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you or your child take REPATHA. Talk about any health conditions or problems you or your child may have, including if you or your child:**

- Use REPATHA together with a statin and other cholesterol lowering medicines, please read the package leaflet of that particular medicine.

### **Other warnings you should know about:**

#### **Children and adolescents**

The use of REPATHA has been studied in children 10 years of age and older being treated for heterozygous or homozygous familial hypercholesterolemia.

The use of REPATHA has not been studied in children under 10 years of age or in children with other types of hypercholesterolemia.

#### **Pregnancy and Breastfeeding**

REPATHA has not been tested in pregnant women. It is not known if REPATHA will harm your unborn baby.

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\* Prefilled syringes are not available in Canada

If you are trying to get pregnant or think you may be pregnant when taking REPATHA:

- Inform your doctor
- If you are also taking a statin along with REPATHA, stop taking REPATHA and read the package leaflet of the statin that you are taking with REPATHA

Women who become pregnant during REPATHA treatment, or their healthcare provider, are encouraged to call Amgen at 1-866-502-6436 to report the pregnancy.

It is not known whether REPATHA is found in breast milk. It is important to tell your doctor if you are breastfeeding or plan to do so. Your doctor will then help you decide whether to stop breastfeeding, or whether to stop taking REPATHA, considering the benefit of breastfeeding to the baby and the benefit of REPATHA to the mother.

**Tell your healthcare professional about all the medicines you or your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

#### **The following may interact with REPATHA:**

No important drug interactions have been identified for REPATHA. No drug-drug interaction studies have been carried out for REPATHA.

#### **How to take REPATHA:**

REPATHA is given as an injection under the skin (subcutaneous or SC). REPATHA is available in the presentations listed below. Your doctor will prescribe the type that is best for you or your child.

- Single-use prefilled autoinjector (SureClick®)
- Single-use automated mini-doser
- Single-use prefilled syringe\*

If your doctor decides that you or your child or a caregiver (e.g. parent) can give the injections of REPATHA, you or your child or your caregiver should receive training on the right way to prepare and inject REPATHA. Do not try to inject REPATHA until you, your child or a caregiver have been shown the right way by your healthcare provider.

Always take REPATHA exactly as your doctor has told you or your child. Check with your doctor if you are not sure.

- Before starting REPATHA, you or your child should be on a diet to lower cholesterol.
- You or your child should stay on this cholesterol lowering diet while taking REPATHA.

If your doctor has prescribed REPATHA along with a statin or other cholesterol lowering medicine for you or your child, follow your doctor's instructions on how to take these medicines together. In this case, please read the dosage instructions in the package leaflet of the other medicines.

Ask your doctor if you or your child have any further questions on how to use REPATHA.

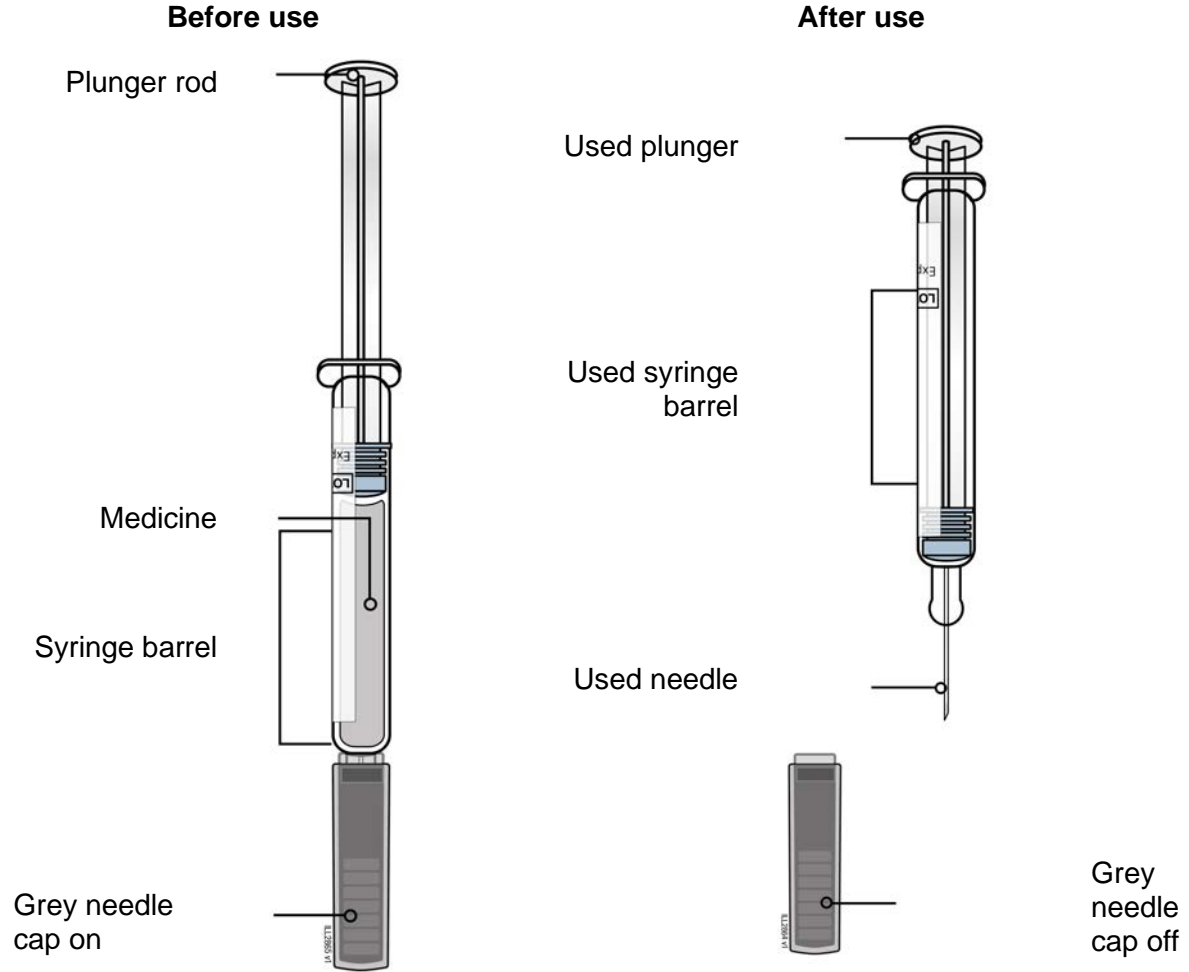
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\* Prefilled syringes are not available in Canada

**REPATHA Single-Use Prefilled Syringe\***

The following instructions are for preparing and giving an injection of REPATHA using a single-use prefilled syringe\*.

**Guide to Parts**



**Important:** Needle is inside

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\* Prefilled syringes are not available in Canada

## Important

Before you use a Single-Use REPATHA Prefilled Syringe\*, read this important information:

- Keep the REPATHA prefilled syringe\* in the original carton to protect from light during storage.
- The REPATHA prefilled syringe\* should be kept in the refrigerator between 2°C to 8°C.
- It is important that you do not try to give yourself the injection unless you have received training from your healthcare provider.
- The prefilled syringe\* is not made with natural rubber latex.
- Keep the REPATHA prefilled syringe\* out of the sight and reach of children.
- **DO NOT:**
  - Use the REPATHA prefilled syringe\* if the packaging is open or damaged.
  - Freeze the REPATHA prefilled syringe\* or use one that has been frozen.
  - Use the REPATHA prefilled syringe\* if it has been dropped onto a hard surface. Part of the REPATHA prefilled syringe\* may be broken even if you cannot see the break. Use a new REPATHA prefilled syringe\*.
  - Remove the grey needle cap from the REPATHA prefilled syringe\* until you are ready to inject.

A healthcare provider familiar with REPATHA should be able to answer your questions. For more information, contact the RepathaREADY® Support Program at 1-888-Repatha (1-888-737-2842) or visit [www.repatha.ca](http://www.repatha.ca).

### Step 1: Prepare

#### A. Remove the REPATHA prefilled syringe\* carton from the refrigerator and wait 30 minutes.

Wait at least 30 minutes for the prefilled syringe\* in the carton to naturally reach room temperature before injecting.

Check that the name REPATHA appears on the carton label.

- **DO NOT:**
  - Try to warm the REPATHA prefilled syringe\* by using a heat source such as hot water or microwave.
  - Leave the REPATHA prefilled syringe\* exposed to direct sunlight.
  - Shake the REPATHA prefilled syringe\*.

#### B. Gather all materials needed for your injection.

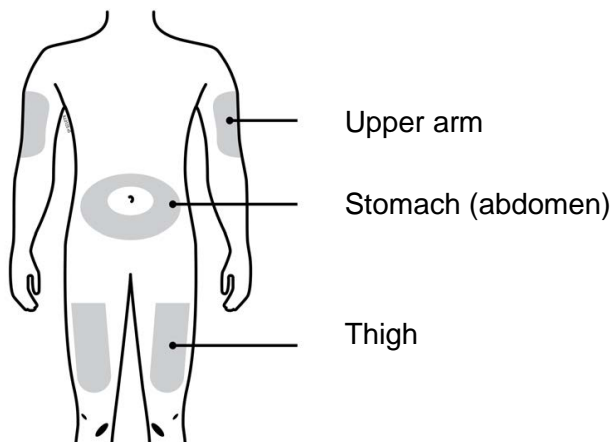
Wash your hands thoroughly with soap and water. **On a clean, well-lit, flat work surface, place:**

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\*Prefilled syringes are not available in Canada

- One REPATHA prefilled syringe\* in carton
- Alcohol wipes
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container
- **DO NOT** use if expiration date on the REPATHA prefilled syringe\* carton has passed.

**C. Choose your injection site.**



**You can use:**

- Thigh
- Stomach (abdomen), except for the **5** centimetres (2 inches) around the belly button
- Outer area of upper arm (only if someone else is giving you the injections)
- **DO NOT** choose an area where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

**D. Clean your injection site.**




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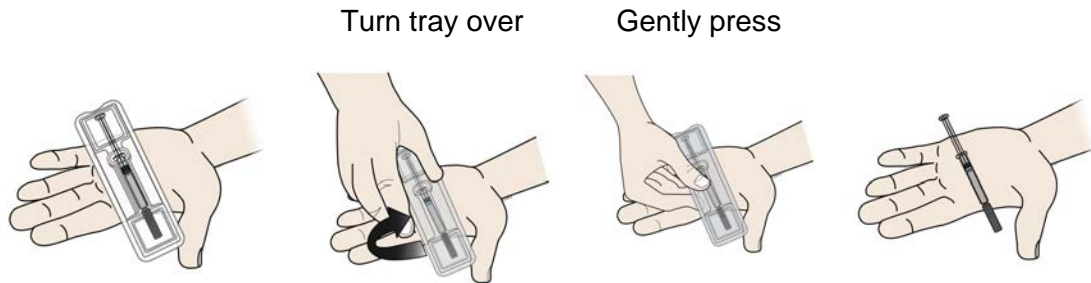
Clean your injection site with an alcohol wipe. Let your skin dry before injecting.

- **DO NOT** touch this area of skin again before injecting.

**Important:** 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. Avoid injecting into areas with scars or stretch marks.

#### E. Remove prefilled syringe\* from tray.



To remove:

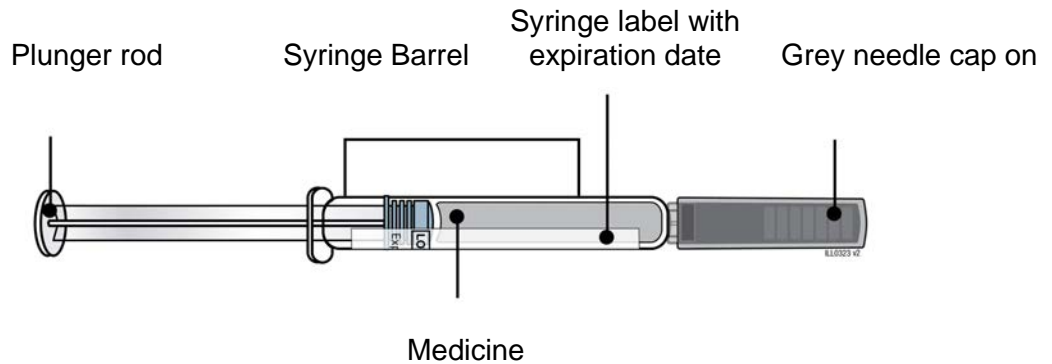
- Peel paper off of tray.
- Place the tray on your hand.
- Turn the tray over and gently press the middle of the tray's back to release the syringe into your palm.
- If prefilled syringe\* does not release from tray, gently press on back of tray.
- **DO NOT:**
  - Pick up or pull the prefilled syringe\* by the plunger rod or grey needle cap. This could damage the syringe.
  - Remove the grey needle cap from the prefilled syringe\* until you are ready to inject.

**Important:** Always hold the prefilled syringe\* by the syringe barrel.

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\* Prefilled syringes are not available in Canada

**F. Inspect medicine and syringe.**



**Always hold the prefilled syringe\* by the syringe barrel.**

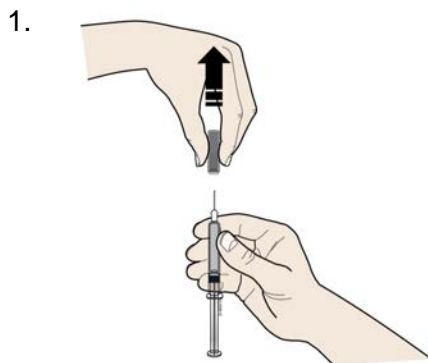
**Check that:**

- The name REPATHA appears on the prefilled syringe\* label.
- The medicine in the prefilled syringe\* is clear and colourless to slightly yellow.
- **DO NOT** use the prefilled syringe\* if:
  - any part of the prefilled syringe\* appears cracked or broken.
  - the grey needle cap is missing or not securely attached.
  - the medicine is discoloured or contains large lumps, flakes or coloured particles.
  - the expiration date on the prefilled syringe\* has passed.

In any above cases, use a new prefilled syringe\* and contact the RepathaREADY® Support Program at 1-888-Repatha (1-888-737-2842).

**Step 2: Get Ready**

**G. Carefully pull the grey needle cap straight out and away from your body. DO NOT leave the grey needle cap off for more than 5 minutes.** This can dry out the medicine.



It is normal to see a drop of medicine at the end of the needle.

Immediately place the cap in the sharps disposal container.

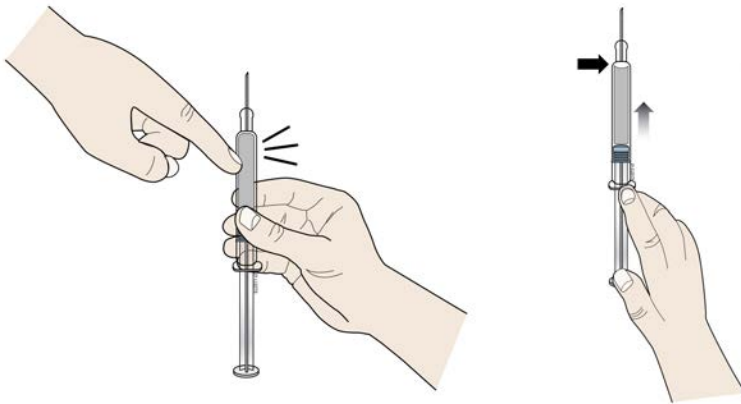
- **DO NOT:**
  - twist or bend the grey needle cap. This can damage the needle.
  - put the grey needle cap back onto the prefilled syringe\*.

#### H. Remove the air bubble/gap.

You may notice an air bubble/gap in the REPATHA prefilled syringe\*.

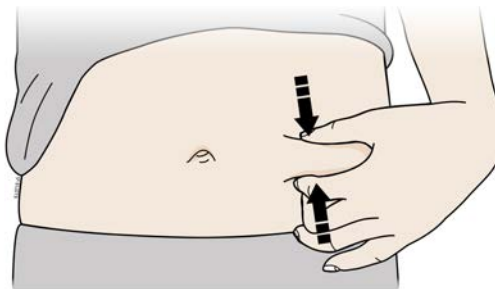
##### If you notice an air bubble/gap:

- Hold the prefilled syringe\* with the needle facing up.
- Gently tap the syringe barrel with your fingers until the air bubble/gap rises to the top of the syringe.
- Slowly and gently push the plunger rod up to get the air out of the prefilled syringe\*. Be very careful not to push out any medicine.



- **DO NOT** tap the syringe needle.

#### I. PINCH your injection site to create a firm surface.



Pinch skin firmly between your thumb and fingers, creating an area about 5 centimetres (2 inches) wide.

**Important:** It is important to keep the skin pinched while injecting.

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### Step 3: Inject

J. Hold the PINCH. Insert the needle into skin using a 45 to 90 degree angle.

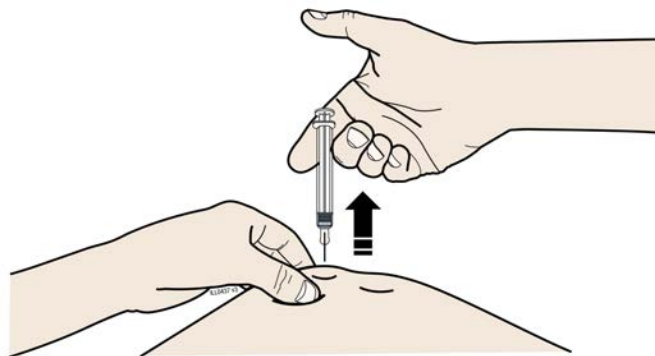


- **DO NOT** place your finger on the plunger rod while inserting the needle.

K. Using slow and constant pressure, **PUSH** the plunger rod all the way down until the syringe is empty.



L. When done, **RELEASE** your thumb, and gently lift the syringe off skin.



- **DO NOT** put the grey needle cap back onto the used syringe.

#### Step 4: Finish

M. Immediately place the used syringe in a sharps disposal container.



- **DO NOT:**

- reuse the used syringe.
- use any medicine that is left in the used syringe.
- recycle the syringe or the sharps disposal container or throw it into household trash.

**Important:** Keep the used syringe and sharps container out of the sight and reach of children.

N. **Examine 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.

**Usual dose:**

*Prevention of Cardiovascular Events and Primary Hyperlipidemia in Adult Patients (including HeFH and atherosclerotic cardiovascular disease) and HeFH in Pediatric Patients (aged 10 years and older)*

The usual dose for REPATHA is 140 mg every 2 weeks or 420 mg once monthly. If you or your child and your doctor have decided that you should switch from one dosing regimen to the other, take the first dose of the new regimen on the day you were scheduled to take the previous one.

*Homozygous Familial Hypercholesterolemia*

Adult and Pediatric Patients (aged 10 years and older): The usual dose for REPATHA is 420 mg, either once monthly or every 2 weeks. If you or your child are on apheresis you may initiate treatment with 420 mg every 2 weeks to correspond with your apheresis schedule.

**Overdose:**

If you think you, or a person you are caring for, have taken too much REPATHA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you or your child forget to take your every 2 week or once monthly dose of 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 your 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 or your child are not sure when to take REPATHA after a missed dose, ask your healthcare provider or pharmacist.

**What are possible side effects from using REPATHA?**

Like all medicines, REPATHA can cause side effects, although not everybody gets them. REPATHA may cause allergic reactions. Call your healthcare provider or go to the nearest hospital emergency room right away if you or your child have any symptoms of an allergic reaction including a severe rash, redness, severe itching, a swollen face or trouble breathing.

The following are not all the possible side effects you or your child may have when taking REPATHA. If you or your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

- Flu or flu-like symptoms (high temperature, sore throat, runny nose, cough and chills)
- Common cold, such as runny nose, sore throat or sinus infections (nasopharyngitis or upper respiratory tract infections)
- Nausea
- Back pain
- Joint pain (arthralgia)
- Muscle pain (myalgia), with or without associated muscle weakness
- Injection site reactions (redness, bruising, pain, swelling, or bleeding)
- Allergic reactions including rash, hives, red itchy bumps on your skin (urticaria), and in rare cases, swelling of face, mouth, tongue or throat (angioedema).

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store in a refrigerator at 2°C to 8°C in the original carton. When removed from the refrigerator, REPATHA should be kept at controlled room temperature (up to 25°C) in the original carton and must be used within 30 days. Protect REPATHA from direct light and do not expose to temperatures above 25°C. Do not freeze. Do not shake.

Keep REPATHA and all medicines out of the reach and sight of children.

Do not throw away any medicines via wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use.

### **If you want more information about REPATHA:**

- 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>; the RepathaREADY® Support Program at 1-888-Repatha (1-888-737-2842) or by visiting [www.repatha.ca](http://www.repatha.ca).

This leaflet was prepared by Amgen Canada Inc.

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