

# Getting started with Repatha<sup>®</sup> (evolocumab injection)

Your guide to treatment –  
Information, guidance and support



# Understanding your treatment

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This guide was developed to help you understand your treatment with Repatha®, including how it works to lower cholesterol levels, how to take it and other treatment considerations. It also contains information about why it is important to manage your cholesterol, and how changing your diet – or continuing the good diet habits you already have – can help with that goal.

You will also learn about the RepathaREADY® Patient Support Program (by Amgen Entrust™ Patient Support Services)\*, your resource to help you with your Repatha® treatment.

\* AMGEN Entrust is our new unified patient support services platform, built on the legacy of our branded support programs.

**RepathaREADY**  
PATIENT SUPPORT PROGRAM  
YOUR PARTNER IN CARE, EVERY STEP OF THE WAY

 **Repatha**®  
evolocumab injection

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# Getting started with Repatha®

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## What is Repatha® and what is it used for?

Repatha® is a medicine used to lower levels of cholesterol.

## Why have I been prescribed Repatha®?

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;
- alone or together with other cholesterol-lowering therapies, along with diet, in adults with primary hyperlipidemia (high cholesterol level in your blood) to reduce LDL cholesterol.
- along with diet and other LDL-C lowering therapies in people with homozygous familial hypercholesterolemia 12 years and older (an inherited condition that causes high levels of LDL-C) who need additional lowering of LDL cholesterol.

It is not known if Repatha® is safe and effective in children with homozygous familial hypercholesterolemia (HoFH) who are younger than 12 years of age or in children with primary hyperlipidemia who are younger than 18 years of age.



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## How does Repatha® lower cholesterol?

Evolocumab, the active ingredient of Repatha®, works by helping the liver's ability to remove LDL-C, or "bad" cholesterol from the blood. Evolocumab also lowers the level of the fatty substances called triglycerides, and raises the level of high-density lipoprotein cholesterol, or HDL-C, often referred to as "good" cholesterol.

## Why is lowering cholesterol important?

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL (low-density lipoprotein) and HDL (high-density lipoprotein) cholesterol. LDL cholesterol, referred to as LDL-C or "bad" cholesterol, can build up in the walls of your arteries as plaque, which can lead to a narrowing of arteries that 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.

Therefore, lowering cholesterol, particularly LDL-C, is important to help reduce the health risks that excess LDL-C may be associated with, including heart attack, stroke and other health problems.

For more information on cholesterol and its effects on the body, refer to the section, **Managing your cholesterol.**



# How do I take Repatha®?

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**Repatha® is available in the following dosage forms.**

Repatha® is given as an injection just under the skin (subcutaneous, or SC). You can take Repatha® **every two weeks** with the 140 mg/mL single-use prefilled SureClick autoinjector, or **once monthly** with the 420 mg/3.5 mL single-use prefilled cartridge with an automated mini-doser.

If your doctor decides that you or a caregiver can give your Repatha® injections with either the SureClick autoinjector or the automated mini-doser, you or your caregiver should receive training on the right way to prepare and inject Repatha®.

**Do not try to inject Repatha® until you have been shown the right way by a healthcare professional, such as a doctor, nurse or pharmacist.**

Always take Repatha® exactly as your doctor has told you. Check with your doctor if you are not sure.

The autoinjector contains a needle (which is hidden throughout the injection). The needle cover (located inside the removable cap) contains dry natural rubber, which is made from latex. There is no dry natural rubber in the automated mini-doser with prefilled cartridge. Tell your healthcare provider if you are allergic to latex.

**Continue with your cholesterol-lowering diet**

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

**Continue with your current cholesterol-lowering medicine**

If your doctor has prescribed Repatha® along with a statin or other cholesterol-lowering medicine, 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.

Following are the **main steps** in using the SureClick autoinjector. The main steps in using the automated mini-doser can be found on page 10.

Once you have been trained to administer Repatha®, please refer to the **Patient Medication Information** leaflet that comes with your Repatha® medication for **step-by-step instructions** and **helpful illustrations**. Ask your doctor if you have any further questions on how to use Repatha®.



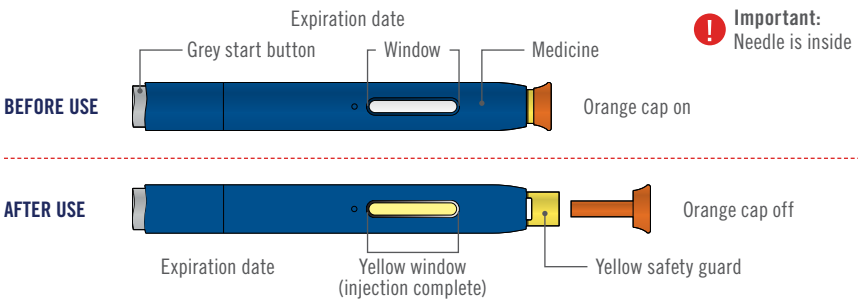
You can also call the RepathaREADY® Patient Support Program for nurse support (see page 16 for more information) at **1-888-Repatha (1-888-737-2842)**.

# How to use the SureClick autoinjector

## Summary of the main steps

**Important:** Before you use the SureClick autoinjector, refer to the **Patient Medication Information** leaflet that comes with your Repatha® medication for **important information** about **using and storing** the SureClick autoinjector, along with **step-by-step instructions**.

## Guide to parts



## Step 1: Prepare

- Remove one SureClick autoinjector from the package.
- Wait at least 30 minutes for the autoinjector to naturally reach room temperature before injecting. 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.
- Inspect the SureClick autoinjector to 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. Check the expiration date.
- Gather all materials needed for your injection: alcohol wipes; cotton ball or gauze pad; adhesive bandage; sharps disposal container.
- Prepare and clean your injection site with an alcohol wipe. You can use: thigh, belly, except for a two-inch area around the navel; outer area of upper arm (if someone else is giving the injection).



## Step 2: Get ready

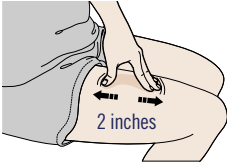
- Pull the orange cap straight off only when you are ready to inject.

**Important:** 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.

Do not leave the orange cap off for more than five minutes. This can dry out the medicine and may clog the needle when you give the injection.

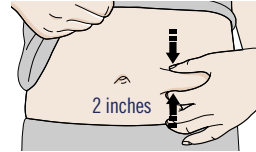
- Stretch or pinch your injection site to create a firm surface.

### Stretch method



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

### Pinch method

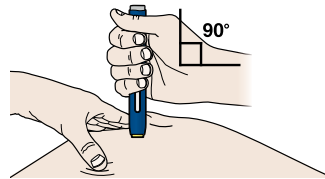


Pinch skin firmly between your thumb and fingers, creating an area about 2 inches (5 centimetres) wide.

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

### Step 3: Inject

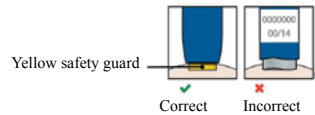
- Hold the stretch or pinch to create a firm surface.
- With the **orange cap** off, **place the yellow end** of the autoinjector on the skin at a 90-degree angle before injecting.



**Important: Do not** touch the grey start button yet.

- Firmly **push** autoinjector down onto 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.



- When you are ready to inject, **press** the grey start button. You will hear a **click**.
- Keep **pushing** down on skin. Then **lift** thumb. Your injection takes about 15 seconds.
- You will know the injection is done when you hear a second **click**, and see that the window turns **yellow**. (Note: after you remove the autoinjector from your skin, the needle will be automatically covered.)
- If you did not hear a second **click** after pushing the autoinjector down on your skin for 15 seconds, the yellow window still confirms the injection is done.

### 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 thumb up off the grey start button and place the prefilled autoinjector back on your injection site. Then, you can push the grey start button again.

### 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.

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### Step 4: Finish

- Discard the used autoinjector and orange needle cap in a sharps disposal container.
- Examine the injection site. If there is blood, press (**do not** rub) a cotton ball or gauze pad on the injection site. Apply a bandage if needed.

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

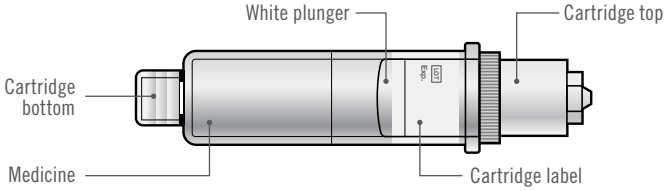
You can call the RepathaREADY® Patient Support Program for assistance at **1-888-Repatha (1-888-737-2842)**, Monday to Friday, 8:00 am to 8:00 pm EST.



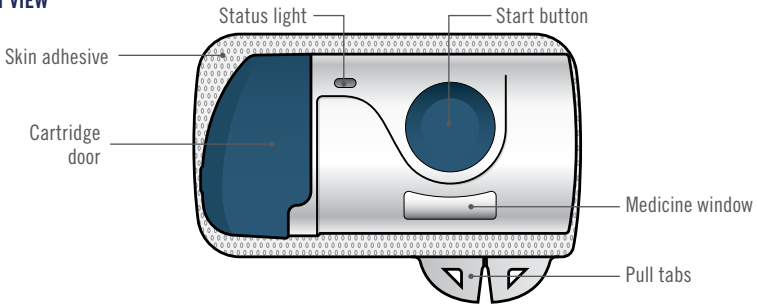
# How to use the automated mini-doser

## Guide to parts

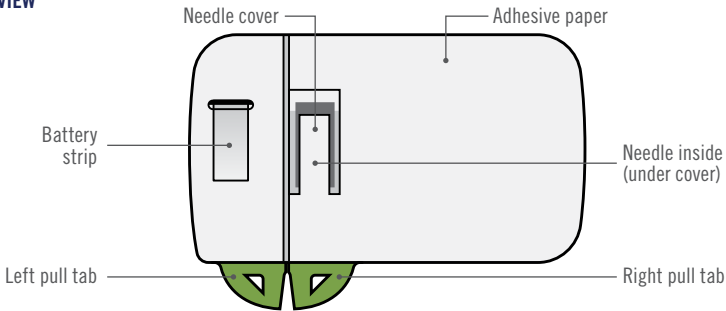
### PREFILLED CARTRIDGE



### AUTOMATED MINI-DOSER FRONT VIEW



### AUTOMATED MINI-DOSER BACK VIEW



**!** Important:  
Needle is inside

## Summary of the main steps

**Important:** Before you use the Repatha® automated mini-doser and prefilled cartridge, refer to the **Patient Medication Information** leaflet that comes with your Repatha® medication for **important information** about **using and storing** the Repatha® automated mini-doser and prefilled cartridge, along with **step-by-step instructions**.

### Step 1: Prepare

- 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. Do not try to warm the automated mini-doser and prefilled cartridge by using a heat source such as hot water or microwave.

- Open the carton and peel away the white paper cover. Remove the automated mini-doser cover from the clear tray.
- Gather all materials needed for your injection: alcohol wipes; cotton ball or gauze pad; adhesive bandage; sharps disposal container.
- Prepare and clean your injection site with an alcohol wipe.
  - You can use: thigh, belly, except for a two-inch area around the navel; outer area of upper arm (if someone else is giving the injection).

**Important:** 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 hair in the area. It is important to use a **firm and flat** skin surface.

### Step 2: Get ready

- 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.
- Inspect the cartridge to make sure the medicine in the window is clear and colourless to slightly yellow. **Do not** use if the medicine is cloudy or discoloured or contains flakes or particles. Check the expiration date.
- Clean the cartridge bottom with an alcohol wipe.
- Load the cleaned cartridge, bottom first, into the automated mini-doser. 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.
- Swing the door to the left and squeeze firmly until it **snaps shut**.
- Proceed to the next step **without delay**.

### Step 3: Inject

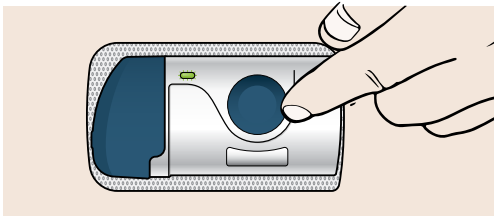
- Peel away both green pull tabs to show the adhesive. The automated mini-doser is ON when the **blue status light flashes** and you will hear beeping.
- Choose your automated mini-doser placement site.
  - Only use the outer arm if someone else is giving the injection.
  - If using the belly, **stretch the skin** to create a firm surface.
  - **Do not stretch** for the thigh or arm.

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

#### Stretch method for belly

Stretch skin firmly by moving your thumb and fingers in opposite directions, creating an area about 2 inches (5 centimetres) wide. **Do not stretch** for thigh or upper arm.

- 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. Make sure the adhesive is secured.



- Firmly **press and release** the start button. A **flashing green light** and a **click** signals the injection has started. You may hear a pumping sound and feel a pinch.
- The injection takes about **5 minutes**. When the **status light turns solid green** and the automated mini-doser **beeps**, the injection is **complete**.

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

This means that an error has occurred. The injection will automatically stop. Carefully remove the automated mini-doser from your body. **DO NOT** attempt to re-use this automated mini-doser.

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

Although this is unlikely to happen, the injection will stop and you will see the blinking red light and hear beeps. **DO NOT** attempt to re-use this automated mini-doser.

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

Check to see if both green pull tabs have been fully removed from the automated mini-doser, including the paper over the battery strip and needle cover. If both 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.

### **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.

## **Step 4: Finish**

- When the injection is done, pull carefully on the skin adhesive to peel the automated mini-doser off the skin. 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.
- After removal, check the medicine window. The **used plunger** should completely fill the medicine window. The **green light** should now be **off**.
- Discard the used automated mini-doser in a sharps disposal container.
- Examine the injection site. If there is blood, press (do not rub) a cotton ball or gauze pad on the injection site. Apply a bandage if needed.

### **Who do I contact if I need help with the automated mini-doser or my injection?**

You can call the RepathaREADY® Patient Support Program for assistance at **1-888-Repatha (1-888-737-2842)**, Monday to Friday, 8:00 am to 8:00 pm EST.

# How do I store Repatha®?

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 from 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.



Please note: Your Repatha® package may be different from that shown.



# Does Repatha® cause any side effects?

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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 have any symptoms of an allergic reaction including a severe rash, redness, severe itching, a swollen face or trouble breathing.

## Possible side effects include:





- 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 (also known as arthralgia)
- High blood sugar levels (diabetes)
- 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)

These are not all the possible side effects you may feel when taking Repatha®.

If you have troublesome symptoms or a side effect that is not listed here, or one that becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

## What is the Repatha**READY**<sup>®</sup> Patient Support Program?

The Repatha**READY**<sup>®</sup> Patient Support Program is your resource for personalized support to help you get started and stay on track with your Repatha<sup>®</sup> treatment.

-  Assistance accessing drug coverage
-  One-on-one training with a nurse to use the Repatha<sup>®</sup> SureClick autoinjector or automated mini-doser
-  Ongoing educational resources on Repatha<sup>®</sup> and cardiovascular health
-  Nurse support, ongoing personalized contact and treatment reminders



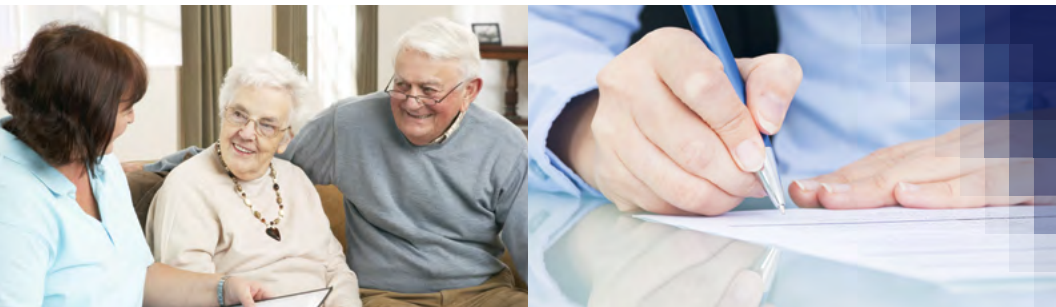
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# Be ready for your treatment with Repatha®

Immediately upon your enrolment, the RepathaREADY® Program begins to provide personalized services and support throughout your treatment. Ongoing status updates will be provided to your doctor's office.

## Questions?

**RepathaREADY® Patient Support Program is ready to help.  
Call 1-888-Repatha (1-888-737-2842),  
Monday to Friday, 8:00 am to 8:00 pm EST.**



# Managing your cholesterol

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## What is cholesterol?

Cholesterol is a soft waxy lipid (fat) made by our bodies. The liver makes about 80 percent of the cholesterol in your body. The other 20 percent comes from the foods you eat.

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 (LDL-C)** is often called “**bad**” **cholesterol** because it can build up in the walls of your arteries, forming **plaque**. Eventually this plaque buildup 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 (HDL-C)** 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, in excess, may increase your risk for heart disease.



# How do I know if my cholesterol is high?

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## High blood cholesterol – a condition that may have no symptoms

**In many cases, high blood cholesterol may not cause symptoms** – many people may be unaware that their cholesterol level is high.

The only way to know if you have high cholesterol levels is to have your blood tested.

## Having your cholesterol levels tested – what do test results say?

When your blood is tested for cholesterol, you will usually receive five categories of results, described below with some general target levels. Your doctor will determine your personal target levels based on your cardiovascular risk factors – including age, total cholesterol level, smoking status, HDL-C level and systolic blood pressure.

### 1. Total cholesterol

Total cholesterol means the total amount of cholesterol in your blood. This includes LDL-C and HDL-C.

### 2. LDL-C

For moderate- and high-risk individuals, the LDL-C target is less than 2 mmol/L or a greater than 50% decrease from baseline (the level measured before treatment). For low-risk individuals, the treatment target would be a reduction in LDL-C of 50% or greater from baseline.

### 3. HDL-C

Generally, the HDL-C level should be higher than 1.3 mmol/L for women, and higher than 1.9 mmol/L for men.

### 4. Triglycerides

High triglyceride levels are linked to low levels of HDL-C, excess body weight and poorly controlled diabetes. In general, the target triglyceride level is less than 1.7 mmol/L.

### 5. Total cholesterol/HDL-C ratio

This ratio shows how high your HDL-C is relative to your overall cholesterol levels. A lower number is associated with a lower risk of heart disease.

# What can I do to help lower my cholesterol levels, in addition to taking my cholesterol-lowering medication?

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## Where to start: Healthy diet, healthy lifestyle

Adopting a healthy lifestyle is an important step toward achieving and maintaining healthy cholesterol levels. The Heart and Stroke Foundation recommends:

- Eating a diet that is lower in saturated and trans fats, and includes plenty of fruit, vegetables and whole grains
- Being physically active, and accumulating 150 minutes of moderate- to vigorous-intensity physical activity per week in bouts of 10 minutes or more
- Achieving and maintaining a healthy weight
- Limiting excess alcohol intake
- Being smoke-free

## Healthy eating – an important part of managing your cholesterol levels



# What is a cholesterol-lowering diet?

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A cholesterol-lowering diet is a diet that is nutritious, balanced, and contains foods from each of the four major food groups: vegetables and fruit; grains; milk and alternatives; and meat and alternatives.

- Follow a lower-fat diet with 20% to 35% of calories from fat. That's equal to 45 to 75 grams of fat per day for women and 60 to 100 grams per day for men.
- Avoid trans fat, which is found in foods made with shortening or partially hydrogenated vegetable oil, such as fast foods and many packaged foods. Trans fat raises “bad” LDL-C and lowers “good” HDL-C levels.
- Reduce your intake of foods that are high in saturated fat, such as fatty meats, and dairy products such as butter, cheese, cream or homogenized milk.
- Choose healthy unsaturated fat found in oils (olive, canola, peanut, safflower, sunflower and corn oils; not coconut, palm, and palm kernel oils, which are saturated oils), nuts and fish.
- Include more vegetables and fruits, whole grains, legumes and nuts in your diet.

The foods that raise your blood cholesterol the most are saturated fat and trans fat. Dietary cholesterol only has an effect in some people. Foods that have high levels of dietary cholesterol include egg yolks, organ meats (liver, kidney), shrimp, squid and fatty meats.

# How can I increase my fibre?

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A heart-healthy diet includes foods that are high in fibre.

A healthy adult needs 21 to 38 grams of fibre a day, but the average daily Canadian intake is about 14 grams. Good sources of fibre are fruit and vegetables, and whole-grain products such as bread, wild and brown rice and oatmeal.

There are two kinds of fibre: soluble and insoluble. Soluble fibre may help lower cholesterol and control blood sugar. The best sources are oatmeal and oat bran; legumes such as dried beans, peas and lentils; and pectin-rich foods such as apples, strawberries and citrus fruit.

When shopping, check food product labels for 100% whole grain or 100% whole wheat with the germ at the beginning of the ingredient list, and check the fibre content in the Nutrition Facts table. Products with 2 grams of fibre or more are a healthy choice.





# Important information about Repatha®

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**Do not use Repatha®** if you have ever had an allergic reaction to Repatha® or any of the ingredients in Repatha®.

Do not use Repatha® if you are allergic or sensitive to rubber or latex, as the needle cap on the SureClick autoinjector contains dry natural rubber. There is no dry natural rubber in the automated mini-doser with prefilled cartridge.

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

If you use Repatha® together with a statin and other cholesterol-lowering medicines, please read the package leaflet of that medicine.

## **Children and adolescents**

The use of Repatha® has not been studied in children under 18 years of age being treated for primary hyperlipidemia. The use of Repatha® has not been studied in children under 12 years of age being treated for homozygous familial hypercholesterolemia.

## **Other medicines and Repatha®**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

## **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 become pregnant while 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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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 medications you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**



# Where can I find more information?

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The **Patient Medication Information** leaflet that is included with your Repatha® medication provides a summary of information about Repatha®. This leaflet is also available online at [repatha.ca](http://repatha.ca) (SureClick autoinjector DIN 02446057; automated mini-doser DIN 02459779).

## Online resources

### **Canadian Physical Activity Guidelines for Adults**

[www.csep.ca/CMFiles/Guidelines/CSEP\\_PAGuidelines\\_adults\\_en.pdf](http://www.csep.ca/CMFiles/Guidelines/CSEP_PAGuidelines_adults_en.pdf)

### **Dietitians of Canada**

[www.dietitians.ca](http://www.dietitians.ca)

### **Eating Well with Canada's Food Guide**

[www.hc-sc.gc.ca/fn-an/food-guide-aliment/index-eng.php](http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/index-eng.php)

### **Healthy Living: Healthy Eating & Physical Activity**

#### **Heart & Stroke Foundation**

[www.heartandstroke.ca/search-results-page?q=healthy+living](http://www.heartandstroke.ca/search-results-page?q=healthy+living)

### **You can quit smoking. We can help.**

#### **Government of Canada**

[www.canada.ca/en/health-canada/services/smoking-tobacco/quit-smoking/tips-help-someone-quit-smoking/you-can-quit-smoking-we-can-help.html](http://www.canada.ca/en/health-canada/services/smoking-tobacco/quit-smoking/tips-help-someone-quit-smoking/you-can-quit-smoking-we-can-help.html)



**RepathaREADY®**  
**Patient Support Program**  
**is ready to help.**

**Call 1-888-Repatha (1-888-737-2842),  
Monday to Friday, 8:00 am to 8:00 pm EST.**

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