

REPATHA[®]

(evolocumab)

INFORMATION AND SUPPORT

Guidance to help you understand and use your Repatha[®]



WELCOME TO REPATHA® (evolocumab)

Your doctor has prescribed Repatha® to lower the levels of bad cholesterol (LDL-C) in your blood. The warnings and instructions in this document are intended for the person taking the medicine. If you are a parent or carer responsible for giving the medicine to someone else, such as a child, you will need to apply the information accordingly.

Please read both this patient booklet and the information leaflet that comes in the carton with your medication or available at www.medicines.ie/medicines/repatha-sureclick-33565/patient-info

An electronic version of this booklet as well as a video demonstration on how to use the Sureclick® pen and other resources are available at **www.amgencare.ie**.

If you have any questions about Repatha® and the treatment of high cholesterol, please contact your doctor.

www.amgencare.ie



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Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.

Please report any potential quality issue with the Amgen product you have received, by calling us on +44 (0) 1223 436441 or Freephone 1800 535 160 and providing us with the details. Please ensure that you keep your packaging, so we are able to identify your product more easily.



ABOUT REPATHA®

WHAT IS REPATHA®

Repatha® is a medicine that lowers levels of 'bad' cholesterol, a type of fat, in the blood.

Repatha® contains the active substance evolocumab, a monoclonal antibody (a type of specialised protein designed to attach to a target substance in the body). Evolocumab is designed to attach to a substance called PCSK9 that affects the liver's ability to take in cholesterol. By attaching to, and mopping up PCSK9, the medicine increases the amount of cholesterol entering the liver and so lowers the level of cholesterol in the blood.


WHAT IS REPATHA® USED FOR?

Repatha® is used in patients who cannot control their cholesterol levels with oral cholesterol drugs and a cholesterol lowering diet alone. You should stay on your cholesterol-lowering diet while taking this medicine.

Repatha® may be used with other medicines that lower your levels of cholesterol.

Repatha® can help prevent heart attack, stroke, and certain heart procedures to restore blood flow to the heart due to a build-up of fatty deposits in your arteries (also known as atherosclerotic cardiovascular disease).

HOW TO USE REPATHA®

 Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Repatha® is given as an injection under the skin (subcutaneous).

The recommended dose for adults with primary hypercholesterolaemia and mixed dyslipidaemia (including heterozygous familial hypercholesterolaemia) the dose is either 140 mg every two weeks or 420 mg once monthly.

For children aged 10 years or older with heterozygous familial hypercholesterolaemia the dose is either 140 mg every two weeks or 420 mg once monthly.

For adults with established atherosclerotic cardiovascular disease the dose is either 140 mg every two weeks or 420 mg once monthly.

For adults or children aged 10 years and over with homozygous familial hypercholesterolaemia the recommended starting dose is 420mg once monthly. After 12 weeks your doctor may decide to increase the dose to 420mg every two weeks. If you also receive apheresis, your doctor may decide to start you on a dose of 420mg every two weeks to coincide with your apheresis treatment.

If you use more Repatha® than you should, contact your doctor or pharmacist immediately.

WHAT YOU NEED TO KNOW BEFORE YOU USE REPATHA®

Contents of the pack and other information

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

Do not use Repatha® if you are allergic to evolocumab or any of the ingredients of this medicine.

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

Each pack contains two single-use SureClick® pre-filled pens.

! Warnings

Talk to your doctor, pharmacist or nurse before using Repatha® if you have liver disease.

The needle cover of the glass pre-filled pen is made from dry natural rubber (a derivative of latex), which may cause severe allergic reactions.



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 hypercholesterolaemia.

The use of Repatha® has not been studied in children under 10 years of age.



Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

It is not known whether Repatha® is found in breast milk.

It is important to tell your doctor if you are breast-feeding or plan to do so. Your doctor will then help you decide whether to stop breast-feeding, or whether to stop taking Repatha®, considering the benefit of breast-feeding to the baby and the benefit of Repatha® to the mother.



Other medicines and Repatha®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If your doctor has prescribed Repatha® along with another 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 that particular medicine as well.



Driving and using machines

Repatha® has no or negligible influence on the ability to drive and use machines.



Repatha® contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.



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®.



Storing Repatha®

Store in the original carton in order to protect from light.

Store in a refrigerator (2°C – 8°C). DO NOT FREEZE.

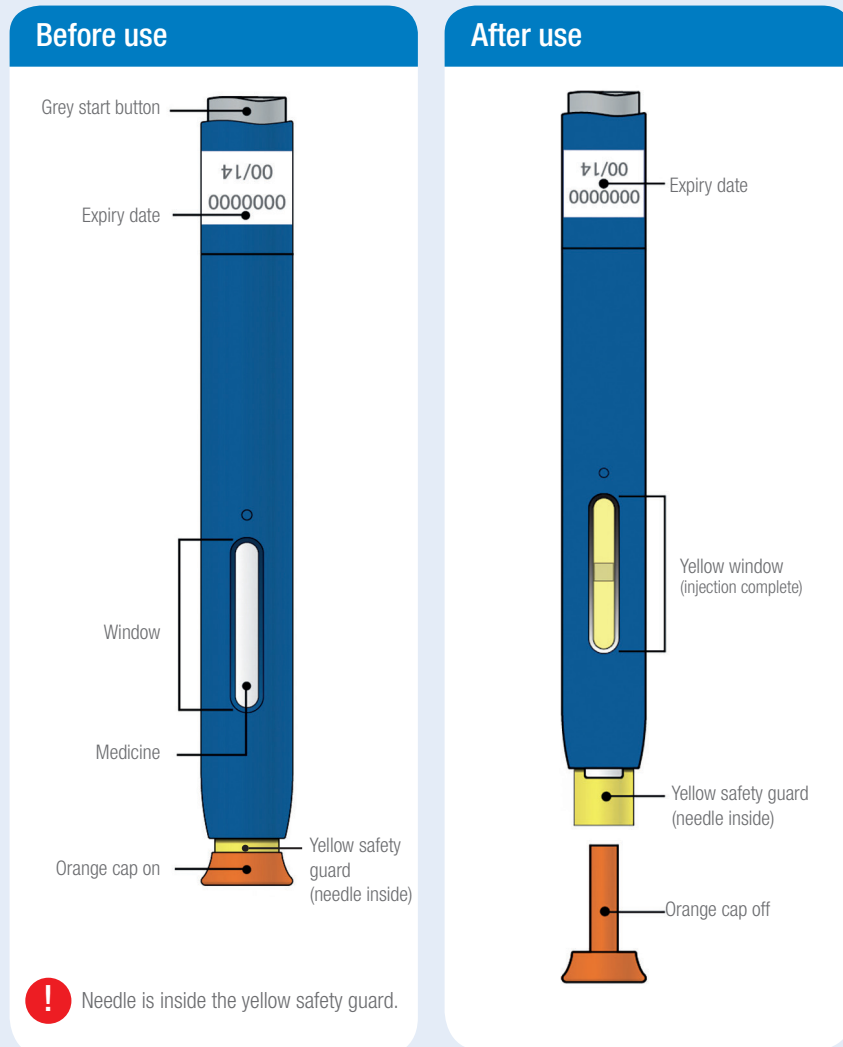
If removed from the refrigerator, Repatha® may be stored at room temperature (up to 25°C) in the original carton and must be used within 1 month.

Keep this medicine out of the sight and reach of children.

Ask your doctor, pharmacist or nurse how to dispose of medicines you no longer use. These measures will help protect the environment.

STEP-BY-STEP GUIDE HOW TO USE REPATHA® SURECLICK® PRE-FILLED PEN

GUIDE TO PARTS



IMPORTANT

Before you use the Repatha® pre-filled pen, read this important information:

- If your doctor decides that you or a caregiver can give the injections of Repatha®, you or your caregiver should receive training on how to prepare and inject Repatha® correctly. Do not try to inject Repatha® until you have been shown how to do it by your doctor or nurse.



Don'ts

Do not freeze or use the Repatha® pre-filled pen if it has been frozen.

Do not remove the orange cap from the Repatha® pre-filled pen until you are ready to inject.

Do not use the Repatha® pre-filled pen if it has been dropped on a hard surface. Part of the Repatha® pre-filled pen may be broken even if you cannot see the break.

Do not use the Repatha® pre-filled pen after the expiry date, which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

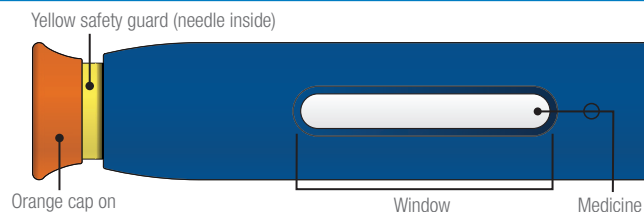
A step by step video demonstration showing how to administer your Repatha® Sureclick® pre-filled pen is available at: www.amgencare.ie

STEP 1: PREPARE

Remove one Repatha® SureClick® pre-filled pen from the package.

- Carefully lift the pre-filled pen straight up out of the box.
- Put the original package with any unused pre-filled pens back in the refrigerator.
- Wait at least 30 minutes for the pre-filled pen to naturally reach room temperature before injecting.
- Make sure the medicine in the window is clear and colourless to slightly yellow.
- Check the expiration date.

Inspect the Repatha® SureClick® pre-filled pen



Don'ts

- Do not use the pre-filled pen if:
 - the medicine is cloudy or discoloured or contains large lumps, flakes, or particles.
 - any part appears cracked or broken.
 - the pre-filled pen has been dropped.
 - the orange cap is missing or not securely attached.
 - the expiration date has passed.

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

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

STEP 1: CONTINUED

Gather all materials needed for your injection

Wash your hands thoroughly with soap and water.

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

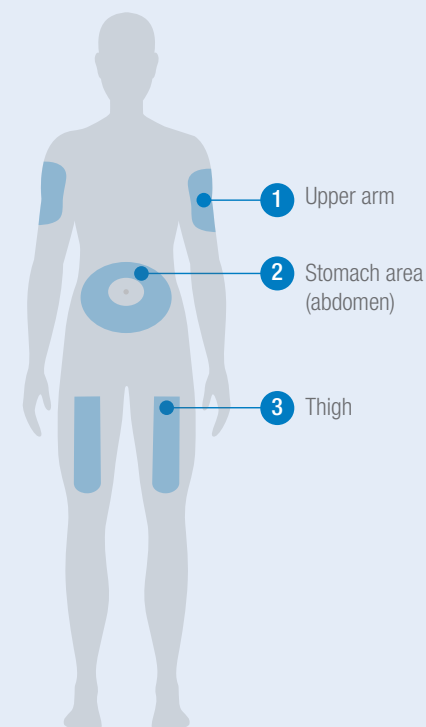
- New pre-filled pen
- Cotton-wool ball or gauze pad
- Plaster
- Alcohol wipes
- Sharps disposal container

Prepare and clean your injection site

Only use these injection sites:

- thigh
- stomach area (abdomen), except for a 2 inch (5 centimetres) area around your belly button
- outer area of upper arm (only if someone else is giving you the injection)

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



Don'ts

Do not touch this area again before injecting.

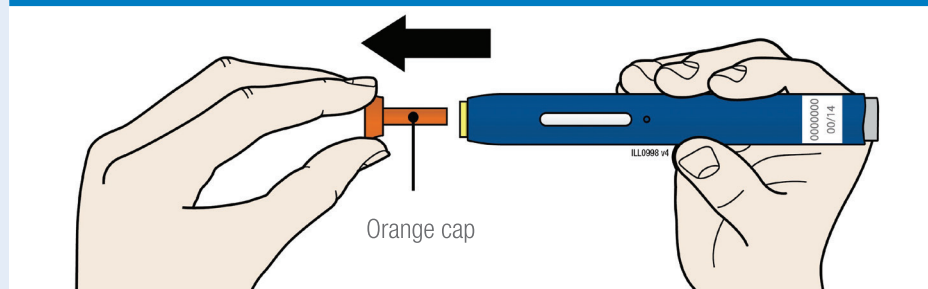
Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

- ! 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.

Don't forget! A step by step video demonstration showing how to administer your Repatha® Sureclick® pre-filled pen is available at: www.amgencare.ie

STEP 2: GET READY

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

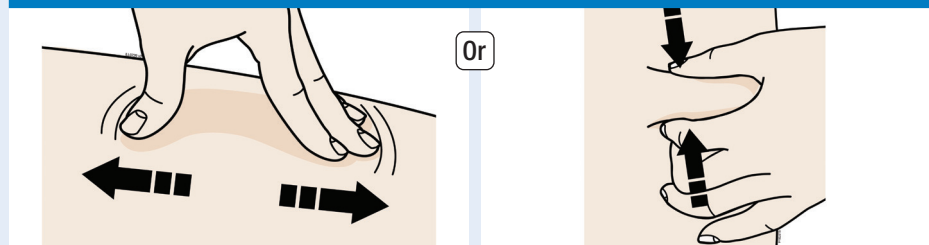


Don'ts

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

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

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 the opposite direction, creating an area about 2 inches (5 centimetres) wide.

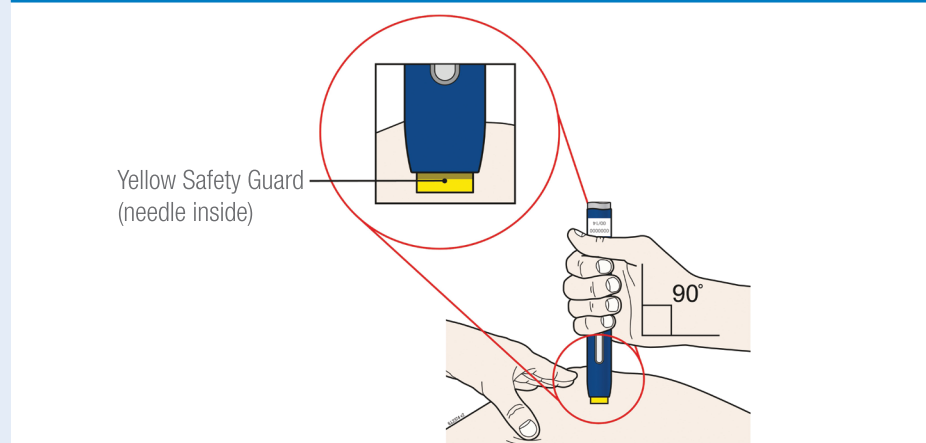
Pinch method:

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

! It is important to keep skin stretched or pinched while injecting.

STEP 3: INJECT

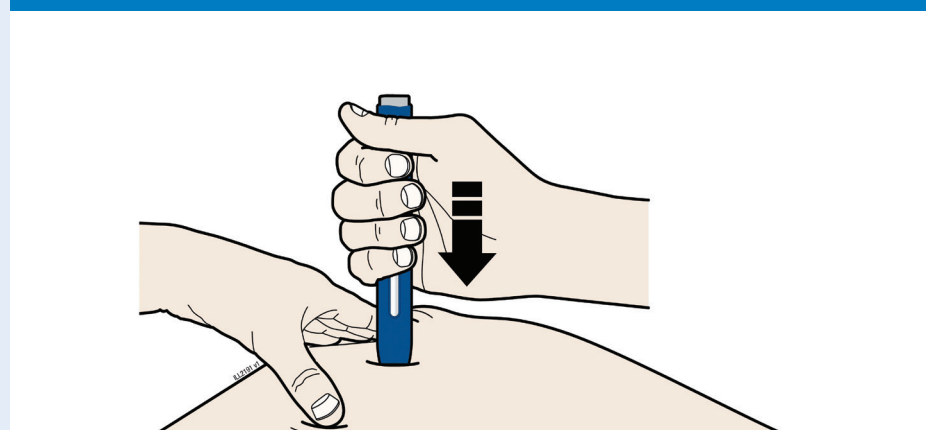
A. Keep holding the stretched or pinched skin.



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.

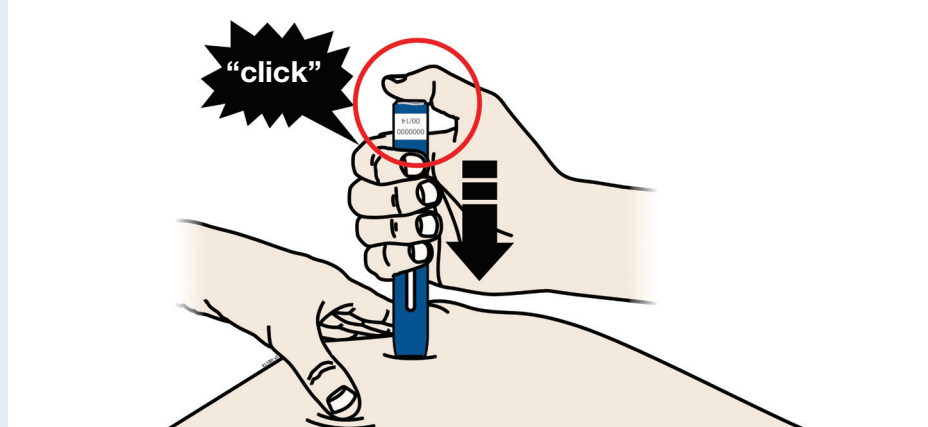
B. Firmly push down the pre-filled pen onto the skin until it stops moving



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

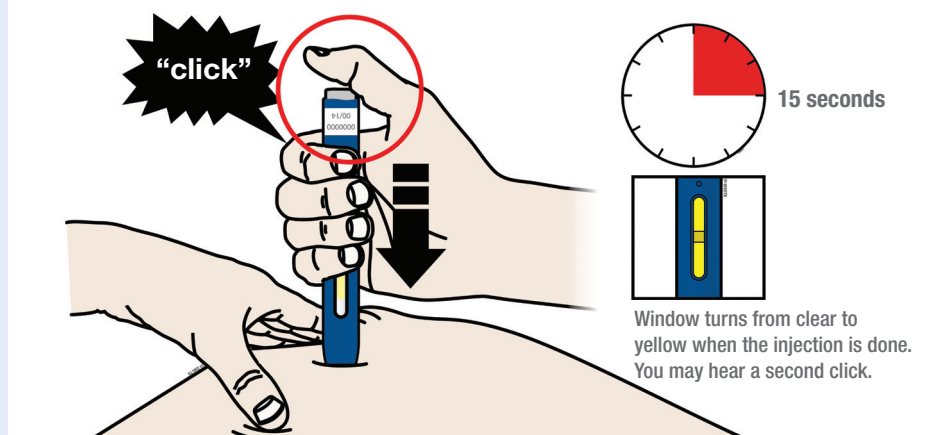
STEP 3: CONTINUED

C. Press the grey start button

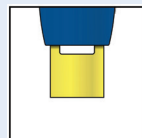


When you are ready to inject, press the grey start button. You will hear a click.

D. Keep PUSHING down on your skin



Keep pushing down on the skin. Then lift your thumb while still holding the pre-filled pen on your skin. Your injection could take about 15 seconds.



Note: After you remove the pre-filled pen from your skin, the needle will be automatically covered.

STEP 4: FINISH

Discard the used pre-filled pen and orange needle cap

Discard the used pre-filled pen and the orange cap in a sharps disposal container.

Talk with your healthcare provider about proper disposal. There may be local guidelines for disposal.

Keep the pre-filled pen and the sharps disposal container out of the sight and reach of children.

Dispose of the used pen



Don'ts

Do not reuse the pre-filled pen.

Do not recap the pre-filled pen or put fingers into the yellow safety guard.

Do not recycle the pre-filled pen or sharps disposal container or throw them into household rubbish.

Examine the injection site

If there is blood present, press a cotton ball or gauze pad onto the injection site.

Do not rub the injection site. Apply a plaster if needed.

FREQUENTLY ASKED PATIENT QUESTIONS

I already take another medicine, should I continue to take it alongside Repatha®?

If your doctor has prescribed Repatha® along with another 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 that particular medicine as well.

Can I administer Repatha® to myself?

If your doctor decides that you or a caregiver can give the injections of Repatha®, you or your caregiver should receive training on how to prepare and inject Repatha® correctly. Do not try to inject Repatha® until you have been shown how to do it by your doctor or nurse.

What will happen if I press the grey start button before I am ready to administer the injection?

Even when you press the grey start button of the pre-filled pen, the injection will only start when the yellow safety guard is also pushed against your skin.

Can I move the pre-filled pen around on my skin while I am choosing an injection site?

It is okay to move the pre-filled pen 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 against your skin, 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 pre-filled pen firmly against your skin during the injection.



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

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

I have been prescribed a dose of 420mg but each pre-filled pen is 140mg, what should I do?

If your doctor prescribes a dose of 420mg you must use three pre-filled pens because each pre-filled pen only contains 140mg of medicine. After naturally reaching room temperature, all injections should be given within a 30-minute period.

I've forgotten to take my Repatha®, what should I do?

If you forget to take Repatha®, take Repatha® as soon as you can after the missed dose. Then, contact your doctor who will tell you when you should schedule your next dose, and follow the new schedule exactly as your doctor has told you.

I think I have used too much Repatha®, what should I do?

If you use more Repatha® than you should, contact your doctor or pharmacist immediately.

Whom do I contact if I need help with the pre-filled pen or my injection?

If you have questions about using Repatha® and the SureClick® pen, please contact your doctor.

Can I travel with my Repatha®?

Once removed from the fridge, Repatha® may be stored at room temperature (up to 25°C) in the original carton and must be used within 1 month..

FURTHER QUESTIONS YOU MAY WISH TO DISCUSS WITH YOUR DOCTOR:

01 How is LDL cholesterol measured?

02 What is my current LDL cholesterol level?

03 What should my LDL cholesterol level be to reduce my risk of heart disease?

04 How often should I have my cholesterol measured?

05 Does having high cholesterol put me at risk of any other conditions besides heart disease?

06 What else can I do (besides taking my medication) to bring my cholesterol level down to a lower level?

07 Do I need to lose weight?

08 Are there certain foods I should eat less or stop eating?

09 Should I stop smoking?

10 How much exercise should I be doing?

11 Which kinds of exercises can help lower my cholesterol?

Remember to write down any other questions that occur to you before your next visit.

Don't feel shy about asking your doctor questions and take notes to help you remember the information.

POSSIBLE SIDE EFFECTS:

Like all medicines, Repatha® can cause side effects, although not everybody gets them.

Common: may affect up to 1 in 10 people

- flu (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)
- feeling sick (nausea)
- back pain
- joint pain (arthralgia)
- muscle pain
- headache
- injection site reactions, such as bruising, redness, bleeding, pain or swelling
- allergic reactions including rash

Uncommon: may affect up to 1 in 100 people

- hives, red itchy bumps on your skin (urticaria)
- flu-like symptoms

Rare: may affect up to 1 in 1,000 people

- swelling of the face, mouth, tongue, or throat (angioedema)

Reporting of side effects:

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CHOLESTEROL DIARY

Take charge of cholesterol
Ask your doctor for your numbers

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NOTES:

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INJECTION TRACKING CHART

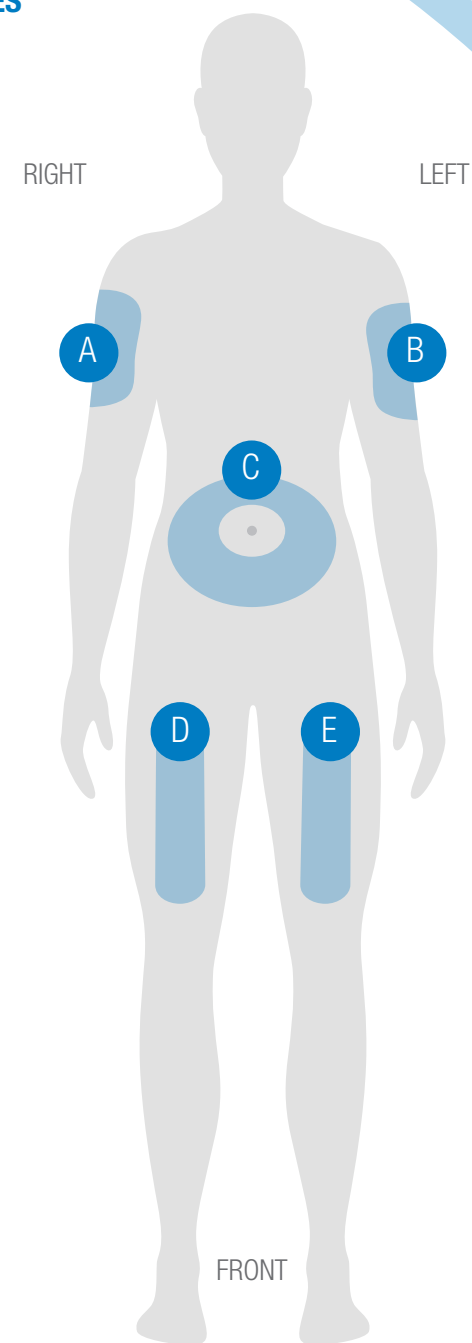
This chart is to help you to track injection sites on your body

[illegible]

* The Lot number can be found on your Repatha® carton.

To improve the traceability of this medicine, your doctor or pharmacist should record the name and the lot number of the product you have been given in your patient file. You may also wish to make a note of these details in case you are asked for this information in the future.

INJECTION SITES



PLEASE REFER TO THE PATIENT INFORMATION LEAFLET THAT
CAME WITH YOUR MEDICINE, OR AVAILABLE AT
[https://www.medicines.ie/medicines/repatha-sureclick-33565/
patient-info](https://www.medicines.ie/medicines/repatha-sureclick-33565/patient-info)

Visit the patient website www.amgencare.ie for more information
(for quick access, scan the below QR code with your phone's
camera or QR reader app)



The information on this booklet is not
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with your healthcare professional.

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