

Package leaflet: Information for the user

Repatha 140 mg solution for injection in pre-filled pen evolocumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Repatha is and what it is used for
2. What you need to know before you use Repatha
3. How to use Repatha
4. Possible side effects
5. How to store Repatha
6. Contents of the pack and other information

1. What Repatha is and what it is used for

What Repatha is and how it works

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.

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

What Repatha is used for

Repatha is used in addition to your cholesterol lowering diet if you are:

- an adult with a high cholesterol level in your blood (primary hypercholesterolaemia [heterozygous familial and non-familial] or mixed dyslipidaemia). It is given:
 - together with a statin or other cholesterol lowering medication, if the maximum dose of a statin does not lower levels of cholesterol sufficiently.
 - alone or together with other cholesterol lowering medications when statins do not work well or cannot be used.
- 12 years and older with a high cholesterol level in your blood because of a condition that runs in your family (homozygous familial hypercholesterolaemia or HoFH). It is given:
 - together with other cholesterol lowering treatments.
- an adult with a high cholesterol level in your blood and established atherosclerotic cardiovascular disease (a history of heart attack, stroke or blood vessel problems). It is given:
 - together with a statin or other cholesterol lowering medication, if the maximum dose of a statin does not lower levels of cholesterol sufficiently.
 - alone or together with other cholesterol lowering medications when statins do not work well or cannot be used.

2. What you need to know before you use Repatha

Do not use Repatha if you are allergic to evolocumab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Repatha if you have:

- liver disease,
- severe kidney problems.

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

Children and adolescents

The use of Repatha has not been studied in children under 18 years of age being treated for primary hypercholesterolaemia and mixed dyslipidaemia.

The use of Repatha has not been studied in children under 12 years of age being treated for homozygous familial hypercholesterolaemia.

Other medicines and Repatha

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

Pregnancy and breast-feeding

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

Inform your doctor if you are trying to get pregnant, think you may be pregnant or become pregnant taking Repatha.

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.

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'.

3. 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 depends on the underlying condition:

- for adults with primary hypercholesterolaemia and mixed dyslipidaemia the dose is either 140 mg every two weeks or 420 mg once monthly.
- for adults or adolescents with homozygous familial hypercholesterolaemia the recommended starting dose is 420 mg once monthly. After 12 weeks your doctor may decide to increase the dose to 420 mg every two weeks. If you also receive apheresis, a procedure similar to dialysis where cholesterol and other fats are removed from the blood, your doctor may decide to start you on a dose of 420 mg every two weeks to coincide with your apheresis treatment.
- for adults with established atherosclerotic cardiovascular disease (a history of heart attack, stroke or blood vessel problems) the dose is either 140 mg every two weeks or 420 mg once monthly.

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

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.

See the detailed "Instructions for Use" at the end of this leaflet for instructions about how to store, prepare, and give your Repatha injections at home. If using the pre-filled pen, **place the correct (yellow) end of the pen on the skin before injecting.**

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

If you use more Repatha than you should

Contact your doctor or pharmacist immediately.

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.

4. Possible side effects

Like all medicines, this medicine 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)
- 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

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Repatha

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

Do not use this medicine 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.

Store in a refrigerator (2°C–8°C). Do not freeze. Store in the original carton in order to protect from light.

Your pre-filled pen may be left outside the refrigerator to reach room temperature (up to 25°C) before injection. This will make the injection more comfortable. After removal 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.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Repatha contains

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

What Repatha looks like and contents of the pack

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 one, two, three or six single use SureClick pre-filled pens. Not all pack sizes may be marketed.

Site of Manufacture of the Drug Product:

Amgen Manufacturing Limited
State Road 31
Kilometer 24.6
Juncos 00777-4060
Puerto Rico
USA

Marketing Authorisation Holder and Manufacturer:

Amgen Europe B.V.
Minervum 7061
4817 ZK Breda
The Netherlands

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in November 2019.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>.

THIS MEDICINE

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.

AMGEN
Repatha

EN



MCKO1820

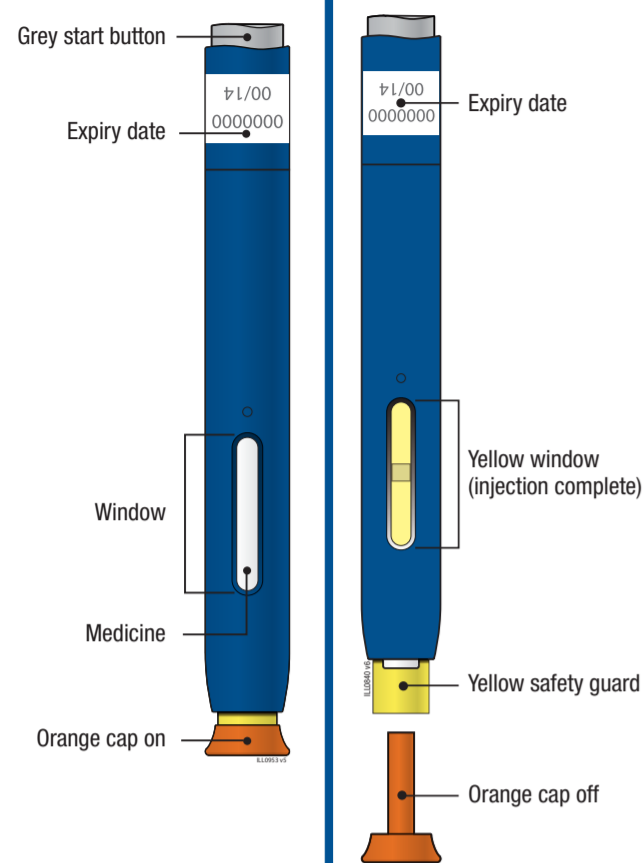


MCKO1820

Guide to parts

Before use

After use



Important: Needle is inside

Important

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

- Your healthcare provider will tell you how many Repatha pre-filled pens are needed for your dose. If injecting more than one Repatha pre-filled pen, after reaching room temperature, all injections should be given within a 30 minute period.
- Keep the Repatha pre-filled pen in original carton to protect it from light.
- The Repatha pre-filled pen is to be stored in the refrigerator (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 orange cap on a Repatha pre-filled pen contains a needle cover (located inside the cap) that is composed of dry natural rubber, which is made from latex. Tell your healthcare provider if you are allergic to latex.
- Keep the Repatha pre-filled pen out of the sight and reach of children.
- Do not** freeze or use the Repatha pre-filled pen if it has been frozen.
- Do not** shake the Repatha pre-filled pen.
- 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 expiration date.

Step 1: Prepare

A Remove one Repatha 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.

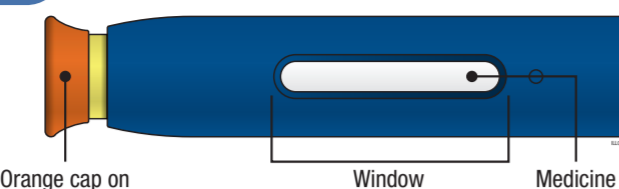
Do not try to warm the pre-filled pen by using a heat source such as hot water or microwave.

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.

B Inspect the Repatha pre-filled pen.



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

Check the expiration date.

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

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

C Gather all materials needed for your injection.

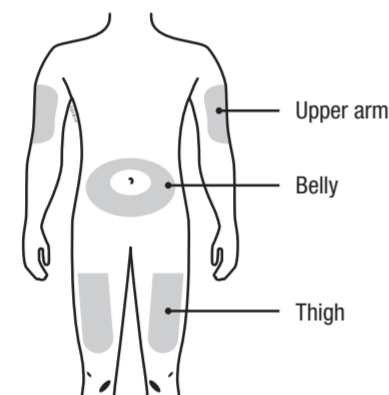
Wash your hands thoroughly with soap and water.

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

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



D Prepare and clean your injection site.



You can use:

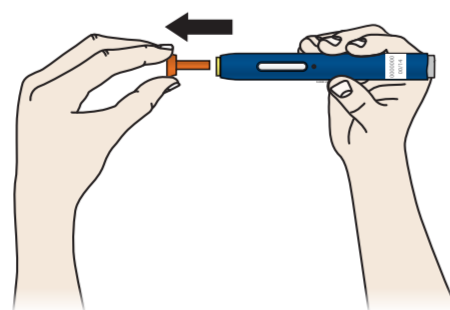
- Thigh.
- Belly, except for a 2 inch (5 centimetres) area around your belly button.
- Outer area of upper arm (only if someone else is giving you the injection).

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

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

Step 2: Get ready

A 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.



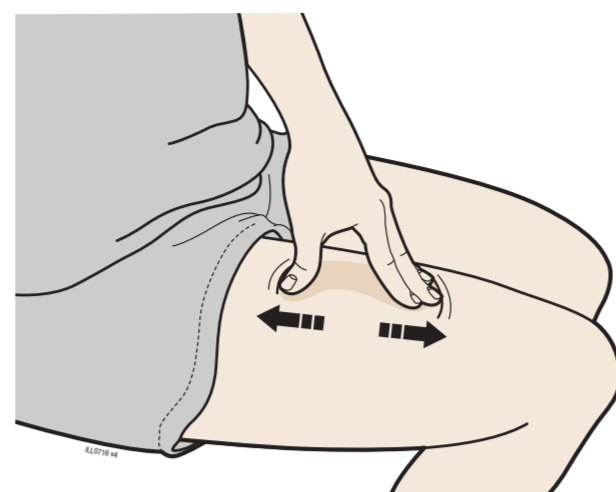
It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

- 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.

Important: **Do not** remove the orange cap from the pre-filled pen until you are ready to inject.

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

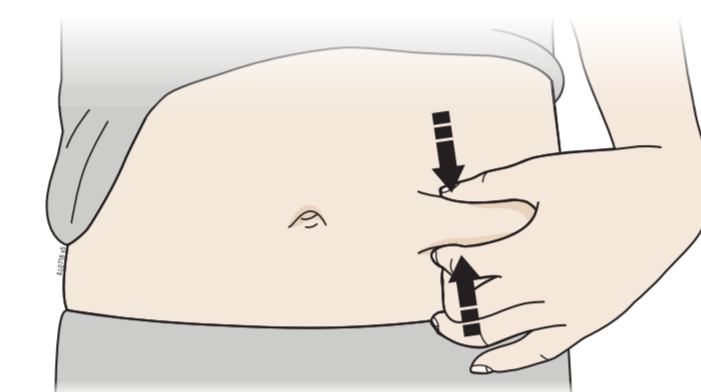
Stretch method



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

OR

Pinch method

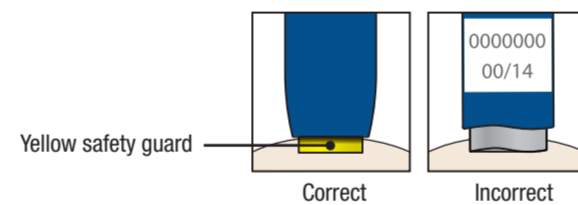


Pinch skin firmly between your thumb and fingers, creating an area about 2 inches (5 centimetres) wide.

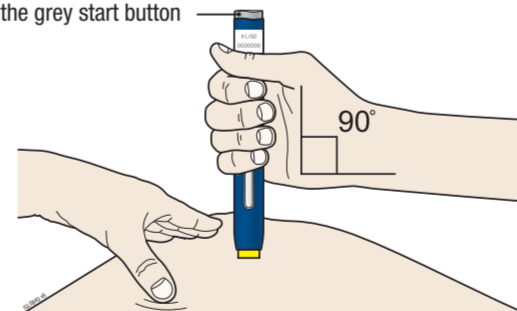
Important: It is important to keep skin stretched or pinched while injecting.

Step 3: Inject

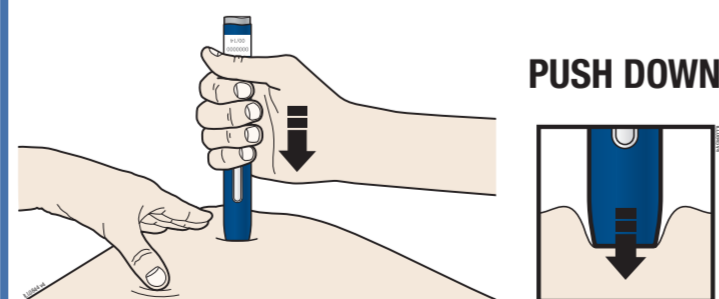
A Hold the stretch or pinch to create a firm surface. With the cap off, **place** the yellow end of the pre-filled pen on the skin at 90 degrees.



Do not touch the grey start button

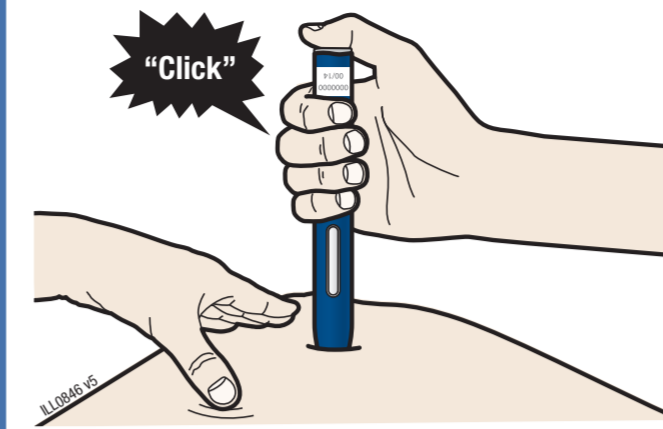


B Firmly **PUSH** down the pre-filled pen onto the skin until it stops moving.

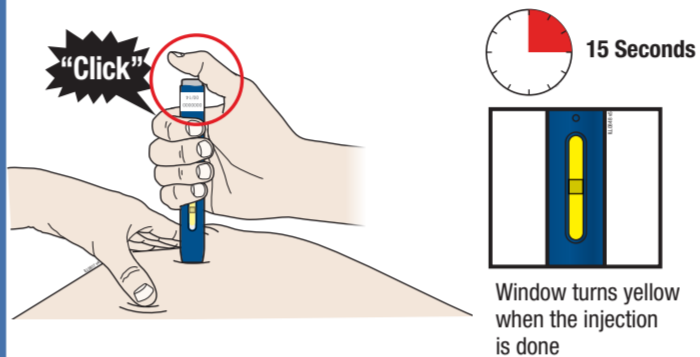


Important: You must push all the way down but **do not** touch the grey start button until you are ready to inject.

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



D Keep **PUSHING** down on the skin. Then **LIFT** thumb. 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

A 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.

- 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.

B Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. **DO NOT** rub the injection site. Apply a plaster if needed.