Repatha®
(evolocumab)

Repatha® can help to prevent myocardial infarction and stroke in patients with cardiovascular disease (arteriosclerosis)

Engelska

PATIENT INFORMATION

Distributed only via healthcare professionals

BROCHURE PRODUCED BY AMGEN AB
PO BOX 706
SE-169 27 Solna
+46 (0)8-695 11 00
www.amgen.se

TABLE OF CONTENTS

What is cholesterol? 4
What is Repatha® and what is it used for? 5
Overview injection pen 6
Important 7
How do I use SureClick pen to inject Repatha®? 8
Side effects 13
What else do I need to know before I use Repatha®? 14
Notes 15

REPATHA® AND SURECLICK

Repatha® is a medication that lowers the level of LDL cholesterol in the blood.

Repatha® can help prevent myocardial infarction, stroke and the need for invasive procedures that are performed to increase the blood flow in the heart's coronary arteries due to arteriosclerosis (also called atherosclerotic cardiovascular disease).

Repatha® is given as an injection under the skin (subcutaneously) with a SureClick pen.

The SureClick pen contains a single dose. Your doctor or nurse will instruct you how to use the SureClick pen.

ADVICE FOR WHEN YOU ARE PLANNING TO TAKE REPATHA®

Get started with Repatha® and get into a well-established routine. You can inject yourself or be injected by someone close to you who is trained to give you the injection. Your doctor will instruct you how often you should take your medicine. For most people this is once every two weeks.

Repatha® must be stored in the refrigerator (2ºC to 8ºC). Plan to have the injection when you have some time so that the pre-filled injection pen can reach room temperature before being injected. It may be a good idea to set a timer to make sure that you wait for 30 minutes.

WHAT IS CHOLESTEROL?[1]

Cholesterol is a type of fat (lipid) that is needed for several important bodily functions. Among other things, it is a necessary constituent of cell membranes and it is used to form bile acids which help you absorb fats from your diet. Cholesterol is also needed to make certain hormones.

Although cholesterol is important for the body, too much cholesterol, in the wrong places, is dangerous. Most cardiovascular diseases, such as myocardial infarction and stroke, are caused by cholesterol accumulating in the walls of vessels and leading to fatty deposits/calcification, which result in impaired blood flow and an increased risk of blood clots.

In order for cholesterol to be transported in the blood, it exists in various fat particles. In order to absorb LDL particles from the blood, the liver needs LDL receptors on the surface of liver cells. This is a very important process, as we know that too much LDL cholesterol in the blood increases the risk of cardiovascular disease. Some people have a hereditary deficiency of LDL receptors, which reduces the liver's uptake of LDL. This leads to raised LDL cholesterol levels and the risk of cardiovascular disease even at young age.

Because of the strong connection between the cholesterol in LDL particles and cardiovascular disease such as heart attack and stroke, LDL cholesterol is often referred to as "bad cholesterol". High LDL cholesterol, especially with other risk factors such as smoking, stress, being overweight and high blood pressure, increases the risk of the cholesterol binding to vessel walls and, in the longer term, gives rise to arteriosclerosis and/or atherosclerosis. Eventually the vessels can become completely clogged up. That is why it is important not to have excessively high LDL cholesterol levels.

The fats (lipids) we have in our blood are affected by our diet, but above all else they are affected by hereditary factors to a large extent. A large intake of saturated fat negatively affects the blood lipids profile, while the intake of other types of fat can affect it positively. Factors such as being overweight, stress and diabetes affect blood lipids negatively, while exercise can have a positive effect.

1) Hjärt- Lungfonden (year unknown) [Swedish Heart-Lung Foundation]. Cholesterol. Retrieved 11 March 2020, from Hjärt-Lungfonden, http://www.hjart-lungfonden.se/Sjukdomar/Halsa/Hogt-kolesterol/
2) Repatha® (evolocumab) Summary of Product Characteristics, Amgen March 2023, www.fass.se

WHAT IS REPATHA® AND WHAT IS IT USED FOR?[2]

Repatha® is a medication that lowers the level of "bad" cholesterol, a type of fat, in the blood.

Repatha® can help prevent myocardial infarction, stroke and the need for some invasive procedures that are performed to increase the blood flow in the heart's coronary arteries due to arteriosclerosis (also called atherosclerotic cardiovascular disease).

Repatha® contains the active substance evolocumab, a fully human monoclonal antibody (a type of specialised protein that is designed to bind specifically to a certain substance in the body). Repatha® binds to a substance that affects the liver's ability to absorb cholesterol from the blood – PCSK9.

By attaching and binding to PCSK9, the medicine increases the amount of cholesterol that can be absorbed by the liver, thereby reducing the level of LDL cholesterol in the blood.

Repatha® is given to patients for whom dietary advice and treatment are not sufficient to keep their cholesterol levels under control.

You must continue with your recommended and prescribed diet while taking this medicine.

Repatha® is used in addition to your dietary treatment if you are:

an adult with high cholesterol levels in your blood and have been diagnosed with atherosclerotic cardiovascular disease (and you have had a myocardial infarction, stroke or another vascular disease). *It is given:*

- together with a statin or other lipid-lowering treatment if the highest statin dose does not lower the cholesterol level sufficiently
- on its own or together with other lipid-lowering treatment when statins do not provide sufficient results or cannot be used

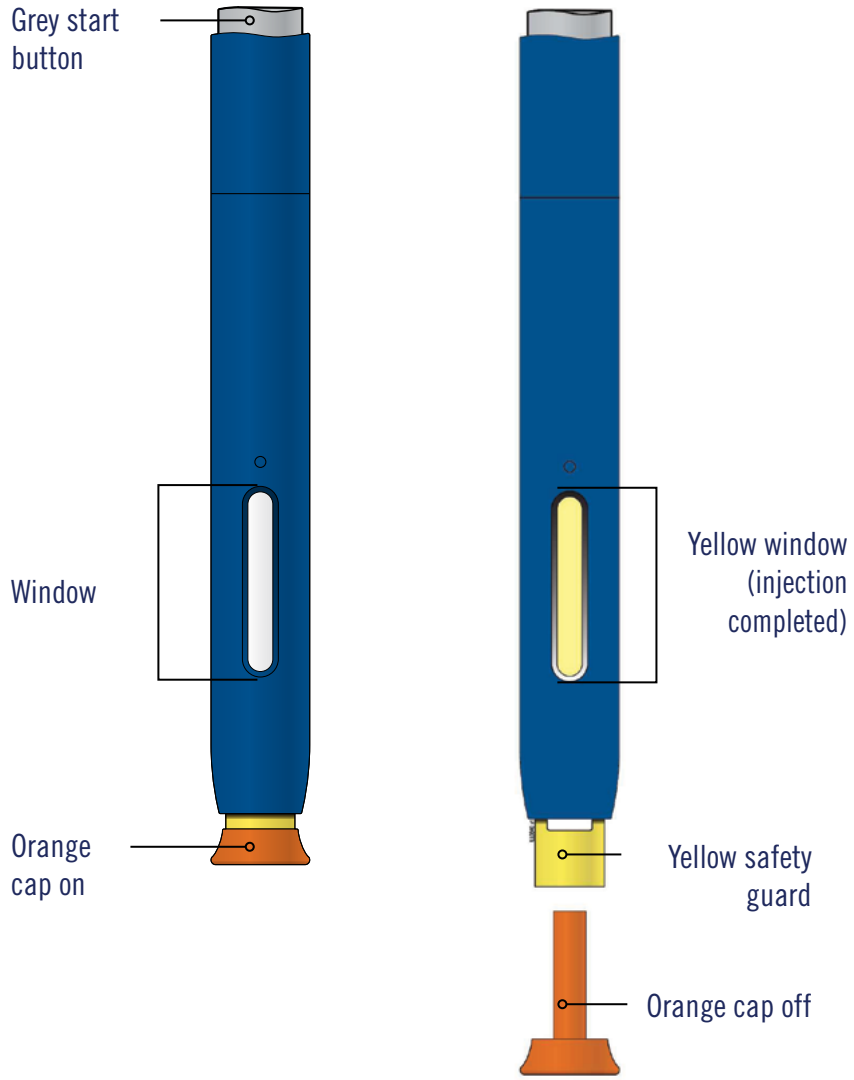
an adult with high blood cholesterol levels (primary hypercholesterolemia [heterozygous familial and non-familial] or mixed dyslipidaemia). *It is given:*

- together with a statin or other lipid-lowering treatment if the highest statin dose does not provide sufficient lowering of the cholesterol level
- on its own or together with other lipid-lowering treatment when statins do not provide sufficient results or cannot be used

an adolescent who is 10 years or older with high blood cholesterol levels due to a hereditary condition (so-called heterozygous familial hypercholesterolemia or HeFH). Repatha® is then given on its own or together with other cholesterol-lowering treatment

an adult or an adolescent who is 10 years or older with high blood cholesterol levels due to a hereditary condition, so-called homozygous familial hypercholesterolemia or HoFH. Repatha® is then also given together with other lipid-lowering treatment

OVERVIEW INJECTION PEN



IMPORTANT

READ THE FOLLOWING IMPORTANT INFORMATION BEFORE USING REPATHA® PRE-FILLED INJECTION PEN:

Store Repatha® in the original packaging as it is sensitive to light.

Store Repatha® in the refrigerator (2°C to 8°C). After taking the syringe out of the refrigerator, Repatha® may be stored at room temperature (up to 25°C) in the original packaging and must be used within 1 month.

It is important that you do not try to give yourself an injection if you have not received instructions from healthcare professionals.

The orange cap on Repatha® contains a needle cover (inside the cap) that is made from dry natural rubber, a type of latex. Tell the healthcare professional if you are allergic to latex.

Keep Repatha® out of the sight and reach of children.

Do not freeze Repatha® and do not use it if it has been frozen.

Do not shake Repatha®.

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

Do not use Repatha® if it has been dropped on a hard surface. Parts of Repatha® may have been damaged even if you cannot see any cracks.

Do not use Repatha® if the expiry date has passed.

TIP:

- Write the date of injection in your calendar and/or as a reminder in you mobile phone.
- Take your injection on certain days, e.g. the first and third Saturday of the month.
- Write your injection date on the packaging and place it so it is clearly visible in the refrigerator.
- Use the reminder function in the Repatha®app (see more information on page 15).

HOW DO I USE THE SURECLICK PEN TO INJECT REPATHA®

STEP 1:

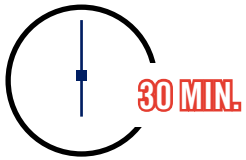
A. PREPARATION

Take one Repatha® SureClick pen out of the packaging.

Carefully lift the pre-filled injection pen straight up out of the box.

Put the original packaging with unused injection pens back in the refrigerator.

Wait at least 30 minutes so that Repatha® is at room temperature before injecting.



PLEASE NOTE:

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

B. CHECK THE PRE-FILLED INJECTION PEN.

Check that the medicine in the window is clear and colourless to slightly yellowish.
Check the expiry date.

DO NOT USE THE PRE-FILLED INJECTION PEN IF:

- the medicine is cloudy or discoloured or contains large lumps, flakes or particles
- any part of the pen seems to be broken or damaged
- you have dropped the pre-filled injection pen
- the orange cap is missing or is not sealed properly before injection
- the expiry date has passed

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

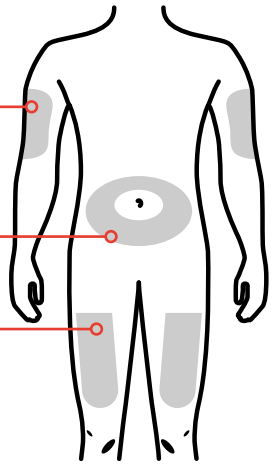
C. GATHER ALL THE MATERIALS YOU NEED FOR THE INJECTION.

Wash your hands properly with soap and water.

Place the following on a clean, well-lit surface:

- A new pre-filled injection pen
- Alcohol wipes
- Cotton pad or gauze
- Plaster
- Sharps bin

D. PREPARE AND WASH THE SITE OF INJECTION



Wipe the injection site with an alcohol wipe.

Let the skin dry. Do NOT touch this area again before injecting.

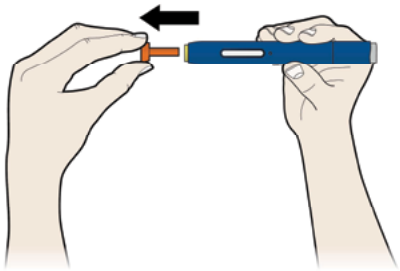
Choose a new site each time you inject. If you have to use the same injection site, you must make sure that it is not exactly the same site as the time before.

Do NOT inject in areas that are tender, bruised, red or hard. Avoid injecting into areas with scars or stretch marks.

STEP 2:

A. PULL THE ORANGE CAP STRAIGHT OFF WHEN YOU ARE READY TO INJECT.

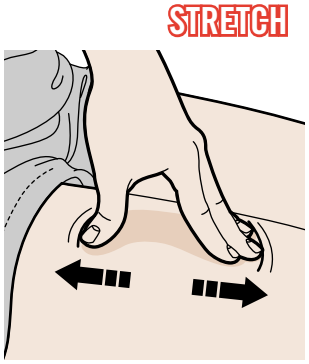
It is normal to see a drop of the medicine on the needle tip or the yellow safety guard



PLEASE NOTE:

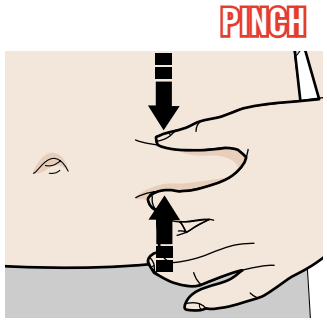
- do not turn or twist the orange cap
- do not put the orange cap back on the pre-filled injection pen
- do not put your fingers into the yellow safety guard
- do NOT remove the orange cap from the pre-filled injection pen before you are ready to inject
- do not leave the orange cap off for longer than 5 minutes, because the medicine can dry out

B. STRETCH OR PINCH TOGETHER THE AREA OF THE INJECTION SITE TO ACHIEVE A TAUT SURFACE.



Stretching method

Stretch out the skin by moving your thumb and fingers in opposite directions to create a taut area of around 5 cm



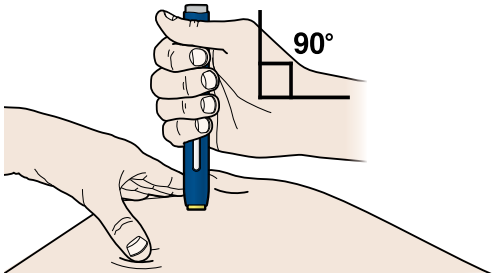
Pinching method

Pinch together the skin between your thumb and fingers to make a fold of approximately 5 cm

It is important to keep the skin stretched or pinched until the injection has finished

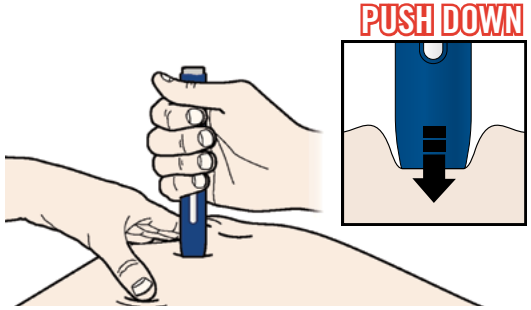
STEP 3:

A. CONTINUE TO KEEP THE SKIN STRETCHED OR PINCHED. PLACE THE PRE-FILLED INJECTION PEN AGAINST THE SKIN AT AN ANGLE OF 90 DEGREES. THE ORANGE CAP MUST BE REMOVED.



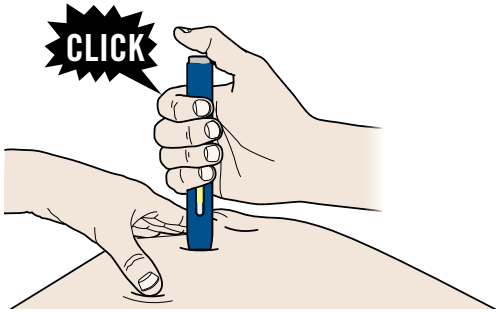
Do NOT touch the grey start button yet

B. PUSH THE PRE-FILLED INJECTION PEN DOWN AGAINST THE SKIN UNTIL IT STOPS.

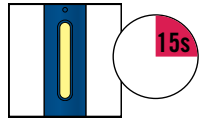


You must press all the way down, but do NOT touch the grey start button before you are ready to inject

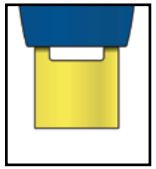
C. WHEN YOU ARE READY TO INJECT, PUSH THE GREY START BUTTON. YOU WILL HEAR A CLICK.



D. CONTINUE TO PUSH DOWN ON THE SKIN. THEN LIFT YOUR THUMB. THE INJECTION CAN TAKE ABOUT 15 SECONDS.



Hold the pen stably in place for 15 seconds. The pen will click again when the injection has finished, but do not worry if you do not hear the click. The window turns yellow when the injection is finished.



NOTE: When lifting the pre-filled injection pen from your skin, the needle will be covered automatically.

STEP 4:

A. DISCARD THE USED INJECTION PEN AND ORANGE NEEDLE CAP.

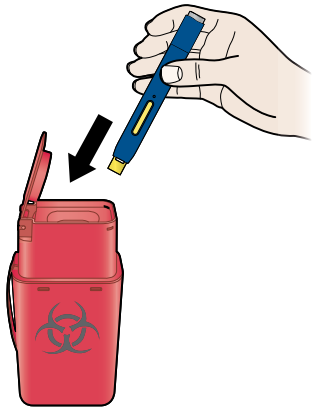
Place the used pre-filled injection pen and the needle cap in a sharps bin.

Talk to the healthcare professional about how the waste must be disposed of. There may be local recommendations for this.

Keep the pre-filled injection pen and sharps bin out of the sight and reach of children.

PLEASE NOTE:

- Do not reuse the pre-filled injection pen.
- Do not put the cap back on the pre-filled injection pen and do not put your fingers into the yellow safety guard.



B. EXAMINE THE INJECTION SITE.

If it bleeds, you can press a cotton swab or compress on the injection site. Do NOT rub the injection site. You can put on a plaster if needed.

View the instruction video at fass.se under the tab “Tips for use”

SIDE EFFECTS

POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

COMMON:

1 in 10 users who took part in the clinical development programme developed:

- Flu (high temperature, sore throat, runny nose, cough and chills)
- Common cold such as runny nose, sore throat or sinus infections
- Nausea
- Back pain
- Joint pain (arthralgia)
- Muscle pain
- Reactions at the injection site, redness, bruising or pain
- Rash
- Headache

UNCOMMON:

1 in 100 people who took part in the clinical development programme developed:

- Hives, red itchy bumps on skin (urticaria)
- Flu-like symptoms

REPORTING OF SIDE EFFECTS

If you get any side effects, talk to your doctor, pharmacist or nurse. This also includes any side effects not listed in this leaflet. You can also report side effects directly to the Swedish Medical Products Agency via http://www.lakemedelsverket.se/en

By reporting side effects, you can help provide more information on the safety of this medicine. The Swedish Medical Products Agency PO Box 26751 03 Uppsala

WHAT ELSE DO I NEED TO KNOW BEFORE I USE REPATHA®?

DO NOT USE REPATHA®

- if you are allergic to evolocumab or any of the other ingredients of this medicine

WARNINGS AND PRECAUTIONS

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

- liver disease

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

PREGNANCY AND BREAST-FEEDING

Inform your doctor if you are trying to get pregnant, think you may be pregnant or become pregnant when taking Repatha®. It is not known whether Repatha® is excreted in breast milk. That is why it is important that you tell the doctor if you are breast-feeding or plan to do so.

NOTES

Repatha® (evolocumab) Summary of Product Characteristics, Amgen March 2023, package leaflet and www.fass.se

For more information always read the package leaflet that accompanies the packaging or online at fass.se

Repatha® (evolocumab) R_x, (F), ATC: C10AX13. 140 mg solution for injection, solution in pre-filled injection pen for single use.

Indication – Established atherosclerotic cardiovascular disease:
Repatha® is indicated for the treatment of adults with established atherosclerotic cardiovascular disease (myocardial infarction, stroke or peripheral artery disease) to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:

- in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

Indication – Hypercholesterolemia and mixed dyslipidaemia:
Repatha® is indicated for treatment of primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia in adults, and in adolescents aged 10 years or older with heterozygous familiar hypercholesterolemia, as an adjunct to diet:

- in combination with a statin or statins in combination with other lipid-lowering therapies in patients unable to reach LDL-C goals but with the maximum tolerated dose of a statin or,
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

Indication – Homozygous familial hypercholesterolemia:
Repatha® is indicated for treatment of homozygous familial hypercholesterolaemia in adults and adolescents aged 10 and over, in combination with other lipid-lowering therapies.

Repatha® is reimbursed for: Patients with diagnosed atherosclerotic cardiovascular disease who, despite maximum tolerated treatment with statin and ezetimibe, have a persistent LDL cholesterol of 1.8 mmol/L or higher. Patients with diagnosed diabetes mellitus and target organ damage (microalbuminuria, retinopathy, or neuropathy), or at least three major risk factors, or early onset of type 1 diabetes mellitus with long duration, who, despite maximum tolerated treatment with statin and ezetimibe, have a persistent LDL cholesterol of 2.6 mmol/L or higher. Patients with diagnosed heterozygous familial hypercholesterolemia who, despite maximum tolerated treatment with statin and ezetimibe, have a persistent LDL cholesterol of 2.6 mmol/L or higher. Patients with diagnosed homozygous familial hypercholesterolemia.

See www.fass.se.

SWE-145-1123-80015 Jan 2024

AMGEN

Gustav III:s Boulevard 54
SE-169 27 SOLNA
www.amgen.se