# PATIENT INFORMATION LEAFLET

## SCHEDULING STATUS: S4

## REPATHA® 140 mg solution for injection in pre-filled syringe

evolocumab

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

- Keep this leaflet. You may need to read it again.

  If you have further questions, please ask your doctor, pharmacist or nurse. REPATHA® 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.
- 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

**What is in this leaflet**

## 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.

### 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.

a child aged 10 years and older with a high cholesterol level in your blood because of a condition that runs in your family (heterozygous familial hypercholesterolaemia or HeFH). It is given alone or together with other cholesterol lowering treatments

- an adult or a child aged 10 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.

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).

## 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 REPATHA® (listed in section 6).

**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 syringe is made from dry natural rubber (a derivative of latex), which may cause severe allergic reactions.

In order 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.

**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.

**Other medicines and REPATHA®**

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

medicine.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, 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 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.

**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 REPATHA® exactly as your doctor has told you. Check with your doctor if you are not sure.

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 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 or children aged 10 years or older 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.

REPATHA® is given as an injection under the skin (subcutaneous).

If your doctor prescribes a dose of 420 mg you must use three pre-filled syringes because each pre-filled syringe 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.

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)
- Muscle pain
- Injection site reactions, such as bruising, redness, bleeding, pain or swelling
- Allergic reactions including rash
- Headache

**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 side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of REPATHA®.

Alternatively, suspected adverse events can be reported to:

Amgen South Africa (Pty) Ltd.

Tel: +27 (0)11 100 5300,

Email: safety-south-africa@amgen.com,

Adverse Event Reporting Fax: 0800 166 513

## 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 syringe may be left outside the refrigerator to reach room temperature (up to 25 °C) before injecting. 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 use this medicine if you notice it is discoloured or contains large lumps, flakes or coloured particles.

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 pre-filled syringe contains 140 mg of evolocumab in 1 ml of solution.
- The other ingredients are proline, glacial acetic acid, polysorbate 80, sodium hydroxide,water for injection.

### 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.

Each pack contains one single-use pre-filled syringe.

**Holder of Certificate of Registration**

Amgen South Africa (Pty) Ltd.

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2021

South Africa

**This leaflet was last revised in**

23 June 2025

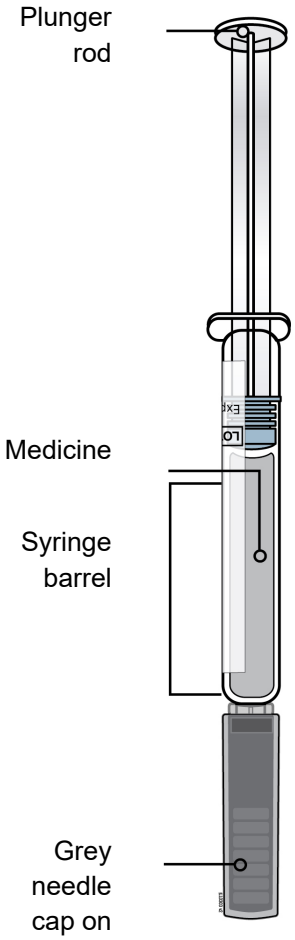
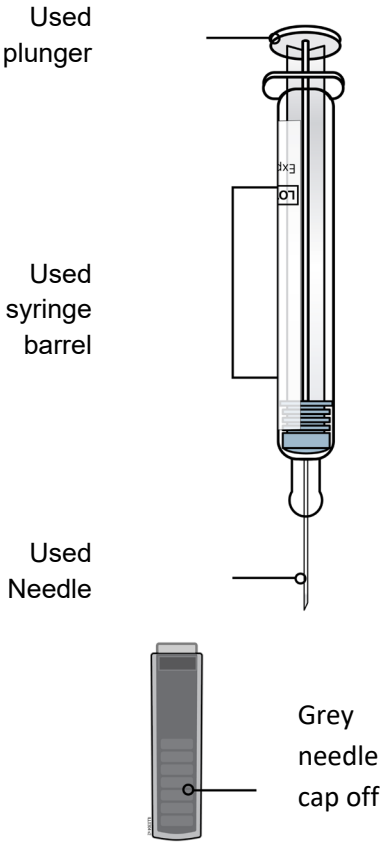
**Registration Number**

49/30.1/1116

Instructions for use:

Repatha® single use pre-filled syringe

Guide to parts

| Before use | After use |
|---|---|
|   |   |

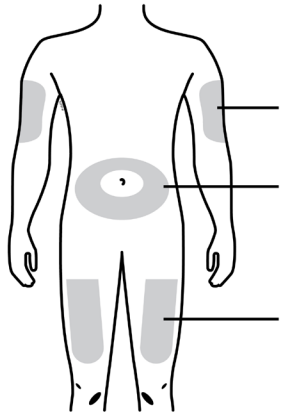
Needle is inside.

| Important |
|---|
| Before you use a single use Repatha® pre-filled syringe, read this important information:<br>• Do not freeze or use the Repatha® pre-filled syringe if it has been frozen.<br>• Do not use the Repatha® pre-filled syringe if the packaging is open or damaged.<br>• Do not use the Repatha® pre-filled syringe if it has been dropped onto a hard surface. Part of the syringe may be broken even if you cannot see the break. Use a new Repatha® pre-filled syringe.<br>• Do not remove the grey needle cap from the Repatha® pre-filled syringe until you are ready to inject. |

| Step 1: Prepare | |
|---|---|
| A | Remove the Repatha® pre-filled syringe carton from the refrigerator and wait 30 minutes. |
| Wait at least 30 minutes for the pre-filled syringe in the carton to naturally reach room temperature before injecting.<br><br>Check that the name Repatha® appears on the carton label.<br>• Do not try to warm the Repatha® pre-filled syringe by using a heat source such as hot water or microwave. | |
| • Do not leave the Repatha® pre-filled syringe exposed to direct sunlight. | |
| • Do not shake the Repatha® pre-filled syringe. | |

| B | Gather all materials needed for your injection. |
|---|---|
| Wash your hands thoroughly with soap and water.<br><br>On a clean, well-lit, flat work surface, place:<br>• One Repatha® pre-filled syringe in its tray.<br>• Alcohol wipes.<br>• Cotton ball or gauze pad.<br>• Plaster.<br>• Sharps disposal container.<br>• Do not use if expiry date on the Repatha® pre-filled syringe carton has passed. | |

| C | Choose your injection site. |
|---|---|

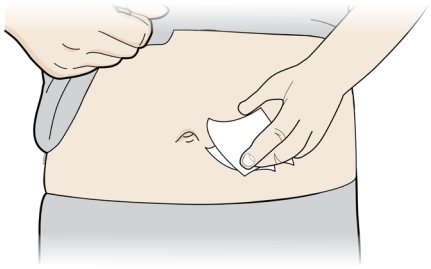



You can use:

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

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.

| D | Clean your injection site. |
|---|---|

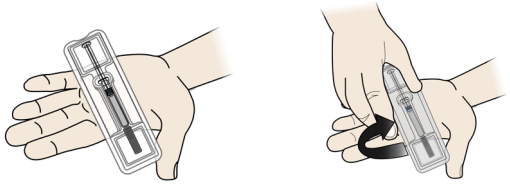


Clean your injection site with an alcohol wipe. Let your skin dry before injecting.

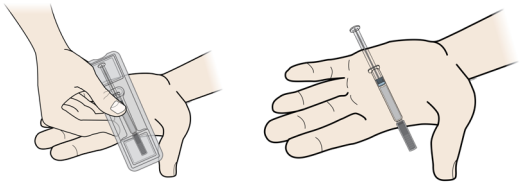
- Do not touch this area of skin again before injecting.

| E | Remove the pre-filled syringe from the tray. |
|---|---|

Turn tray over



Gently Press



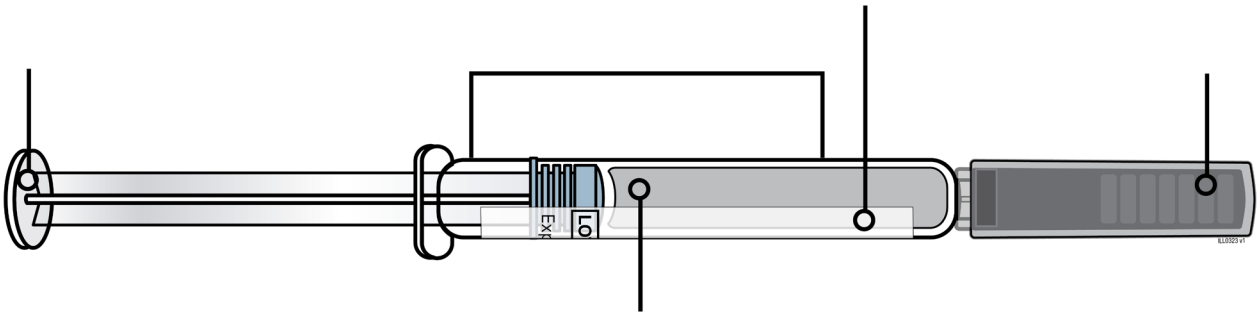
To remove:

- Peel the paper off of the tray.
- Place the tray on your hand.
- Turn the tray over and gently press the middle of the tray's back to release the syringe into your palm.
- If the pre-filled syringe does not release from the tray, gently press on the back of tray.
- Do not pick up or pull the pre-filled syringe by the plunger rod or grey needle cap. This could damage the syringe.
- Do not remove the grey needle cap from the pre-filled syringe until you are ready to inject.

Always hold the pre-filled syringe by the syringe barrel.

| F | Inspect medicine and syringe. |
|---|---|

Plunger rod | Syringe barrel | Syringe label with expiration date | Grey needle cap on



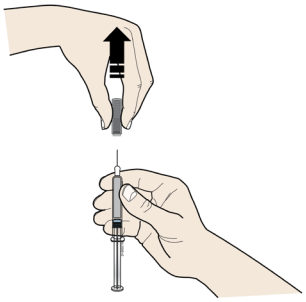
Medicine

Always hold the pre-filled syringe by the syringe barrel.
Check that:

- The name Repatha® appears on the pre-filled syringe label.
- The medicine in the pre-filled syringe is clear and colourless to slightly yellow.
- Do not use the pre-filled syringe if any part of the pre-filled syringe appears cracked or broken.
- Do not use the pre-filled syringe if the grey needle cap is missing or not securely attached.
- Do not use the pre-filled syringe if the medicine is discoloured or contains large lumps, flakes or coloured particles.
- Do not use the pre-filled syringe if the expiration date on the pre-filled syringe has passed.

| Step 2: Get ready | |
|---|---|
| A | Carefully pull the grey needle cap straight out and away from your body. Do not leave the grey needle cap off for more than 5 minutes. This can dry out the medicine. |

1.



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

2.

Immediately place the cap in the sharps disposal container.

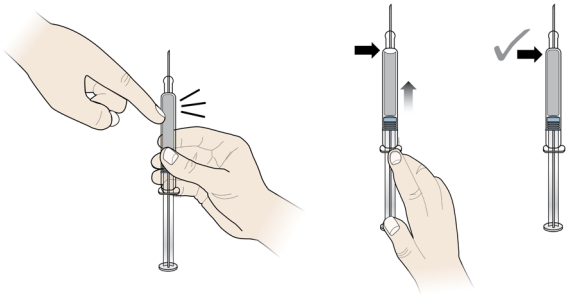
- Do not twist or bend the grey needle cap. This can damage the needle.
- Do not put the grey needle cap back onto the pre-filled syringe.

| B | Remove the air bubble / gap. |
|---|---|

You may notice an air bubble/gap in the Repatha® pre-filled syringe.

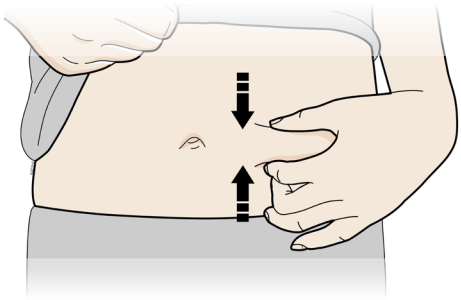
If you notice an air bubble/gap:

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



- Do not tap the syringe needle.

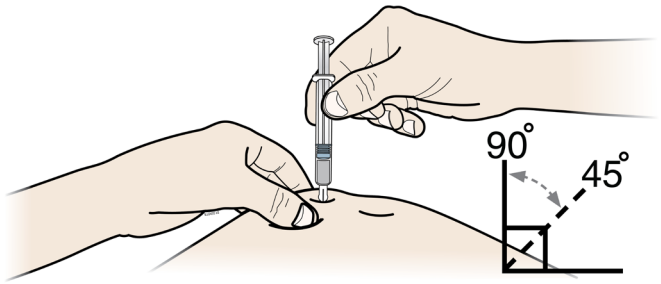
| | |
|---|---|
| C | PINCH your injection site to create a firm surface. |



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

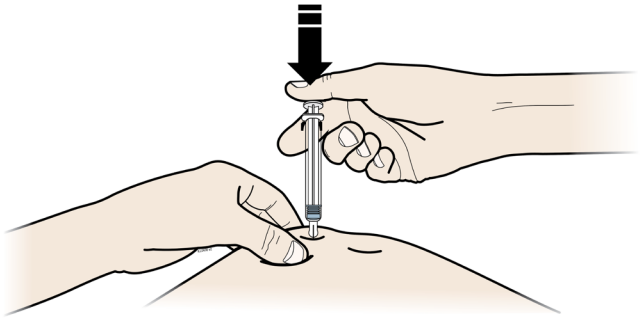
It is important to keep the skin pinched while injecting.

| Step 3: Inject | |
|---|---|
| A | Hold the PINCH. Insert the needle into the skin using a 45 to 90 degree angle. |

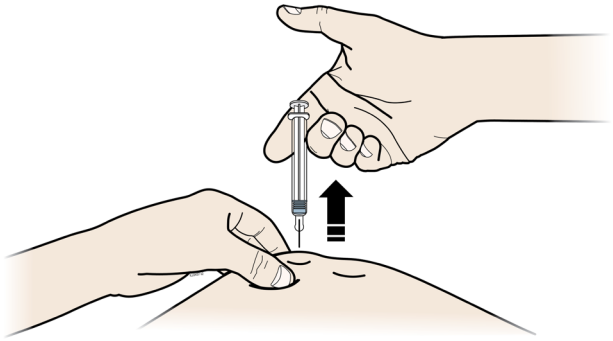



- Do not place your finger on the plunger rod while inserting the needle.

| B | Using slow and constant pressure, PUSH the plunger rod all the way down until the syringe is empty. |
|---|---|



| C | When done, RELEASE your thumb, and gently lift the syringe off skin. |
|---|---|



- Do not put the grey needle cap back onto the used syringe.

| Step 4: Finish | |
|---|---|
| A | Immediately place the used syringe in a sharps disposal container. |

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

- Do not reuse the used syringe.
- Do not use any medicine that is left in the used syringe.
- Do not recycle the syringe or the sharps disposal container or throw it into household rubbish.

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

| B | Examine the injection site. |
|---|---|

If there is blood, press a cotton ball or gauze pad on your injection site. Apply a plaster if needed.

- Do not rub the injection site.

**REFERENCES:**

| | |
|---|---|
| Reference 4: | Module 1.3.2.1 Approved annotated PIL PFS |