

# Repatha<sup>®</sup>

Evolocumab (rch) - e" voe lok' ue mab

## Consumer Medicine Information

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### What is in this CMI

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This leaflet answers some common questions about Repatha.

It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Repatha against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor, pharmacist or nurse.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What Repatha is used for

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Repatha is a medicine to lower increased levels of cholesterol.

Repatha lowers levels of total cholesterol, "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, Repatha raises levels of "good" cholesterol (HDL cholesterol).

Evolocumab, the active ingredient of Repatha, works by helping the liver's ability to remove bad cholesterol from the blood.

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL. LDL cholesterol is often called "bad" cholesterol because it can build up in

the walls of your arteries forming plaque. Eventually this plaque build-up 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 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 may increase your risk for heart disease.

Repatha is used in adults who cannot control their cholesterol levels by a cholesterol lowering diet. You should stay on your cholesterol lowering diet as directed by your doctor while taking this medicine.

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

- An adult with a high cholesterol level in your blood (hyperlipidaemia).
  - Together with other cholesterol lowering medications.
- 12 years and older who has a high cholesterol level in your blood because of a condition that runs in your family (homozygous familial hypercholesterolaemia or HoFH)
  - Together with other cholesterol-lowering treatments.
- Repatha is used to reduce the risk of heart attack, stroke, and certain heart procedures to restore blood

flow to the heart in patients who have or are at risk of heart disease, stroke, or blood vessel problems.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

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### Before you are given Repatha

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#### ***When you must not use it***

Do not use Repatha if you are allergic to evolocumab or any of the other ingredients of this medicine listed under Product Description in this insert.

If you are not sure whether you should start using this medicine, talk to your doctor.

#### ***Before you start to use it***

#### **Warnings and precautions**

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

- liver disease,
- severe kidney problems.

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

The needle cover of the glass pre-filled syringe 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 hyperlipidaemia.

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.

If you are trying to get pregnant or think you may be pregnant when taking Repatha :

- Inform your doctor
- If you are taking a statin or other cholesterol lowering medicine with Repatha, read the package leaflet of the other medicine that you are taking with 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.

### **Repatha contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. it is essentially 'sodium-free' and should not affect a sodium-controlled diet.

If you have not told your doctor about any of the above, tell him/her before you start using Repatha.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a

new medicine for you that you are taking Repatha.

These medicines may be affected by Repatha, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Repatha.

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## **How to use Repatha**

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Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

### **How much to use**

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

The recommended dose depends on the underlying condition:

- for primary hypercholesterolaemia is either 140 mg every two weeks or 420 mg once monthly.
- for 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 2 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.

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 the right way to prepare and inject Repatha. Do not try to inject Repatha until you or your caregiver have been shown the right way by your doctor or nurse.

If using the pre-filled pen, place the correct (yellow) end of the pre-filled pen on the skin before injecting.

See the detailed "Instructions for Use" provided with the medicine for instructions about the right way 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 other cholesterol lowering medicines, follow your doctor's instructions on how to take these medicines together. Please read the patient leaflet for those medicines as well.

### **If you forget to use it**

Use 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 that schedule exactly as your doctor has told you.

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## **While you are using Repatha**

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### **Things you must do**

If you are about to be started on any new medicine, remind your doctor, pharmacist or nurse that you are using Repatha.

If you become pregnant while using this medicine, tell your doctor immediately.

### **Things you must not do**

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine or lower the dosage without checking with your doctor.

### **Things to be careful of**

Be careful driving or operating machinery until you know how it affects you.

Repatha has no known effects on the ability to drive or use machines, but as a general precaution, avoid driving soon after you have an injection.

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### **In case of overdose**

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Immediately telephone your doctor or the National Poisons Centre (telephone 0800POISON or 0800 764 766) or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Repatha.

Do this even if there are no signs of discomfort or poisoning.

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### **Side effects**

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Tell your doctor, pharmacist or nurse as soon as possible if you do not feel well while you are using Repatha.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. Ask your doctor, pharmacist or nurse to answer any questions you may have.

Common: may affect up to 1 in 10 people

- Flu or flu-like symptoms such as 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 (myalgia)
- Headache
- Injection site reactions, redness, bruising, pain, swelling or bleeding.

Uncommon: may affect up to 1 in 100 people

- Allergic reactions including rash, hives, red itchy bumps on your skin (urticaria), swelling of face, mouth, tongue, or throat (angioedema).

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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### **After using Repatha**

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#### **Storage**

Store in a refrigerator at 2°C to 8°C. Do not freeze. Do not shake.

Keep your medicine in the carton in order to protect from light and do not expose to temperatures above 25 °C.

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.

Your medicine 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, your medicine may be stored at room temperature (up to 25°C) in the original carton and must be used within 30 days.

Keep it where children cannot reach it.

#### **Disposal**

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

Ask your pharmacist how to throw away medicines you no longer use.

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### **Product description**

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#### **What it looks like**

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.

Repatha is available as:

- A pack that contains one, two or three single-use SureClick pre-filled pens.
- A pack that contains one single-use pre-filled syringe.

#### **Ingredients**

The active ingredient is evolocumab.

- Each SureClick pre-filled pen or pre-filled syringe contains 140 mg of evolocumab in 1 mL of solution (140 mg/mL).

Other ingredients:

- proline
- glacial acetic acid
- polysorbate 80
- water for injection
- sodium hydroxide

The needle shield on the pre-filled pen and the needle cover on the pre-filled syringe contain a derivative of latex.

#### **Sponsor**

Repatha is supplied in New Zealand by:

Amgen (New Zealand) Limited  
Level 22, PwC Tower  
15 Customs Street West  
Auckland, New Zealand

Telephone: 0800 443 885

Email: [medinfo.JAPAC@amgen.com](mailto:medinfo.JAPAC@amgen.com)

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## **Date of Preparation**

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This CMI was prepared in August 2021