Repatha®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Repatha?

Repatha contains the active ingredient evolocumab. Repatha is used to treat high cholesterol. Repatha is also used to treat high cholesterol in adults and people 12 years and older who have high cholesterol because of a condition that runs in their family. Repatha can be used with other cholesterol lowering medicines in adults with heart disease to reduce the risk of heart attack, stroke, and certain heart procedures to restore blood flow to the heart.

For more information, see Section 1. Why am I using Repatha? in the full CMI.

2. What should I know before I use Repatha?

Do not use if you have ever had an allergic reaction to evolocumab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Repatha? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Repatha and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Repatha?

- Repatha is injected under the skin (subcutaneous)
- Repatha can be self-administered by injection under the skin after training from your doctor or nurse.

More instructions can be found in Section 4. How do I use Repatha? in the full CMI.

5. What should I know while using Repatha?

Things you should do	• Remind any doctor, dentist, pharmacist or nurse you visit that you are using Repatha.

	• Keep all of your doctor's appointments so that your progress can be monitored.
Things you should not do	• Do not stop using this medicine or lower your dose without checking with your doctor. • Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Repatha 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.
Looking after your medicine	• 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.

For more information, see Section 5. What should I know while using Repatha? in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: signs of an allergic reaction, such as rash with, shortness of breath, wheezing or difficulty breathing, swelling of the face, mouth, lips, tongue, throat or other parts of the body.

Common side effects include: flu or flu-like symptoms, such as high temperature, runny nose, cough and chills, sore throat or sinus infections, nausea, rash, joint pain, back pain, injection site reactions including redness, bruising, pain, swelling or bleeding.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Repatha®

Active ingredient(s): *Evolocumab (rch) - e" voe lok' ue mab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Repatha. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Repatha.**

Where to find information in this leaflet:

1. Why am I using Repatha?
2. What should I know before I use Repatha?
3. What if I am taking other medicines?
4. How do I use Repatha?
5. What should I know while using Repatha?
6. Are there any side effects?
7. Product details

1. Why am I using Repatha?

Repatha contains the active ingredient evolocumab. Repatha is a protein (human monoclonal antibody) that lowers cholesterol. Repatha is given as an injection under the skin (subcutaneous).

Repatha is used with other cholesterol lowering medicines in adults with heart disease to reduce the risk of heart attack, stroke, and certain heart procedures to restore blood flow to the heart. Risk factors of heart disease include a history of heart attack, stroke or blood vessel disease.

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

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of Low Density Lipoprotein (LDL) and High Density Lipoprotein (HDL) cholesterol.

Repatha lowers LDL cholesterol and triglycerides. It can raise your HDL cholesterol as well.

LDL cholesterol 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 helps to keep LDL 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 can be used with other cholesterol lowering medicines in adults to treat high cholesterol. When a statin cannot be used or does not work well, Repatha can be used alone or together with other cholesterol lowering medicines.

Repatha can be used with other cholesterol lowering medicines for people 12 years and older who have high cholesterol because of a condition that runs in their family (homozygous familial hypercholesterolaemia).

2. What should I know before I use Repatha?

Warnings

Do not use Repatha if:

- you are allergic to evolocumab, or any of the ingredients listed at the end of this leaflet or medicines or other products that are produced by DNA technology using Chinese Hamster Ovary cells.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

If you are taking another cholesterol lowering medicine with Repatha, read the patient leaflet of that particular medicine as well.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Your doctor will help you decide whether to stop breast-feeding, or whether to stop using Repatha, considering the benefit of breast-feeding to the baby and the benefit of Repatha to the mother.

Your doctor can discuss with you the risks and benefits involved.

Use in children and adolescents

- Do not give this medicine to a child under the age of 18 years except for children over 12 years with a rare form of high cholesterol.

- Repatha has only been studied in children over 12 years with a rare form of high cholesterol which runs in families, called homozygous familial hypercholesterolaemia.
- Repatha has not been studied in children under 12 years and has not been studied in children with high cholesterol due to other causes.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Repatha can be used with other cholesterol lowering medicines unless they cannot be used or do not work well.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Repatha.

4. How do I use Repatha?

How much to take / use

- The recommended dose for adults with high cholesterol and heart disease to reduce the risk of heart attack, stroke and certain heart procedures is either 140 mg single SureClick pen 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 you have been prescribed the 420 mg dose, this can be given as three 140 mg SureClick pens. The three injections should be given consecutively within 30 minutes.
- Follow the instructions provided and use Repatha until your doctor tells you to stop.

When to take / use Repatha

- Before starting Repatha, you should be on a cholesterol lowering diet and regularly exercising to lower your cholesterol.
- You should stay on your cholesterol lowering diet and exercise as directed by your doctor 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.
- Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told

you. Check with your doctor, pharmacist or nurse if you are not sure.

How to use Repatha

- Repatha is injected under the skin.
- If your doctor decides that you or a caregiver can give the injections of Repatha you or your caregiver will receive training on the right way to prepare and inject Repatha.
- If using the pre-filled pen, place the correct (yellow) end of the pre-filled pen on the skin before injecting
- Follow the "Instructions for Use" leaflet in the pack which provides instructions about the right way to store, prepare, and give your Repatha injections at home.

If you forget to use Repatha

Repatha should be used regularly at the same time every 2 weeks or once a month. If you miss your dose at the usual time, use Repatha as soon as you can after the missed dose.

Contact your doctor who will tell you when you should schedule your next dose. Follow that schedule exactly as your doctor has told you.

Do not take a double dose to make up for the dose you missed.

If you use too much Repatha

If you think that you have used too much Repatha, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Repatha?

Things you should do

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

Tell any other doctor, nurses, and pharmacist who treat you that you are using this medicine.

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

Keep all your doctor's appointments so that your progress can be checked.

Things you should not do

- Do not use Repatha to treat any other complaints unless your doctor tells you to.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Repatha 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store in a refrigerator at 2°C to 8°C. Do not freeze. Do not shake.
- Keep your medicine in the carton to protect from light.
- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General: • flu or flu-like symptoms, such as high temperature, sore throat,	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
runny nose, cough and chills • headache • skin rash **Infection-related:** • common cold, such as runny nose, sore throat or sinus infections **Gut-related:** • nausea **Bone-related:** • back pain **Muscle-related:** • joint pain • muscle pain (myalgia) **Injection site-related:** • redness • bruising • pain • swelling • bleeding	

Very serious side effects

Serious side effects	What to do
Signs of a serious allergic reaction: • shortness of breath • wheezing or difficulty breathing • swelling of the face, mouth, lips, tongue, throat or other parts of the body • skin rash with itching, including rash over the whole body, hives	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Repatha contains

Active ingredient **(main ingredient)**	evolocumab
Other ingredients **(inactive ingredients)**	proline glacial acetic acid polysorbate 80 water for injections sodium hydroxide

Do not take this medicine if you are allergic to any of these ingredients.

What Repatha 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 single-use SureClick pre-filled pen with 140 mg of evolocumab in 1 mL of solution (140 mg/mL) (Aust R 231152)

The needle cover of the pre-filled pen may contain dry natural rubber, which is a derivative of latex.

Some pre-filled pens have a needle cover that is not made with natural rubber latex. These cartons state: "Not made with natural rubber latex".

Who distributes Repatha

Amgen Australia Pty Ltd

Level 11, 10 Carrington St

Sydney NSW 2000

Ph: 1800 803 638

www.amgenmedinfo.com.au

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