

Repatha[®]

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

Consumer Medicine Information

What is in this leaflet

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.

What Repatha is used for

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.

Repatha contains the active substance evolocumab, which is a protein (human monoclonal antibody) that lowers cholesterol.

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 and older who have high cholesterol because of a condition that runs in their family (homozygous familial hypercholesterolaemia).

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.

Before you are given Repatha

When you must not use it

Do not use Repatha if you have an allergy to:

- any medicine containing evolocumab
- any of the ingredients listed at the end of this leaflet.
- medicines or other products that are produced by DNA technology using Chinese Hamster Ovary cells.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

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

Repatha has only been studied in children over 12 with a rare form of high cholesterol which runs in families, homozygous familial hypercholesterolaemia.

Repatha has not been studied in children under 12 and has not been studied in children with high cholesterol due to other causes.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to use it

Talk to your doctor, pharmacist or nurse before using Repatha.

If you use Repatha together with other cholesterol lowering medicines, please read the patient leaflet of that particular medicine.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan 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 trying to get pregnant or think you may be pregnant when taking Repatha:

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

If you become pregnant during Repatha treatment, please inform your doctor.

Tell your doctor if you are breast-feeding or plan to do so.

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.

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.

How to use Repatha

Follow all directions given to you by your doctor, pharmacist or nurse carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist or nurse for help.

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

How much to 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 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. Alternatively, the single-use automated mini-doser (AMD) can be used.

How to use it

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.

When to use it

Before starting Repatha, you should be on a cholesterol lowering diet and 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 long to use it

Continue using your medicine for as long as your doctor tells you.

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.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, 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.

While you are using Repatha

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.

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

Things you must 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.

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.

Side effects

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.

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

Ask your doctor, pharmacist or nurse to answer any questions you may have.

Tell your doctor, pharmacist or nurse if you notice any of the following and they worry you:

- unusual tiredness or weakness and looking pale
- stomach upset
- 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
- nausea or vomiting

- back pain
- joint pain
- muscle pain (myalgia)
- headache
- injection site reactions, such as redness, bruising, pain, swelling or bleeding

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen tell your doctor, nurse or pharmacist immediately or go to the Emergency at your nearest hospital.

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, mouth, lips, tongue, throat or other parts of the body
- allergic reactions including rash, itching or hives on the skin

These are very serious side effects. If you experience them, you may be having a serious allergic reaction to the medicine. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor, pharmacist or nurse if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Repatha

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.

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.

Product description

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 single-use SureClick pre-filled pen.
- A pack that contains one single-use automated mini-doser (AMD) and one pre-filled cartridge.

Ingredients

The active ingredient is evolocumab.

- Each SureClick pre-filled pen contains 140 mg of evolocumab in 1 ml of solution (140 mg/mL).
- Each pre-filled cartridge with an automated mini-doser contains 420 mg of evolocumab in 3.5 mL of solution (120 mg/mL).

Other ingredients:

- proline

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

The needle shield on the pre-filled pen contains a derivative of latex.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Repatha is supplied in Australia by:

Amgen Australia Pty Ltd

ABN 31 051 057 428

Level 7, 123 Epping Road

North Ryde NSW 2113

Medical Information: 1800 803 638

Australian Registration Number:

140 mg/mL pre-filled pen: AUST R 231152

120 mg/mL automated mini-doser: AUST R 273084

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