

Repatha[®] Solution for Injection in Pre-filled Syringe/Autoinjector

Evolocumab 140 mg/mL

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What REPATHA is used for

REPATHA is used:

- along with diet and other cholesterol-lowering medicines to reduce the risk of heart attack, stroke and certain types of heart surgery in adults with cardiovascular disease.
- to reduce low-density lipoprotein (LDL) or bad cholesterol in adults with high blood cholesterol levels called primary hyperlipidemia (including a type of high cholesterol called heterozygous familial hypercholesterolemia [HeFH]):
 - along with diet and a statin, with or without other cholesterol-lowering medicines, where additional lowering of LDL cholesterol is required,
 - along with diet, alone or together with other cholesterol-lowering medicines, when statins do not work well or cannot be used.
- Along with diet and other LDL-cholesterol-lowering therapies in pediatric patients aged 10 years and older with HeFH to reduce LDL-C
- along with diet and other LDL-lowering medicine in adults and pediatric patients aged 10 years and older with a type of high cholesterol called homozygous familial hypercholesterolemia (HoFH), who need additional lowering of LDL cholesterol.

It is not known if REPATHA is safe and effective in children with HeFH or HoFH who are younger than 10 years of age or

in children with other types of hyperlipidemia.

How REPATHA 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 specialized 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.

Before you use REPATHA

- *When you must not use it*

Do not use REPATHA if you or your child are allergic to evolocumab or to any of the ingredients in REPATHA. See the end of this leaflet for a complete list of ingredients in REPATHA.

- *Before you start to use it*

Before you or your child start using REPATHA, tell your healthcare provider about all your medical conditions, including if you or your child:

- are allergic to rubber or latex. The needle covers on the *single-use pre-filled syringes* and within the needle caps on the *autoinjectors* contain dry natural rubber.
- are pregnant or plan to become pregnant. It is not known if REPATHA will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking REPATHA.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take REPATHA or breastfeed.

- *Taking other medicines*

Tell your healthcare provider or pharmacist about any prescription and over-the-counter medicines, vitamins, or

herbal supplements you or your child take.

How to use REPATHA

- **See the detailed “Instructions for Use” about the right way to prepare and administer REPATHA.**

- *How much to use*

REPATHA is administered under the skin (subcutaneously), every 2 weeks or 1 time each month.

REPATHA comes as a single-use (1 time) *pre-filled syringe/autoinjector*

The recommended dosage of REPATHA in adults with established cardiovascular disease or in adults with primary hyperlipidemia or in pediatric patients aged 10 years and older with HeFH is either 140 mg every 2 weeks OR 420 mg once monthly administered subcutaneously. If switching dosage regimens, administer the first dose of the new regimen on the next scheduled date of the prior regimen.

The initial recommended dosage of REPATHA in adult and pediatric patients aged 10 years and older with HoFH is 420 mg once monthly administered subcutaneously.

If your healthcare provider prescribes you or your child the monthly dose, you or your child may use:

- 3 separate injections in a row, using a different *single-use pre-filled syringe/autoinjector* for each injection. Give all of these injections within 30 minutes.

If your healthcare provider decides that you or your child or a caregiver can administer REPATHA, you or your child or your caregiver should receive training on the right way to prepare and administer REPATHA.

Do not try to inject REPATHA until you or your child have been shown the right way by your healthcare provider or nurse.

- If you or your child are using the pre-filled autoinjector, put the **yellow safety guard (needle inside) of the SureClick® autoinjector on the skin before injecting.**

Do not inject REPATHA together with other injectable medicines at the same injection site.

If your healthcare provider has prescribed REPATHA along with other cholesterol-lowering medicines for you or your child, follow instructions from your healthcare provider. Read the patient information for those medicines.

- When to use it

Use REPATHA exactly as your healthcare provider tells you or your child to use it.

- How long to use it

Do not stop using REPATHA without talking with your healthcare provider. If you or your child stop using REPATHA, the cholesterol levels can increase.

- If you forget to use it

If you or your child forget to use REPATHA or are not able to take the dose at the regular time, inject your or your child's missed dose as soon as you remember, as long as it is within 7 days of the missed dose. If it is more than 7 days from the missed dose and you or your child are using the every-2-week dose, inject the next dose based on the original schedule. This will put you or your child back on the original schedule. If it is more than 7 days from the missed dose and you or your child are using the 1 time each-month dose, inject the dose and start a new schedule using this date. If you or your child are not sure when to take REPATHA after a missed dose, ask your healthcare provider or pharmacist.

- If you use too much (overdose)

If you or your child use more REPATHA than you should, talk to your healthcare provider or pharmacist.

While you are using it

- Things you must do

Tell your healthcare provider if you become pregnant while taking REPATHA.

- Things you must not do

Do not use REPATHA for a condition for which it was not prescribed. **Do not** give REPATHA to other people, even if they have the same symptoms that you or your child have. It may harm them. You can ask your pharmacist or healthcare provider for information about REPATHA that is written for healthcare professionals.

- Things to be careful of

Always check the label of your *single-use pre-filled syringe/autoinjector* to make sure you have the correct medicine and the correct dose of REPATHA before each injection.

Side effects

REPATHA can cause serious side effects including:

- **Serious allergic reactions.** Some people taking REPATHA have had serious allergic reactions. Stop taking REPATHA and call your healthcare provider or seek emergency medical help right away if you or your child have any of these symptoms:
 - trouble breathing or swallowing
 - raised bumps (hives)
 - rash, or itching
 - swelling of the face, lips, tongue, throat, or arms.

The most common side effects of REPATHA include: runny nose, sore throat, symptoms of the common cold, flu or flu-like symptoms, back pain, high blood sugar levels (diabetes) and redness, pain, or bruising at the injection site.

Tell your healthcare provider if you or your child have any side effect that bothers you or that does not go away. These are not all the possible side effects of REPATHA. Ask your healthcare provider or pharmacist for more information.

Call your healthcare provider for medical advice about side effects. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of REPATHA

- Storage

- Keep the REPATHA *pre-filled syringe/autoinjector* in the original carton to protect from light during storage.
- Keep the REPATHA *pre-filled syringe/autoinjector* in the refrigerator between 2°C to 8°C.
- If removed from the refrigerator, the REPATHA *pre-filled syringe/autoinjector* should be kept at room temperature (up to 25°C) in the original carton and must be used within **30** days.
- **Do not** freeze the REPATHA *pre-filled syringe/autoinjector* or use a REPATHA *pre-filled syringe/autoinjector* that has been frozen.

Keep the REPATHA *pre-filled syringe/autoinjector* out of the sight and reach of children.

- Disposal

Put the used *pre-filled syringe/autoinjector* in a sharps disposal container right away after use. **Do not** throw away (dispose of) the *pre-filled syringe/autoinjector* in your household trash.

Product Description

- What it looks like

REPATHA is a clear to opalescent, colorless to pale yellow solution. **Do not** use if the solution is cloudy or discoloured or contains particles.

- Ingredients

- Active Ingredient: evolocumab
- Inactive Ingredients: proline, glacial acetic acid, polysorbate 80, water for injection, and sodium hydroxide.

- MAL numbers:

Repatha Solution for Injection in Prefilled Syringe 140 mg
MAL17065004AZ

- MAL numbers:

Repatha Solution for Injection in Pre-filled Autoinjector 140 mg
MAL17065005AZ

Manufacturer

Amgen Manufacturing Limited LLC
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Product Registration Holder

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