

Patient Information
REPATHA® (ri-PAth-a)
(evolocumab)
injection, for subcutaneous use

What is REPATHA?

REPATHA is an injectable prescription medicine used:

- in adults with cardiovascular disease to reduce the risk of heart attack, stroke, and certain types of heart surgery.
- along with diet alone or together with other cholesterol-lowering medicines in adults with high blood cholesterol levels called primary hyperlipidemia (including a type of high cholesterol called heterozygous familial hypercholesterolemia [HeFH]) to reduce low density lipoprotein (LDL) or bad cholesterol.
- along with diet and other LDL-lowering medicines in children aged 10 years and older with HeFH to reduce LDL cholesterol.
- along with other LDL-lowering medicines in adults and children aged 10 years and older with a type of high cholesterol called homozygous familial hypercholesterolemia (HoFH), to reduce 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.

Who should not use REPATHA?

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.

What should I tell my healthcare provider before using REPATHA?

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-dose prefilled syringes and within the needle caps on the single-dose prefilled SureClick® autoinjectors contain dry natural rubber. The single-dose Pushtronex® system (on-body infusor with prefilled cartridge) is not made with natural rubber latex.
- 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.

If you or your child are pregnant or breastfeed during REPATHA treatment, you are encouraged to call Amgen at 1-800-772-6436 (1-800-77-AMGEN) or visit <https://wwwext.amgen.com/products/global-patient-safety/adverse-event-reporting> to share information about the health of you and your baby or your child and your child's baby.

Tell your healthcare provider or pharmacist about any prescription and over-the-counter medicines, vitamins, or herbal supplements you or your child take.

How should I use REPATHA?

- **See the detailed “Instructions for Use” that comes with this patient information about the right way to prepare and give REPATHA.**
- Use REPATHA exactly as your healthcare provider tells you or your child to use it.
- REPATHA is given under the skin (subcutaneously), every 2 weeks or 1 time each month.
 - If you or your child have HoFH, the recommended starting dose is 420 mg once monthly. After 12 weeks, your healthcare provider may decide to increase the dose to 420 mg every two weeks. If you or your child receive lipid apheresis, your healthcare provider may decide to start you or your child on a dose of 420 mg every two weeks to coincide with the apheresis treatment and you or your child should take the dose after the apheresis treatment.
- REPATHA comes as a single-dose (1 time) prefilled autoinjector (SureClick® autoinjector), as a single-dose prefilled syringe or as a single-dose Pushtronex® system (on-body infusor with prefilled cartridge). Your healthcare provider will prescribe the type and dose that is best for you or your child.
- If your healthcare provider prescribes you or your child the 420 mg dose, you or your child may use:
 - a single-dose on-body infusor with prefilled cartridge to give the injection over 5 minutes, or
 - 3 separate injections in a row, using a different single-dose prefilled syringe or single-dose prefilled 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 give REPATHA, you or your child 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 child have been shown the right way by your healthcare provider or nurse.
 - If you or your child are using the prefilled autoinjector, put the **yellow safety guard (needle inside) of the SureClick® autoinjector on the skin before injecting.**
- You or your child can inject into the thigh, upper arm, or stomach (abdomen), except for a **two**-inch area around the belly button.
- **Do not** choose an area where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.
- Always check the label of your single-dose prefilled autoinjector, single-dose prefilled syringe, or single-dose on-body infusor with prefilled cartridge to make sure you have the correct medicine and the correct dose of REPATHA before each injection.
- 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 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.
- If you or your child use more REPATHA than you should, talk to your healthcare provider or pharmacist.
- **Do not** stop using REPATHA without talking with your healthcare provider. If you or your child stop using REPATHA, the cholesterol levels can increase.

What are the possible side effects of REPATHA?

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 side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of REPATHA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **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.

What are the ingredients in REPATHA?

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

Manufactured by: Amgen Inc. One Amgen Center Drive, Thousand Oaks, California 91320-1799.

U.S. License Number 1080

Patent: <http://pat.amgen.com/repatha/>

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For more information about REPATHA, go to www.REPATHA.com or call 1-844-REPATHA (1-844-737-2842).

This Patient Information has been approved by the U.S. Food and Drug Administration.

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