

Patient Information
REPATHA® (ri-PATH-a)
(evolocumab)
Injection, for Subcutaneous Use

What is REPATHA?

REPATHA is an injectable prescription medicine called a PCSK9 inhibitor. REPATHA is used:

- along with diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL) or atherosclerotic heart or blood vessel problems, who need additional lowering of LDL cholesterol.
- along with diet and other LDL lowering therapies in people with homozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL), who need additional lowering of LDL cholesterol.

The effect of REPATHA on heart problems such as heart attacks, stroke, or death is not known.

It is not known if REPATHA is safe and effective in children with homozygous familial hypercholesterolemia (HoFH) who are younger than 13 years of age or in children who do not have HoFH.

Who should not use REPATHA?

Do not use REPATHA if you 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 start using REPATHA, tell your healthcare provider about all your medical conditions, including allergies, and if you:

- are allergic to rubber or latex. The needle covers on the single-use prefilled syringes and within the needle caps on the single-use prefilled SureClick® autoinjectors contain dry natural rubber. The single-use 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. You should not do both without talking to your healthcare provider first.

Tell your healthcare provider or pharmacist about any prescription and over-the-counter medicines you are taking or plan to take, including natural or herbal remedies.

How should I use REPATHA?

- **See the detailed “Instructions for Use” that comes with this patient information about the right way to prepare and administer REPATHA.**
- Use REPATHA exactly as your healthcare provider tells you to use it.
- REPATHA is administered under the skin (subcutaneously), every 2 weeks or 1 time each month.
- REPATHA comes as a single-use (1 time) prefilled autoinjector (SureClick® autoinjector), as a single-use prefilled syringe or as a single-use Pushtronex™ system (on-body infusor with prefilled cartridge). Your healthcare provider will prescribe the type and dose that is best for you.
- If your healthcare provider prescribes you the monthly dose, you may use:
 - a single-use on-body infusor with prefilled cartridge over 9 minutes, or
 - 3 separate injections in a row, using a different single-use prefilled syringe or single-use prefilled autoinjector for each injection. Give all of these injections within 30 minutes.
- If your healthcare provider decides that you or a caregiver can administer REPATHA, you or your caregiver should receive training on the right way to prepare and administer REPATHA. **Do not** try to administer REPATHA until you have been shown the right way by your healthcare provider or nurse.
- **Do not** administer REPATHA together with other injectable medicines at the same injection site.
- Always check the label of your single-use prefilled autoinjector, single-use prefilled syringe, or single-use on-body infusor with prefilled cartridge to make sure you have the correct medicine and the correct dose of REPATHA before each administration.
- If you forget to use REPATHA or are not able to take the dose at the regular time, administer your missed dose as soon as you remember, as long as there are more than 7 days until the next scheduled dose. If there are 7 days or less until your next scheduled dose, administer the next dose according to the original schedule. This will put you back on your original schedule. If you are not sure when to take REPATHA after a missed dose, ask your healthcare provider or pharmacist.
- If you 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 stop using REPATHA, your cholesterol

levels can increase.

What are possible side effects of REPATHA?

REPATHA can cause side effects including:

- **allergic reactions.** REPATHA may cause allergic reactions. Call your healthcare provider or go to the nearest hospital emergency room right away if you have any symptoms of an allergic reaction including a severe rash, redness, severe itching, a swollen face, or trouble breathing.

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

Tell your healthcare provider if you 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 Patient Information leaflets. **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 have. It may harm them.

This Patient Information leaflet summarizes the most important information about REPATHA. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about REPATHA that is written for healthcare professionals.

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

What are the ingredients in REPATHA?

- Active Ingredient: evolocumab
- Inactive Ingredients: proline, glacial acetic acid, polysorbate 80, water for injection, 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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This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 07/2016

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