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

What is REPATHA?

REPATHA is an injectable prescription medicine used:

- to reduce the risk of major adverse cardiovascular (CV) events, such as death from cardiovascular disease, heart attack, stroke, certain types of chest pain conditions (unstable angina) requiring hospitalization, or certain types of surgery or procedures to restore arterial blood flow to the heart and other parts of the body, in adults at increased risk for these events.
- Along with diet and exercise to reduce low-density lipoprotein (LDL) or bad cholesterol in:
  - adults with high blood cholesterol levels called hypercholesterolemia.
  - adults and children aged 10 years and older with a type of high cholesterol called heterozygous familial hypercholesterolemia (HeFH).
  - adults and children aged 10 years and older with a type of high cholesterol called homozygous familial hypercholesterolemia (HoFH).

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 hypercholesterolemia.

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. REPATHA is available as prefilled single-dose SureClick® autoinjectors and prefilled single-dose syringes that either contain dry natural rubber (a derivative of latex) in the needle cover or are not made with natural rubber latex. The carton and Instructions for Use will state if your prefilled single-dose SureClick autoinjector or prefilled single-dose syringe contains dry natural rubber.
  - The prefilled single-dose pen 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 one time each month. After 12 weeks, your healthcare provider may decide to increase the dose to 420 mg every two weeks. If you receive or your child receives lipid apheresis, your healthcare provider may decide to start you or your child on a dose of 420 mg every two weeks to match with the apheresis treatment and you or your child should take the dose after the apheresis treatment.
- REPATHA is for use in adults and children aged 10 years and older and comes as a:
  - prefilled single-dose (1 time) pen,
  - prefilled single-dose autoinjector (SureClick autoinjector), or
  - prefilled single-dose syringe.
- 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:
  - 3 separate injections in a row, using a different prefilled pen, prefilled SureClick autoinjector or prefilled syringe 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 single-dose SureClick autoinjector, put the **yellow safety guard (needle inside) of the prefilled single-dose SureClick autoinjector on the skin before injecting.**
- You or your child can use the prefilled single-dose pen, prefilled single-dose SureClick autoinjector, or prefilled single-dose syringe to 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 prefilled single-dose pen, prefilled single-dose SureClick autoinjector, or prefilled single-dose syringe 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 effects that bother you or that do 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.

How should I store REPATHA?

- Store REPATHA in the refrigerator between 36°F to 46°F (2°C to 8°C). Store REPATHA in the original carton until use to protect it from light.
- If needed, REPATHA prefilled single-dose pen, prefilled single-dose SureClick autoinjector, or prefilled single-dose syringe can be stored at room temperature between 68°F to 77°F (20°C to 25°C) in the original carton for up to 30 days. Throw away REPATHA that has been stored at room temperature for more than 30 days.
- Do not freeze REPATHA.
- Do not shake REPATHA.

Keep REPATHA and all medicines out of the reach of children.

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: acetate; polysorbate 80; proline; Water for Injection, USP; and sodium hydroxide may be used to adjust the pH.

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).

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