REPATHA® PRODUCT FACT SHEET

Repatha® (evolocumab) injection 140 mg/mL

INDICATIONS

Prevention of Cardiovascular Events: In adults with established cardiovascular disease, Repatha® is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization.

Primary Hyperlipidemia (including Heterozygous Familial Hypercholesterolemia): Repatha® is indicated as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C).

Homozygous Familial Hypercholesterolemia: Repatha® is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

The safety and effectiveness of Repatha® have not been established in pediatric patients with HoFH who are younger than 13 years old or in pediatric patients with primary hyperlipidemia or HeFH.

SELECT PRODUCT INFORMATION

NEW!

NDC: 72511-0760-02 (New NDC lower priced option for SureClick® autoinjector)
Description: 140 mg/mL single-use prefilled SureClick® autoinjector
Quantity: Two pack
Wholesale Acquisition Cost (WAC): $450 | **Annual Cost:** $5,850

NDC: 55513-0760-02
Description: 140 mg/mL single-use prefilled SureClick® autoinjector
Quantity: Two pack
WAC: $1,117.16 | **Annual Cost:** $14,523

NEW!

NDC: 72511-0770-01 (New NDC lower priced option for Pushtronex® system)
Description: 420 mg/3.5mL single-use Pushtronex® system (on-body infusor with prefilled cartridge)
Quantity: One Pack
Wholesale Acquisition Cost (WAC): $487.50 | **Annual Cost:** $5,850

NDC: 55513-0770-01
Description: 420 mg/3.5 mL single-use Pushtronex® system (on-body infusor with prefilled cartridge)
Quantity: One pack
WAC: $1,210.25 | **Annual Cost:** $14,523

STORAGE AND HANDLING REQUIREMENTS

Repatha® is a sterile, clear to opalescent, colorless to pale yellow solution for subcutaneous administration supplied in a single-use pre-filled syringe, a single-use prefilled SureClick® autoinjector, or a single-use Pushtronex® system (on-body infusor with prefilled cartridge). Each single-use prefilled syringe or single-use prefilled SureClick® autoinjector of Repatha® is designed to deliver 1 mL of 140 mg/mL solution. Each single-use Pushtronex® system is designed to deliver 420 mg Repatha® in 3.5 mL solution.

- 140 mg/mL single-use prefilled syringe 1 pack NDC 72511-0750-01 and NDC 55513-0750-01
- 140 mg/mL single-use prefilled SureClick® autoinjector 2 pack NDC 72511-0760-02 and NDC 55513-0760-02
- 420 mg/3.5 mL single-use Pushtronex® system (on-body infusor with prefilled cartridge) 1 pack NDC 72511-0770-01 and NDC 55513-0770-01

Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze. Do not shake.

Alternatively, for patients/caregivers, Repatha® can be kept at room temperature at 68°F to 77°F (20°C to 25°C) in the original carton; however, under these conditions, Repatha® must be used within 30 days. If not used within the 30 days, discard Repatha®.

Protect Repatha® from direct light and do not expose to temperatures above 25°C (77°F).

PRODUCT EXPIRATION

The expiration date is printed on each carton.

Please see Important Safety Information on last page.

Repatha® (evolocumab) injection 140 mg/mL

PRODUCT RETURNS

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-Amgen (1-800-282-6436). Credit for returns is subject to Amgen's current Returned Goods Policy.

PRODUCT INFORMATION Medical Information: 1-800-77-AMGEN (1-800-772-6436)

COVERAGE INFORMATION 1-844-REPATHA (1-844-737-2842)

SUPPLIED AND MARKETED BY

Amgen USA Inc. • Phone 1-800-28-AMGEN (1-800-282-6436) • Fax 1-800-29-AMGEN (1-800-292-6436)
www.amgen.com www.repathahcp.com

IMPORTANT SAFETY INFORMATION

- **Contraindication:** Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to Repatha®. Serious hypersensitivity reactions including angioedema have occurred in patients treated with Repatha®.
- **Allergic Reactions:** Hypersensitivity reactions (e.g. angioedema, rash, urticaria) have been reported in patients treated with Repatha®, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with Repatha®, treat according to the standard of care, and monitor until signs and symptoms resolve.
- **Adverse Reactions in Primary Hyperlipidemia (including HeFH):** The most common adverse reactions (>5% of patients treated with Repatha® and occurring more frequently than placebo) were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

  From a pool of the 52-week trial and seven 12-week trials: Local injection site reactions occurred in 3.2% and 3.0% of Repatha®-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising.

  Allergic reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0% versus 0.5% for Repatha® and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).
- **Adverse Reactions in the Cardiovascular Outcomes Trial:** The most common adverse reactions (>5% of patients treated with Repatha® and occurring more frequently than placebo) were: diabetes mellitus (8.8% Repatha®, 8.2% placebo), nasopharyngitis (7.8% Repatha®, 7.4% placebo), and upper respiratory tract infection (5.1% Repatha®, 4.8% placebo).

  Among the 16,676 patients without diabetes mellitus at baseline, the incidence of new-onset diabetes mellitus during the trial was 8.1% in patients assigned to Repatha® compared with 7.7% in those assigned to placebo.
- **Adverse Reactions in Homozygous Familial Hypercholesterolemia (HoFH):** The adverse reactions that occurred in at least two patients treated with Repatha® and more frequently than placebo were: upper respiratory tract infection, influenza, gastroenteritis, and nasopharyngitis.
- **Immunogenicity:** Repatha® is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity with Repatha®.

Click here to see Full Prescribing Information.

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
www.amgen.com

AMGEN® Cardiovascular