





**INDICATIONS AND IMPORTANT SAFETY INFORMATION**

**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.

**Contraindication:** Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to Repatha®.

**Allergic Reactions:** Hypersensitivity reactions (e.g., 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 Repatha®-treated patients and occurring more frequently than placebo) in clinical trials in primary hyperlipidemia (including HeFH) were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

In a 52-week trial, adverse reactions led to discontinuation of treatment in 2.2% of Repatha®-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to Repatha® treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for Repatha® and placebo, respectively).

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. The proportions of patients who discontinued treatment due to local injection site reactions in Repatha®-treated patients and placebo-treated patients were 0.1% and 0%, respectively.

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 safety profile of Repatha® in this trial was generally consistent with the safety profile described above in the 12- and 52-week controlled trials involving patients with primary hyperlipidemia (including HeFH). Serious adverse events occurred in 24.8% and 24.7% of Repatha®-treated and placebo-treated patients, respectively. Adverse events led to discontinuation of study treatment in 4.4% of patients assigned to Repatha® and 4.2% assigned to placebo. Common adverse reactions (> 5% of patients treated with Repatha® and occurring more frequently than placebo) included 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):** In 49 patients with HoFH studied in a 12-week, double-blind, randomized, placebo-controlled trial, 33 patients received 420 mg of Repatha® subcutaneously once monthly. The adverse reactions that occurred in at least two (6.1%) Repatha®-treated patients, and more frequently than in placebo-treated patients, included upper respiratory tract infection (9.1% versus 6.3%), influenza (9.1% versus 0%), gastroenteritis (6.1% versus 0%), and nasopharyngitis (6.1% versus 0%).

**Immunogenicity:** Repatha® is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with Repatha®.

**Please see the accompanying full Prescribing Information.**



**RepathaReady® Program  
Privacy Notice and Authorization**



In accordance with my signature below, I understand and consent to Amgen contacting me using the contact information provided in this form to enroll me in, operate, and administer Amgen patient support services and/or RepathaReady® program as described in the Patient Privacy Authorization other than promotional communications by telephone or SMS/text (to which I can separately opt-in below). I understand that the operation and administration of certain of these services and/or programs may require that Amgen contact me by telephone or SMS/text.

**My preferred method(s) of contact:**

Email     Phone     Mail     SMS/text (standard text message charges may apply from your wireless provider)

In addition to the above consent, I understand that by checking this box and signing below, I consent to Amgen calling and texting me at the phone number(s) I have provided with promotional communications relating to Amgen products and services and/or my condition or treatment. Amgen may use automatic dialing machines or artificial or prerecorded messages to contact me and may leave a voicemail or text message (standard text messaging rates may apply). I understand that I am not required to provide this consent as a condition of purchasing any goods or services.

Amgen may contact me using the contact information provided in this form for participation in market research activities associated with Amgen’s products, services and/or my condition or treatment.     I agree /  I disagree

My signature below certifies that I am at least 18 years old and that I have **read, understood, and agreed** to the Privacy Notice and Patient Authorization to release my personal health information as described in full detail on the next page.

Patient Name: \_\_\_\_\_

Name of Legal Guardian (if needed): \_\_\_\_\_

Patient Signature (or Legal Guardian):   X   \_\_\_\_\_ Date: \_\_\_\_\_

**Amgen’s Privacy Pledge to Patients**

Amgen respects patients and customers and takes the protection of their privacy very seriously. Amgen pledges the following:

- ✓ Amgen does not and will not sell or rent your information to marketing companies or mailing list brokers.
- ✓ Amgen is careful to only collect and/or use personal identifiable information for the purposes stated in this Authorization and, as necessary, to provide the services and/or programs the patient or customer chooses to enroll into.
- ✓ Amgen practices are consistent with federal and state privacy laws, including HIPAA.
- ✓ Amgen program enrollment is voluntary and always provides patients with an easy option to cancel participation.

**Uses and Disclosure of Personal Information**

I authorize Amgen and its contractors and business partners (“Amgen”) to use and/or disclose my personal information, *including my personal health information, only for the following purposes:*

- To operate, administer, enroll me in, and/or continue my participation in Amgen’s RepathaReady® program or any other Amgen-affiliated patient support services and activities related to my condition or treatment (e.g., co-pay card programs, reimbursement assistance programs, drug coverage verification, nurse educator services, adherence program, and disease management support);
- To contact, with my permission, my doctor and the rest of my healthcare team and share with them my health information that may be useful for my care;

## RepathaReady® Program Privacy Notice and Authorization



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- To provide me with informational and promotional materials relating to Amgen products and services, and/or my condition or treatment; and/or
- To improve, develop, and evaluate products, services, materials, and programs related to my condition or treatment.

In order for Amgen to provide me with the services and/or programs described above, Amgen needs to collect and use my personal information, including *my personal health information*. I understand that *my personal health information* may include any information, in electronic or physical form, in the possession of or derived from a healthcare provider, healthcare plan, pharmacy, pharmaceutical company, laboratory, and/or their contractor ("Healthcare Provider"). This may include select information from or about my medical history and general health, my healthcare plan benefits, payment limits or restrictions covered by my healthcare plan policy, and/or my adherence to my treatment.

I authorize my Healthcare Providers to disclose *my personal health information* to Amgen, and between themselves, as necessary, but only for the purposes stated above in this Authorization. I understand that certain of my Healthcare Providers (such as pharmacies and specialty pharmacies) may receive remuneration from Amgen in exchange for disclosing *my personal health information* and/or for using my information to contact me with communications about Amgen products that have been prescribed to me (e.g., adherence programs) and other patient support services.

### Expiration, Right to Obtain a Copy, and Right to Cancel

I understand that by signing this form, I authorize my Healthcare Providers or others who might hold my health information to only release it to Amgen employees, as well as to its contractors and business partners, who are performing the services set forth in this Authorization. I also understand I am authorizing my personal information, including *my personal health information*, to be used for the purposes described above. I understand and agree that by signing below, I am authorizing those who rely on this Authorization to release my personal health information for the earlier of five (5) years or until my participation in the program ends through my cancellation, unless a shorter time period is required by state law.

I understand that I can obtain a copy of this Authorization or cancel this Authorization at any time by calling Amgen at 1-844-REPATHA or by writing to PO Box 220326; Charlotte, NC 28222. If I cancel my consent, I will no longer qualify for the services described. I also understand that if a Healthcare Provider is disclosing my personal health information to Amgen on an authorized ongoing basis, my cancellation with Amgen will be effective with respect to any such Healthcare Providers as soon as they receive notice of my cancellation.

### No Effect on Treatment

I understand I do not have to sign this Authorization and that my enrollment in any of the services and/or programs described above is entirely voluntary. I understand that Amgen, as well as Healthcare Providers, cannot require me, as a condition of having access to medications, prescription drugs, treatment or other care, to sign this Authorization. Federal Law (including HIPAA) requires a signed authorization in order for Amgen to collect this information from my Healthcare Providers. I understand I cannot participate in the listed services and/or programs without signing this Authorization or an equivalent authorization with my Healthcare Providers.

### Information Received From Healthcare Providers

I understand that once my personal health information has been disclosed to Amgen, federal privacy laws may no longer apply and protect it from further disclosure. Amgen agrees, however, to protect my personal health information by only using and disclosing it as stated in the Authorization or as otherwise allowed or required by law. I understand that Amgen does not and will not sell or rent my information to marketing companies or mailing list brokers.

