Repatha® Pushtronex® Device Discontinuation

FREQUENTLY ASKED QUESTIONS (FAQ)

Q: How many presentations of Repatha® are there in the US?

- Today there are 3 device presentations of Repatha® in the US:
  - 140 mg/mL single-dose prefilled SureClick® autoinjector
  - 420 mg/3.5 mL single-dose Pushtronex® System (on-body infusor with prefilled cartridge)
  - 140 mg/mL single-dose prefilled syringe

  The SureClick® autoinjector, administered every two weeks, is the #1 prescribed Repatha® device and the Pushtronex® System is the least prescribed Repatha® device.

Q: Why has Amgen decided to discontinue the Pushtronex® System? When does that go into effect?

- This decision was made globally to uphold the high standards that Amgen has set to enable the most optimal patient experience.
- Amgen plans to discontinue Repatha® Pushtronex® System June 30th, 2024, followed by the prefilled syringe in mid-2025. All patients should transition to another device presentation, preferably SureClick®, by Q3 2024.

Q: Is Amgen discontinuing Pushtronex® System globally?

- Yes. In addition to the U.S. this presentation will be discontinued in all countries where it is available, including Canada, EU/Germany, Japan, and Australia.

Q: Is the SureClick® Autoinjector appropriate for all patients?

- The labeled indication and drug product for both devices is the same. There are no patient population or indication differences, except:
- For patients with an allergy to latex, our current recommendation is to continue utilizing the Pushtronex® System as the needle shield inside the orange cap of the SureClick® presentation contains dry natural rubber. For proper dosing, please refer to the Repatha Prescribing Information.

Q: What about patient who have an allergy to latex?

- The orange cap on the Repatha® SureClick® Autoinjector contains a needle cover located inside the cap that contains dry natural rubber, which is made from latex. Speak with your healthcare provider if you are allergic to latex.
- For patients with a latex allergy, our current recommendation is to continue utilizing the Pushtronex® System.
- Amgen is committed to ensuring that patients with latex allergies have a dosing option available to them. For this reason, Amgen is preserving inventory of the Pushtronex System for these patients with latex allergies.

Q: Now that the Pushtronex® device is going off the market, how can my HoFH patients continue receiving their Repatha® 420 mg monthly dose?

- Please refer to the Repatha® Prescribing Information.
- Similar to patients with a latex allergy, for patients with HoFH, our current recommendation is to continue utilizing the Pushtronex® System to deliver the 420 mg dose. Currently, Amgen does not have a 3-pack of the 140 mg/mL SureClick(R) autoinjector presentation available in the US market. Amgen is working closely with payers, and additional details closer to the discontinuation date will be provided, offering clarification on a long-term solution for these patients.
- We recognize that the transition for this small subset of patients is more complicated. Therefore, Amgen strongly encourages these patients to sign up for AmgenSupport Plus to receive further support.

Q: Are there differences between the devices in terms of adverse event / side effects?

- The side effect profile of Repatha® was not differentiated based on the device or administration. Adverse events in the Repatha® clinical study groups, including 140 mg and 420 mg dosing groups, were balanced across treatment arms in short- and long-term studies.[1-5]

Q: Were there safety or quality issues with the Pushtronex® System?

- There are no concerns about the drug product quality, efficacy, or patient safety for any of the three Repatha® device presentations.

Q: How will Amgen support current patients on the Pushtronex® System?

- Amgen intends to support the transition of all existing patients and onboarding new patients to our #1 prescribed device the SureClick® autoinjector.
- We understand patients will need to transition from their current device. Amgen is prepared to support them through that transition. Resources will include:
  - Nurse Partner Support, including supplemental injection support.
  - Additional SureClick® Demo Devices and Samples for healthcare practitioners
  - Dedicated support through 844-Repatha (1-844-737-2842), prompt 2.
    - Note, if patients select the option for a callback, they will be contacted promptly when the next line opens during operating hours.

Q: What should patients do with their existing Repatha® Pushtronex® System device?

- Patients who are currently in possession of the Repatha® Pushtronex® System device can continue to take their medicine as directed by their health care professional.

Q: Why is Amgen focused on transitioning patients to the SureClick® autoinjector?

- The overwhelming majority of patients are prescribed SureClick®.
- Injection with SureClick® on an annualized basis takes approximately 6.5* minutes for the SureClick® Autoinjector vs. 60 minutes with the Pushtronex® System.
- Through Amgen SupportPlus services patients can access supplemental injection support, reminders, cost, and co-pay support information (for eligible, commercially insured patients), etc.
- For patients with fear of needles, the needle in the SureClick® autoinjector is hidden which may make it more patient friendly compared to the Prefilled Syringe. Additionally, a caregiver may administer the SureClick® if available.

Q: Will this action lead to supply shortages?

- Amgen has sufficient product to supply patients during their transition from the Pushtronex® System.

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[1] Koren et al. J Am Coll Cardiol. 2014;63:2531–2540.
[2] Robinson et al. JAMA. 2014;311:1870–1882.
[3] Raal et al. Lancet. 2015;385:331–340.
[4] Stores et al. J Am Coll Cardiol.
[5] Toth et al. Circulation. 2017;135:1819-1831

**Not inclusive of preparation and time for autoinjector to reach room temperature before injecting.*

INDICATIONS

Repatha® is indicated:

- In adults with established cardiovascular disease to reduce the risk of myocardial infarction, stroke, and coronary revascularization
- As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C
- As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C
- As an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C

The safety and effectiveness of Repatha® have not been established in pediatric patients with HeFH or HoFH who are younger than 10 years old or in pediatric patients with other types of hyperlipidemia.

IMPORTANT SAFETY INFORMATION

- **Contraindication:** Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to evolocumab or any of the excipients in Repatha®. Serious hypersensitivity reactions including angioedema have occurred in patients treated with Repatha®.
- **Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema, have been reported in patients treated with Repatha®. If signs or symptoms of serious hypersensitivity reactions occur, discontinue treatment with Repatha®, treat according to the standard of care, and monitor until signs and symptoms resolve.
- **Adverse Reactions in Adults with Primary Hyperlipidemia:** The most common adverse reactions (>5% of patients treated with Repatha® and 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. Hypersensitivity reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common hypersensitivity 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 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 treated with Repatha® compared with 7.7% in patients that received placebo.
- **Adverse Reactions in Pediatric Patients with HeFH:** The most common adverse reactions (>5% of patients treated with Repatha® and more frequently than placebo) were: nasopharyngitis, headache, oropharyngeal pain, influenza, and upper respiratory tract infection.
- **Adverse Reactions in Adults and Pediatric Patients with HoFH:** In a 12-week study in 49 patients, 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. In an open-label extension study in 106 patients, including 14 pediatric patients, no new adverse reactions were observed.
- **Immunogenicity:** Repatha® is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity with Repatha®.

Please see full Prescribing Information.