Repatha® Pushtronex® System (on-body-infusor with prefilled cartridge) Discontinuation

FREQUENTLY ASKED QUESTIONS (FAQ)

Q: Why has Amgen decided to discontinue Repatha® Pushtronex® System?

- This decision was made globally to uphold the high standards that Amgen has set to enable the most optimal patient experience. The prefilled syringe will be discontinued in mid-2025 for this same reason.
- At this time, any patients without homozygous familial hypercholesterolemia (HoFH) or a latex allergy should transition to the single-dose prefilled Repatha® SureClick® autoinjector, 140 mg administered every 2 weeks or the single-dose prefilled syringe, 140 mg administered every 2 weeks. A new prescription will be needed for the new device presentation.

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

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

  The SureClick® autoinjector is the #1 prescribed Repatha® device.

- As of January 6, 2025, a new device will be available for patients with latex allergies:
  - 140 mg/mL single-dose prefilled syringe not made with natural rubber latex (140 mg/mL single-dose prefilled SureClick® autoinjector not made with natural rubber latex will be available in limited quantity April 2025, with full inventory expected by summer 2025.)

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: 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: What should I do with my existing Repatha® Pushtronex® System device?

- If you are currently in possession of the Repatha® Pushtronex® System device, you can continue to take your medicine as directed by your health care provider.

Q: Who should I contact if I have further questions about transitioning from Pushtronex®?

- Please ask your healthcare provider for more information about switching devices, or call 1-844-Repatha for further assistance.

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

- Administration with the SureClick® autoinjector on an annualized basis requires fewer steps and less time than the Pushtronex® System.

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

- Each SureClick® autoinjector delivers 140 mg of the medication.
- The labeled indication and drug product for all devices is the same. There are no patient population or indication differences, except that historically, the prefilled syringe and SureClick® autoinjector contained dry natural rubber (a derivative of latex). This is why Amgen is introducing a prefilled syringe not made with natural rubber latex into the market, followed by a SureClick® autoinjector next year that will not be made with natural rubber latex.

Q: I have a needle phobia (fear of needles), is there a device that I can use where I don't see the needle?

- We understand your concern. The needle in the SureClick® autoinjector is hidden, so you do not see the needle. We advise you to consult with your physician or healthcare provider for further discussion.

HoFH Patients

Q: Now that the Pushtronex® System is being discontinued, as a HoFH patient, how can I continue receiving my REPATHA® 420 mg monthly dose?

- The 420 mg monthly dose may be administered by taking three 140 mg/mL Repatha® SureClick® autoinjectors subcutaneously, or three 140 mg/mL REPATHA® prefilled syringes. All these injections should be given within 30 minutes.
  - Amgen does not have a 3-pack of the 140 mg/mL Repatha® SureClick® autoinjector presentation available in the US market.
  - Note, an exception from your insurance plan may be required.
- HoFH patients who need the 420mg biweekly (i.e., Repatha® SureClick® autoinjector 28-day supply) should inject 420mg (3 autoinjectors) subcutaneously every 2 weeks. An exception from your insurance plan may be required.
- For 3 separate injections in a row using a single-dose prefilled syringe:
  - Give all of these injections within 30 minutes. (Example: One injection, (first), in the left thigh, followed by one injection, (second) in the right thigh followed by one injection, (third) in the abdomen. All 3 injections will be completed within 30 minutes of the first injection.
  - It is recommended that you choose a different site each time you give yourself an injection. If you want to use the same injection site location, (Example: left thigh), make sure it is not the same injection spot you used for the last injection.
  - You can use your thigh, stomach (abdomen), except for a two-inch area around your navel (belly button).
  - Outer area of upper arm (outer arm only if someone else is giving you the injection).
  - Do not inject into areas where the skin is tender, bruised, red, or hard.

Please see Approved Use and Important Safety Information at the end of this FAQ.

- 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.
- Avoid injecting into areas with wrinkles, skin folds, scars, stretch marks, moles, or excessive hair. Avoid injecting directly into a raised, thick, red, or scaly skin patch or lesion. Please contact your healthcare provider for further guidance.

- Please refer to the Repatha® Prescribing Information.
- We recognize that the transition is more complicated if you have HoFH. Therefore, Amgen strongly encourages you to sign up for Amgen® SupportPlus to receive further support.

Q: If I move from 420mg Pushtronex® System once a month to the recommended 140mg SureClick® autoinjector or prefilled syringe every 2 weeks (total monthly dose 280mg), will I lose efficacy as the total monthly dose is less?

- No. Repatha® 140 mg every two weeks and 420 mg monthly result in similar reductions in LDL-C over a monthly dosing interval.

Cost and Coverage:

Q: Will my out-of-pocket cost for the SureClick® autoinjector be more expense for me since it's given every two weeks?

- The cost of your REPATHA® prescription should remain the same based upon SureClick® autoinjector administration every two weeks. Questions about cost and coverage should be directed to your insurance company.

Q: Can I get reimbursed for any unused medication?

- No, if you are currently in possession of a REPATHA® Pushtronex® System device, you can continue to take your medicine as directed by your healthcare professional. There are no concerns about the REPATHA® drug product, efficacy, or patient safety. This device is being discontinued, not recalled.
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Q: Will Insurance cover once monthly dosing for Repatha® (3x 140mg SureClick® autoinjectors within 30 mins) for HoFH patients?

- Payors will likely ask doctors to submit for an exception for HoFH patients. Amgen Access Specialists can provide live or virtual coverage and access resources to assist your doctor in understanding the necessary documentation for individual patient support.

Q: Will HoFH patients out of pocket cost for Repatha® SureClick® autoinjector be more expensive than Repatha® Pushtronex® system?

- If you are an HoFH patient, the cost of your Repatha prescription should remain the same as long as you are prescribed and dispensed as directed above. Individual patient insurance coverage varies including out of pocket cost. Please be sure to consult with your particular insurance plan.

Latex Allergy Patients:

Q: I have a latex allergy, what are my options?

- As of January 6, 2025, a prefilled syringe that is not made with natural rubber latex will be available. Shortly thereafter we expect starting April 2025, a SureClick® that is not made with natural rubber latex will be available with full availability expected by summer 2025.
- A new prescription will be required.

SureClick® Autoinjector

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

- The overwhelming majority of patients are prescribed the Repatha® SureClick® autoinjector.
- Injection with Repatha® SureClick® on an annualized basis takes approximately 6.5* minutes for the Repatha® SureClick® autoinjector for the 140 mg every 2-week administration vs. 60 minutes with the Repatha® Pushtronex® System for the 420 mg once a month administration.
- Through Amgen® SupportPlus services patients can access supplemental administration support, reminders, cost, and co-pay support information (for eligible, commercially insured patients).
- For patients with fear of needles, the needle in the Repatha® SureClick® autoinjector is hidden which may make it more patient friendly compared to the Prefilled Syringe. Additionally, a caregiver may administer the SureClick® autoinjector if available.

Q: Is the Repatha® SureClick® autoinjector appropriate for all patients?

- The labeled indication and drug product for the devices is the same. There are no patient population or indication differences, except patients with an allergy to latex. (See 'Latex Allergy Patients' section above.)

Support

Q: How will Amgen support current patients who are transitioning off of 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, or if they have a latex allergy, the prefilled syringe not made with natural rubber latex.
- We understand patients will need to transition from their current device. Amgen continues to support them through the transition. Resources include:
  - Nurse Partner Support*
  - Dedicated support through 844-Repatha (1-844-737-2842) prompt 2. Note, if you select the option for a callback, you will be contacted promptly when the next line opens during operating hours.

**Amgen Nurse Partners are only available to patients that are prescribed certain Amgen products. They are not part of your treatment team and do not provide medical advice, nursing, or case management services. Amgen Nurse Partners will not inject patients with Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.*

Please see Approved Use and Important Safety Information at the end of this FAQ.

APPROVED 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 heart surgery, in adults with cardiovascular disease.
- along with diet alone or together with other cholesterol-lowering medicines in adults with high blood cholesterol levels called primary hyperlipidemia (including a type of high cholesterol called heterozygous familial hypercholesterolemia [HeFH]) to reduce low density lipoprotein (LDL) or bad cholesterol.
- along with diet and other LDL-lowering medicines in children aged 10 years and older with HeFH to reduce LDL cholesterol.
- along with other LDL-lowering medicines in adults and children aged 10 years and older with a type of high cholesterol called homozygous familial hypercholesterolemia (HoFH), to reduce LDL cholesterol.

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 hyperlipidemia.

IMPORTANT SAFETY INFORMATION

Do not use Repatha® if you or your child is allergic to evolocumab or to any of the ingredients in 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, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. 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 single-dose Pushtronex® system (on-body infusor with prefilled cartridge) is not made with natural rubber latex.

Tell your healthcare provider or pharmacist about any prescription and over-the-counter medicines, vitamins, or herbal supplements you or your child take.

What are the possible side effects of Repatha®?

Repatha® can cause serious side effects including serious allergic reactions. Stop taking Repatha® and call your healthcare provider or seek emergency 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 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 are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch** or call **1-800-FDA-1088**.

Please see full **Prescribing Information**.