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

FREQUENTLY ASKED QUESTIONS (FAQ)

Q: Why has Amgen decided to discontinue 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 Repatha® presentation, preferably the SureClick® autoinjector, 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.

Q: If I want to stay on a monthly dosing schedule with the Repatha® SureClick® autoinjector device, can you provide more details on asking my HCP about it?

- SureClick® autoinjector every two weeks is the most commonly prescribed Repatha® device and treatment schedule.
  - The vast majority of patients choose Repatha® SureClick® autoinjector every two weeks as their preferred dosing schedule.
  - Amgen strives to provide a high-quality experience for all patients; hence, administering three injections within 30 minutes may not be the most desirable alternative for most patients.

- Amgen does not recommend receiving Repatha® 420 mg monthly by administering 3 injections each with a 140mg dose.
  - While the package inserts states that patients may self-administer three SureClick® autoinjector doses within 30 minutes, Repatha® SureClick® autoinjector is not currently available as a three-pack or a single unit. Therefore, patients may run into difficulty with cost and coverage through their respective insurers. Questions about cost and coverage should be directed to patients insurance company.

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

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

Q: If I want to stay on a monthly dosing schedule, can you provide more detail on how to do the 3 injections within 30 minutes? Can I inject in the same location?

- Please review the REPATHA® Patient Information section regarding, "How should I use REPATHA® for injection support. Work with your healthcare provider or nurse on the right way to administer Repatha®.
- Amgen does not recommend receiving Repatha® 420 mg monthly by injecting a 3 x 140mg dose within 30 minutes.
  - Please note Amgen currently does not have a 3-pack of the 140 mg/mL SureClick® autoinjector presentation available in the US market. Please speak with your doctor to discuss alternative device presentation for Repatha®.
  - If your HCP prescribes you the 420 mg dose, you may use the prefilled syringe. However, if you are a patient with HoFH or have a latex allergy, Amgen is preserving inventory of the Pushtronex® System for you during the transition period. (Please refer to Latex Allergy question for further information)
  - If your HCP prescribes your child the 420 mg dose, your child may use the prefilled syringe. However, if your child has HoFH or has a latex allergy, Amgen is preserving inventory of the Pushtronex® System for them during the transition period. (Please refer to Latex Allergy question for further information)
- For 3 separate injections in a row utilizing 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.
  - 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 see Approved Use and Important Safety Information at the end of this FAQ.

Q: Does Amgen intend to discontinue any of the other devices? What about the PFS?

- In the future, Amgen does intend to discontinue the prefilled syringe presentation but not at this time. Please ask your prescriber to consider selecting the SureClick® autoinjector presentation if appropriate for you in order to avoid a future transition.

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

- Injection with 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?

- SureClick® autoinjector delivers 140 mg of the medication.
- 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® autoinjector presentation contains dry natural rubber. Please consult your healthcare professional on what is the right approach for you.

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.

Q: Will my out-of-pocket cost for Sureclick® autoinjector be more expensive 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. The device is being discontinued, not recalled.

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

- 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.
- 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® System is being discontinued, as an HoFH patient how can I continue receiving my Repatha® 420 mg monthly dose?

- Please refer to the Repatha® Prescribing Information.
- For HoFH patients, 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 140mg SureClick® autoinjector presentation available in the US.
- We recognize that the transition for HoFH patients is more complicated. Therefore, Amgen strongly encourages patients to sign up for AmgenSupport Plus to receive further support.

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

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

Q: Is this a product recall?

- No. There are no concerns about the drug product quality, efficacy, or patient safety.

Q: Are there different injection site reactions with SureClick® autoinjector compared to the Pushtronex® System?

- The side effect profile of evolocumab was not differentiated based on device or administration.

Q: Which hurts more during drug delivery – SureClick® autoinjector, Pushtronex® System or PFS?

- There were no specific studies conducted to compare the difference in pain with the Pushtronex® System, SureClick® autoinjector or PFS.
- The prefilled syringe and the SureClick® autoinjector are both supplied with a ½ inch [long] 27-gauge needle.

Q: How will Amgen support me as a current Pushtronex® System patient?

- Amgen intends to support your transition and assist you with onboarding to our #1 prescribed device, the SureClick® autoinjector.

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

- The first step is to talk to your doctor about obtaining a SureClick® autoinjector prescription. Next, the doctor should train you on how to inject using the SureClick® autoinjector. Then, through Amgen SupportPlus, we can connect you with Amgen Nurse Partner Support which can provide supplemental injection support for your new SureClick® autoinjector when you are ready for your first dose.

Q: Will this action lead to supply shortages?

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

Q: Is there a difference in needle gauge/size?

- The prefilled syringe and the SureClick® autoinjector are both supplied with ½ inch 27 gauge needle. The Pushtronex® System uses a 29 gauge needle.

Q: Are there differences in efficacy for a patient and does SureClick® autoinjector work better in the body than PUSHTRONEX® System?

- There is no difference in efficacy between the SureClick® autoinjector and the Pushtronex® System. Both devices contain the same active ingredient – evolocumab.

Q: Am I required to switch to SureClick® autoinjector or can I use the PFS?

- No. You can use the SureClick® autoinjector or the prefilled syringe interchangeably, but a different prescription would be needed for each device.

Q: What do I need to do in order to switch to SureClick® autoinjector?

- You will need to contact your HCP to obtain a new prescription for the Repatha® SureClick® autoinjector device.
- Your HCP office will complete any prior authorization steps required by your insurance provider.
- Once you receive training from your doctor on how to inject using the SureClick® autoinjector, and pick up your new SureClick® autoinjector at the pharmacy, you can reach out to an Amgen Nurse Partner before your first injection by calling 844-REPATHA and selecting option [3 or 2]

Q: Should I call my doctor or pharmacist?

- Yes, you will need to contact your doctor in order to obtain a new prescription for the Repatha® SureClick® autoinjector.

Q: What do I do with any unused supply of PUSHTRONEX® System? Can I return it to Amgen and receive a credit or replacement with SureClick® autoinjector?

- You can continue to take your medicine using the Repatha® Pushtronex® System as directed by your health care professional. There are no concerns about the drug product quality, efficacy, or patient safety. There are no concerns about the drug product quality, efficacy, or patient safety.

Q: Can I use the Sharps container I already have or do I need a new one?

- You can continue to use the Sharps container you already have until it is full.

Q: Are there other alternatives if I don't want to switch?

- We understand your concern about switching. We recommend that you consult with your doctor or health care professional on the option that is right for you for taking Repatha®.

APPROVED USE

What is Repatha®:

Repatha® is an injectable prescription medicine used:

- in adults with cardiovascular disease to reduce the risk of heart attack, stroke, and certain types of heart surgery.
- 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. The needle covers on the single-dose prefilled

syringes and the inside of the needle caps on the single-dose prefilled SureClick® autoinjectors contain 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.