


Patient Reported Ease-of-Use with a Disposable Autoinjector in Individuals with Migraine

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Purpose: Erenumab-aooe (erenumab, Aimovig[®])—a fully human monoclonal antibody that inhibits the calcitonin gene-related peptide (CGRP) receptor—is approved for the prevention of migraine in adults in a number of countries. The approved monthly dosage of erenumab (70 and/or 140 mg, depending on the country) is available as a single, prefilled autoinjector for subcutaneous administration in most countries where it is approved. This study evaluated the patient-reported ease-of-use, ability to learn self-injection, confidence in performing a simulated self-injection, and ergonomics of a prefilled autoinjector device for erenumab (SureClick[®] autoinjector) in individuals in the US with migraine.

Patients and Methods: Participants with migraine headaches, all of whom were naïve to the use of an autoinjector for migraine or another condition and CGRP therapy, were recruited from three US-based headache centers. Each participant received a supervised demonstration of the autoinjector during a 30-minute one-on-one session using a standard protocol-driven script. Participants then practiced a simulated injection into an artificial tissue pad using the autoinjector and were asked to rate their agreement with 19 statements about the device on a 5-point Likert scale (1 = completely disagree, 2 = somewhat disagree, 3 = neutral, 4 = somewhat agree, 5 = completely agree).

Results: Participants who completed the study and provided responses (n = 204) were between 21 and 85 years of age, inclusive, and 73% were female. More than 90% of the participants completely or somewhat agreed with 16/19 statements relating to the device, including ease-of-use, ability to self-inject, and confidence in using the device, with an average rating of >4.5 on the 5-point Likert scale. Participants rated the size of the device and the compactness of the device as 4.23/5 and 4.26/5, respectively.

Conclusion: The erenumab-prefilled disposable autoinjector was consistently highly rated across categories by individuals with migraine, with an average rating of >4.5 on the 5-point Likert scale; results were consistent across the three study centers.

Keywords: autoinjector, erenumab, migraine, subcutaneous injection, ease of use, calcitonin gene-related peptide

Introduction

Approved biologic therapies are typically self-injected via prefilled syringes or autoinjectors.¹⁻⁴ These technologies aim to address challenges associated with self-injection including injection anxiety and a lack of patient self-confidence in accurate injection.⁵ Prefilled syringes ensure accurate dosing, sterility, and improved safety.⁶ Consequently, the development of self-injection devices has improved patient acceptance of injections, ease of use compared with the conventional needle and syringe,⁷ and patient experience and preference.⁸ Newer autoinjector technologies are designed to further ease patient

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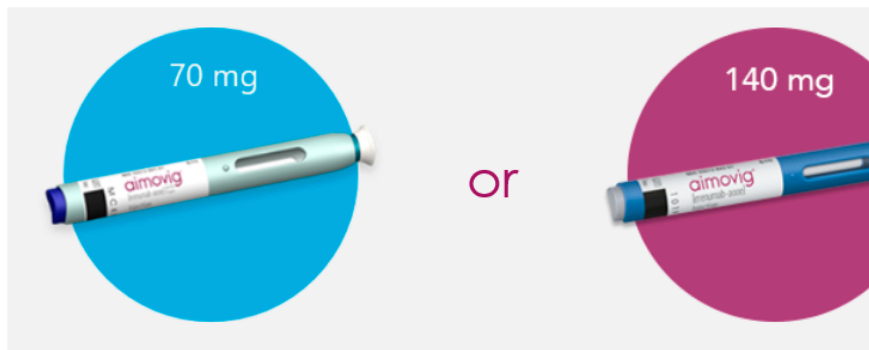


Figure 1 Photograph of the injectors.

burden, facilitate self-injection, and improve treatment adherence and convenience;^{6,8} these are considered by health-care professionals to be advantageous to manual syringe

injections.⁹ In a recent study, participants reported a high likelihood (86% very likely or somewhat likely) of adherence to treatment using an autoinjector device.¹⁰

A

Instructions for Use
AIMOVIG® (AIM-oh-veg) (terimomab-ooee) Injection, For Subcutaneous Use
Single-Dose Prefilled SureClick® Autoinjector
70 mg/mL

Guide to parts

Before use

After use

Important: Needle is inside

Important

Before you use AIMOVIG SureClick autoinjector, read this important information:

Storing your AIMOVIG SureClick autoinjector

- Keep the autoinjector out of the reach of children.
- Keep the autoinjector in the original carton to protect from light.
- The autoinjector should be kept in the refrigerator at 36°F to 46°F (2°C to 8°C).
- After removing AIMOVIG from the refrigerator, it can be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to 7 days.
- Throw away AIMOVIG that has been left at room temperature for more than 7 days.
- Do not freeze.

Using your AIMOVIG SureClick autoinjector

- The needle shield within the white cap of the AIMOVIG autoinjector contains dry natural rubber, which is made from latex. Tell your healthcare provider if you are allergic to latex.
- It is important that you do not try to give the injection unless you or your caregiver has received training from your healthcare provider.
- Do not use the autoinjector after the expiration date on the label.
- Do not shake the autoinjector.
- Do not freeze or use the autoinjector if it has been frozen.
- Do not use the autoinjector if it has been dropped on a hard surface. Part of the autoinjector may be broken even if you cannot see the break. Use a new autoinjector, and call 1-800-77-AMGEN (1-800-772-6436).

Step 1: Prepare

AIMOVIG comes as a single-dose (1 time) prefilled autoinjector. Your healthcare provider will prescribe the dose that is best for you. Before you inject, always check the label of your single-dose prefilled autoinjector to make sure you have the correct medicine and the correct dose of AIMOVIG.

A Remove autoinjector from the carton.

Carefully lift the autoinjector straight up out of the carton. Leave the autoinjector at room temperature for at least 30 minutes before injecting.

- Do not put the autoinjector back in the refrigerator after it has reached room temperature.
- Do not try to warm the autoinjector by using a heat source such as hot water or microwave.
- Do not leave the autoinjector in direct sunlight.
- Do not shake the autoinjector.
- Do not remove the white cap from the autoinjector yet.

B Inspect the autoinjector.

Make sure the medicine in the window is clear and colorless to slightly yellow.

- Do not use the autoinjector if the medicine is cloudy or discolored or contains flakes or particles.
- Do not use the autoinjector if any part appears cracked or broken.
- Do not use the autoinjector if the autoinjector has been dropped.
- Do not use the autoinjector if the white cap is missing or not securely attached.
- Do not use the autoinjector if the expiration date printed on the label has passed.

In all cases, use a new autoinjector, and call 1-800-77-AMGEN (1-800-772-6436).

C Gather all materials needed for your injection.

Wash your hands thoroughly with soap and water. On a clean, well-lit work surface, place the:

- New autoinjector
- Cotton balls or gauze pads
- Adhesive bandages
- Sharps disposal container

D Prepare and clean your injection site.

You can use:

- Your thigh
- Stomach area (abdomen), except for a 2 inch area right around your navel
- Outer area of upper arm (only if someone else is giving you the injection)

Clean your injection site with an alcohol wipe. Let your skin dry.

- Do not touch this area again before injecting.
- Do not inject into areas where the skin is tender, bruised, red, or hard.
- Avoid injecting directly into raised, thick, red, or scaly skin patches or lesions, or areas with scars or stretch marks.

Step 2: Get ready

E Pull the white cap straight off, only when you are ready to inject. Do not leave the white cap off for more than 5 minutes. This can dry out the medicine.

It is normal to see a drop of liquid at the end of the needle or green safety guard.

- Do not twist or bend the white cap.
- Do not put the white cap back onto the autoinjector.
- Do not remove the white cap from the autoinjector until you are ready to inject.

F Stretch or pinch your injection site to create a firm surface.

Stretch method

Stretch skin firmly by moving your thumb and fingers in opposite directions, creating an area about 2 inches wide.

OR

Pinch method

Pinch skin firmly between your thumb and fingers, creating an area about 2 inches wide.

Important: Keep skin stretched or pinched while injecting.

Step 3: Inject

G Hold the stretch or pinch. With the white cap off, place the autoinjector on your skin at 90 degrees.

Important: Do not touch the purple start button yet.

H Firmly push the autoinjector down onto skin until the autoinjector stops moving.

Important: You must push all the way down but do not touch the purple start button until you are ready to inject.

I When you are ready to inject, press the purple start button. You will hear a click.

click!

J Keep pushing down on your skin. Your injection could take about 15 seconds. When the injection is complete, you may hear or feel a click and the window will turn yellow.

15 seconds

click!

Window turns yellow when injection is done

Note: After you remove the autoinjector from your skin, the needle will be automatically covered.

Important: When you remove the autoinjector, if the window has not turned yellow, or if it looks like the medicine is still injecting, this means you have not received a full dose. Call your healthcare provider immediately.

Step 4: Finish

K Discard the used autoinjector and the white cap.

Put the used AIMOVIG autoinjector and white cap in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) the SureClick autoinjector in your household trash.

If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

- Made of a heavy-duty plastic
- Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- Upright and stable during use
- Leak-resistant
- Properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>

- Do not reuse the autoinjector.
- Do not recycle the autoinjector or sharps disposal container or throw them into household trash.

Important: Always keep the sharps disposal container out of the reach of children.

L Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. Do not rub the injection site. Apply an adhesive bandage if needed.

Commonly asked questions

What will happen if I press the purple start button before I am ready to do the injection on my skin?

Even when you press the purple start button, the injection will only happen when the green safety guard is also pushed into the autoinjector.

Can I move the autoinjector around on my skin while I am choosing an injection site?

If it is okay to move the autoinjector around on the injection site as long as you do not press the purple start button. However, if you press the purple start button and the green safety guard is pushed into the autoinjector, the injection will begin.

Can I release the purple start button after I start my injection?

You can release the purple start button, but continue to hold the autoinjector firmly against your skin during the injection.

Will the purple start button pop up after I release my thumb?

The purple start button may not pop up after you release your thumb if your thumb is still down during the injection. This is okay.

What do I do if I did not hear a click after pushing the device down on my skin for 15 seconds?

If you did not hear a click, you can confirm a complete injection by checking that the window has turned yellow.

When do I contact if I need help with the autoinjector or my injection?

If you need more information or help, visit www.aimovig.com or call 1-800-77-AMGEN (1-800-772-6436).

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AMGEN **NOVARTIS**
AIMOVIG® (terimomab-ooee)

Manufactured by:
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799 USA
U.S. License No. 1080

Marketed by:
Amgen Inc. (Thousand Oaks, CA 91320), and
Novartis Pharmaceutical Corporation (East Hanover, NJ 07930)

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Symbol table

This product contains dry natural rubber	Do not use	CAUTION, consult accompanying documents	Lot number

This Instructions for Use has been approved by the U.S. Food and Drug Administration. Approval: 02/019 10200112

Figure 2 Continued.

B Instructions for Use
AIMOVIG® (Aim-oh-vig) (erenumab-ooe) Injection, For Subcutaneous Use
 Single-Dose Prefilled SureClick® Autoinjector
 140 mg/mL

Guide to parts

Before use

After use

Important: Needle is inside

Important

Before you use AIMOVIG SureClick autoinjector, read this important information:

Storing your AIMOVIG SureClick autoinjector

- Keep the autoinjector out of the reach of children.
- Keep the autoinjector in the original carton to protect from light.
- The autoinjector should be kept in the refrigerator at 36°F to 46°F (2°C to 8°C).
- After removing AIMOVIG from the refrigerator, it can be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to 7 days.
- Throw away AIMOVIG that has been left at room temperature for more than 7 days.
- Do not freeze.

Using your AIMOVIG SureClick autoinjector

- The needle should be within the orange cap of the AIMOVIG autoinjector. The needle is made of natural rubber which is made from latex. Tell your healthcare provider if you are allergic to latex. It is important that you do not try to give the injection unless you or your caregiver has received training from your healthcare provider.
- Do not use the autoinjector after the expiration date on the label.
- Do not shake the autoinjector.
- Do not remove the orange cap from the autoinjector until you are ready to inject.
- Do not freeze or use the autoinjector if it has been frozen.
- Do not use the autoinjector if it has been dropped on a hard surface. Part of the autoinjector may be broken even if you cannot see the break. Use a new autoinjector, and call 1-800-77-AMGEN (1-800-772-6436).

Step 1: Prepare

AIMOVIG comes as a single-dose (1 time) prefilled autoinjector. Your healthcare provider will prescribe the dose that is best for you. Before you inject, always check the label of your single-dose prefilled autoinjector to make sure you have the correct medicine and the correct dose of AIMOVIG.

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Carefully lift the autoinjector straight up out of the carton. Leave the autoinjector at room temperature for at least 30 minutes before injecting.

- Do not put the autoinjector back in the refrigerator after it has reached room temperature.
- Do not try to warm the autoinjector by using a heat source such as hot water or microwave.
- Do not leave the autoinjector in direct sunlight.
- Do not shake the autoinjector.
- Do not remove the orange cap from the autoinjector yet.

B Inspect the autoinjector.

Make sure the medicine in the window is clear and colorless to slightly yellow.

- Do not use the autoinjector if the medicine is cloudy or discolored or contains flakes or particles.
- Do not use the autoinjector if any part appears cracked or broken.
- Do not use the autoinjector if the autoinjector has been dropped.
- Do not use the autoinjector if the orange cap is missing or not securely attached.
- Do not use the autoinjector if the expiration date printed on the label has passed.
- In all cases, use a new autoinjector, and call 1-800-77-AMGEN (1-800-772-6436).

C Gather all materials needed for your injection.

Wash your hands thoroughly with soap and water. On a clean, well-ill work surface, place the:

- New autoinjector
- Alcohol wipes
- Cotton balls or gauze pads
- Adhesive bandages
- Sharps disposal container

D Prepare and clean your injection site.

You can use:

- Your thigh
- Stomach area (abdomen), except for a 2 inch area right around your navel
- Outer area of upper arm (only if someone else is giving you the injection)

Clean your injection site with an alcohol wipe. Let your skin dry.

- Do not touch this area again before injecting.
- Do not inject into areas where the skin is tender, bruised, red, or hard.
- Avoid injecting directly into raised, thick, red, or scaly skin patches or lesions, or areas with scars or stretch marks.

Step 2: Get ready

E Pull the orange cap straight off, only when you are ready to inject. Do not leave the orange cap off for more than 5 minutes. This can dry out the medicine.

It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

- Do not twist or bend the orange cap.
- Do not put the orange cap back onto the autoinjector.
- Do not remove the orange cap from the autoinjector until you are ready to inject.

F Stretch or pinch your injection site to create a firm surface.

Stretch method

Stretch the skin firmly by moving your thumb and fingers in opposite directions, creating an area about 2 inches wide.

OR

Pinch method

Pinch skin firmly between your thumb and fingers, creating an area about 2 inches wide.

Important: Keep skin stretched or pinched while injecting.

Step 3: Inject

G Hold the stretch or pinch. With the orange cap off, place the autoinjector on your skin at 90 degrees.

Important: Do not touch the gray start button yet.

H Firmly push the autoinjector down onto skin until the autoinjector stops moving.

Important: You must push all the way down but do not touch the gray start button until you are ready to inject.

I When you are ready to inject, press the gray start button. You will hear a click.

J Keep pushing down on your skin. Your injection could take about 15 seconds. When the injection is complete, you may hear or feel a click and the window will turn yellow.

Important: When you remove the autoinjector from your skin, the needle will be automatically covered.

Step 4: Finish

K Discard the used autoinjector and the orange cap.

Put the used AIMOVIG autoinjector and orange cap in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) the SureClick autoinjector in your household trash. If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

- Made of a heavy-duty plastic
- Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- Upright and stable during use
- Leak-resistant
- Properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>

- Do not reuse the autoinjector.
- Do not recycle the autoinjector or sharps disposal container or throw them into household trash.

Important: Always keep the sharps disposal container out of the reach of children.

L Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. Do not rub the injection site. Apply an adhesive bandage if needed.

Commonly asked questions

What will happen if I press the gray start button before I am ready to do the injection on my skin?

Can when you press the gray start button, the injection will only happen when the yellow safety guard is also pushed into the autoinjector.

Can I reuse the autoinjector around on my skin while I am choosing an injection site?

It is important to make the autoinjector around on the injection site as long as you do not press the gray start button. However, if you press the gray start button and the yellow safety guard is pushed into the autoinjector, the injection will begin.

Can I release the gray start button after I start my injection?

You can release the gray start button, but continue to hold the autoinjector firmly against your skin during the injection.

Will the gray start button pop up after I release my thumb?

The gray start button may not pop up after you release your thumb if you hold your thumb down during the injection. This is okay.

What do I do if I did not hear a click after pushing the device down on my skin for 15 seconds?

If you did not hear a click, you can confirm a complete injection by checking that the window has turned yellow.

Whom do I contact if I need help with the autoinjector or my injection?

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 Amgen Inc. (Thousand Oaks, CA 91320), and
 Novartis Pharmaceuticals Corporation (East Hanover, NJ 07936)
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Symbol table

This product contains dry natural rubber	Do not use	CAUTION: consult accompanying documents	Lot number

The instructions for Use has been approved by the U.S. Food and Drug Administration. Approval: 02/2019 101923 v1

Figure 2 Autoinjector instructions for use. (A) Autoinjector: 70 mg/mL. (B) Autoinjector: 140 mg/mL.

Erenumab was the first calcitonin gene-related peptide (CGRP) pathway-targeted monoclonal antibody approved by the US Food and Drug Administration and the European Medicines Agency for the preventive treatment of migraine in adults.^{4,11–13} It is administered monthly/4-weekly in doses of 70 and 140 mg via subcutaneous injection via a single-dose prefilled SureClick® disposable autoinjector device. The autoinjector device was designed with features to enhance patient experience.⁴ For example, each disposable autoinjector is supplied in a single prefilled dose to ensure sterility, improve dosing accuracy and safety, and reduce the time needed to inject. Visible needles are considered a potential barrier to patient adherence to self-injection;¹⁰ therefore, the needle in the autoinjector device is shielded prior to use, alleviating needle phobia and risk of inadvertent needle stick injury. Finally, its shape and size is easy to hold in one hand, easy to operate

with one click of the button, and it provides auditory and visual feedback when the injection is complete.

The objective of this study was to evaluate satisfaction (ease-of-use, the ability to learn self-injection, confidence in performing self-injections, and look and feel) with the sample single-dose, prefilled autoinjector device for erenumab among individuals with migraines. This study did not evaluate performance-based usability of the autoinjector device or clinical efficacy and safety, as injections were administered by the participant into an injection pad and no study drug was administered.

Patients and Methods Study Design

This US-based multicenter study occurred between March 4 and March 13, 2019, at three test facilities in Chicago, IL; Oakbrook Terrace, IL; and Atlanta, GA. Institutional Review

Board approval was not required as study participants simulated drug administration into an injection pad using a sample autoinjector device prefilled with sterile fluid and did not inject into their body (Figure 1). The prototype autoinjector devices were identical to the commercially available device, but were labelled “not for medical use,” “contains a sterile needle,” “does not contain drug,” and “not for sale,” and contained sterile fluid rather than any study drug. Participants were not asked to evaluate labelling content.

Evaluations and data gathered about the device were based upon the personal experience and perspective of the user. The study employed a 30-minute one-on-one interview in which a session moderator guided the participants to operate the prototype autoinjector using the Instructions for Use (IFU) (Figure 2), allowing participant familiarization with the device for up to 10 minutes. Per the IFU, participants were informed that they were using a device containing a sterile needle and fluid, and were instructed not to remove the needle cap until injection. Each study session was live-streamed remotely to the onsite study sponsor, and participant identification was blinded. Patients were aware that the sponsor may or may not be observing, and were instructed not to state their name while in the room or any medications they are taking. The study setting included tables, chairs, and a microphone. Participant actions were captured via two cameras, one overhead and another to capture the patient during injection simulation, but cameras were pointed at participant hands or action areas, not at the participant’s face. An observer watched the live video feed from an adjacent room during the entire session to allow for intervention as needed to avoid risk to the patient during the simulated autoinjector use (ie, needle stick injury, inadvertent self-administration of sterile test fluid).

Participants

In total, 226 participants were recruited by a third-party telephone screen, with the goal of including those with a migraine diagnosis who were 21 to 85 years of age, predominantly female, and 100% autoinjector- and anti-CGRP therapy-naïve. Recruited participants were either from a recruiter’s pre-existing database of potential participants or were identified through their response to targeted ads on social media, specifically looking for those with interest in migraine information. Patients from the latter group were then screened to ensure eligibility. Exclusion criteria included current or past erenumab use, a pacemaker, blindness, aged 86 or older, and study participation with the

sponsor in the previous 6 months. All participants provided signed informed consent.

Study Assessments

Participants were randomly assigned to use the 70 mg or 140 mg autoinjector, with 50% of each user group injecting into an artificial skin pad placed on the thigh, and the other 50% injecting into an artificial skin pad placed on the abdomen (Figure 3). Immediately following the skin pad injection, participants provided feedback on the use and characteristics of the device by rating their agreement with 19 statements (ie, ease-of-use, learnability, confidence self-injecting, and look and feel) using a 5-point Likert scale questionnaire (1 = completely disagree, 2 = somewhat disagree, 3 = neutral, 4 = somewhat agree, 5 = completely agree) (Table 1).

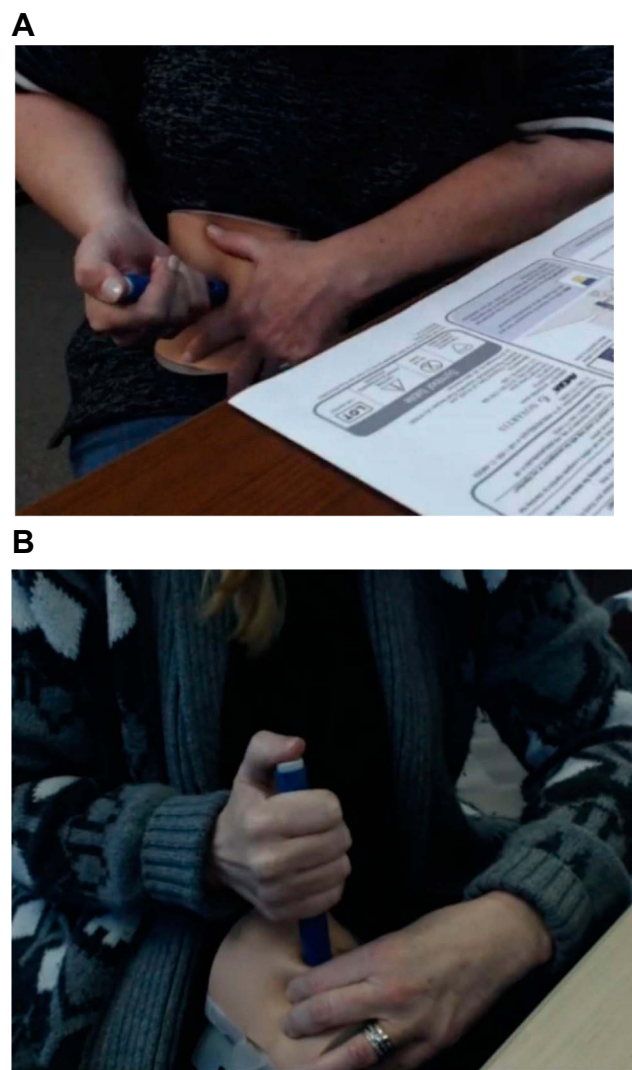


Figure 3 Simulated injections were performed using an artificial injection pad. (A) Simulation of an abdomen injection. (B) Simulation of a thigh injection.

Table 1 Study Survey and Rating Scale

	Statement				
1	Overall, the device is easy to use				
2	Overall, the device is simple to use				
3	Learning to use the device is easy				
4	The device is easy to hold in my hand when I inject				
5	It is easy to remove the cap				
6	It is easy to inject by pressing the start button				
7	I feel confident in my ability to use the device				
8	It is easy to know when the injection has completed				
9	I feel confident the full dose was injected				
10	I would continue to use a single-dose device				
11	I would recommend this device to other patients who need injections				
12	I am confident in my ability to inject without the help of a caregiver				
13	I am confident that I am using the injection device correctly				
14	The device would be easy to travel with				
15	The device is convenient				
16	The device is stable in my hand during administration				
17	The device is comfortable in my hand				
18	I like the size of the device				
19	The device is compact				
Rating					
1	2	3	4	5	
Completely disagree	Somewhat disagree	Neutral	Somewhat agree	Completely agree	

Data Analysis

During each test session, the observer recorded all activities performed by the participants including participants' ease-of-use, learnability, confidence self-injecting, and look and feel. Average (mean) ratings and the top two box scores were then calculated for each statement across all participants at all study sites. The observer recorded the participants' performance parameters to support disposition and root cause analyses. All averages and top two box scores were calculated in Microsoft Excel (Redmond, WA). Qualified researchers may request data from Amgen clinical studies. Complete details are available at <http://www.amgen.com/datasharing>.

Results

Participant Population

A total of 226 participants were recruited into the study, of which 204 (73% female, 27% male) completed the study. Twenty-two participants with prior autoinjector experience (ie, Epi-Pen[®] [epinephrine injection, USP] and insulin injectors) were excluded, and one participant refused to

wear the injection pad for the injection simulation stage and was dismissed.

Participant Device Acceptance

More than 90% of participants completely or somewhat agreed with 16/19 statements on ease-of-use of the device, ability to self-inject, and patient confidence in using the device, with an average rating of >4.5 on a 5-point Likert scale (Table 2). A total of 79% (161/204) of participants completely agreed that the autoinjector was easy to use, and 82% (168/204) completely agreed that the device was simple to use (Table 3). Over 84% (173/204) of participants completely agreed that the device was easy to inject by pressing the start button, 80% were confident in their ability to use the device, and 69% were confident that they were using the injection device correctly (Table 3). Statements related to preference of the size of the device and its compactness were rated 4.23 and 4.26, respectively. No protocol amendments were made, and no adverse events were reported during the study.

Table 2 Participant Ratings on the Ease of Use of the Autoinjector

	Statement	Average Rating Score	Rating Score of 4 or 5 ^a (%)
1	Overall, the device is easy to use	4.75	96
2	Overall, the device is simple to use	4.79	98
3	Learning to use the device is easy	4.65	94
4	The device is easy to hold in my hand when I inject	4.69	96
5	It is easy to remove the cap	4.65	93
6	It is easy to inject by pressing the start button	4.79	96
7	I feel confident in my ability to use the device	4.77	98
8	It is easy to know when the injection has completed	4.73	93
9	I feel confident the full dose was injected	4.69	94
10	I would continue to use a single-dose device	4.52	86
11	I would recommend this device to other patients who need injections	4.68	93
12	I am confident in my ability to inject without the help of a caregiver	4.78	97
13	I am confident that I am using the injection device correctly	4.60	94
14	The device would be easy to travel with	4.66	92
15	The device is convenient	4.69	93
16	The device is stable in my hand during administration	4.75	96
17	The device is comfortable in my hand	4.63	92
18	I like the size of the device	4.23	82
19	The device is compact	4.26	81

Notes: Ratings were based on a sample size of 204; ^a4, somewhat agree; 5, completely agree.

Table 3 Participant Rating Distribution on the Ease of Use of the Autoinjector

	Statement	Participant Rating ^a				
		1	2	3	4	5
1	Overall, the device is easy to use	0	1 (0.5)	7 (3.4)	35 (17.2)	161 (78.9)
2	Overall, the device is simple to use	0	1 (0.5)	4 (2.0)	31 (15.2)	168 (82.4)
3	Learning to use the device is easy	0	2 (1.0)	10 (4.9)	46 (22.5)	146 (71.6)
4	The device is easy to hold in my hand when I inject	0	5 (2.5)	4 (2.0)	40 (19.6)	155 (76.0)
5	It is easy to remove the cap	1 (0.5)	2 (1.0)	12 (5.9)	38 (18.6)	151 (74.0)
6	It is easy to inject by pressing the start button	0	3 (1.5)	6 (2.9)	22 (10.8)	173 (84.8)
7	I feel confident in my ability to use the device	0	2 (1.0)	3 (1.5)	35 (17.2)	164 (80.4)
8	It is easy to know when the injection has completed	1 (0.5)	4 (2.0)	9 (4.4)	21 (10.3)	169 (82.8)
9	I feel confident the full dose was injected	1 (0.5)	5 (2.5)	7 (3.4)	30 (14.7)	161 (78.9)
10	I would continue to use a single-dose device	2 (1.0)	5 (2.5)	22 (10.8)	31 (15.2)	144 (70.6)
11	I would recommend this device to other patients who need injections	0	2 (1.0)	12 (5.9)	36 (17.6)	154 (75.5)
12	I am confident in my ability to inject without the help of a caregiver	1 (0.5)	3 (1.5)	3 (1.5)	25 (12.3)	172 (84.3)
13	I am confident that I am using the injection device correctly	1 (0.5)	3 (1.5)	9 (4.4)	50 (24.5)	141 (69.1)
14	The device would be easy to travel with	1 (0.5)	6 (2.9)	9 (4.4)	29 (14.2)	159 (77.9)
15	The device is convenient	0	4 (2.0)	10 (4.9)	31 (15.2)	159 (77.9)
16	The device is stable in my hand during administration	0	4 (2.0)	5 (2.5)	29 (14.2)	166 (81.4)
17	The device is comfortable in my hand	0	4 (2.0)	12 (5.9)	39 (19.1)	149 (73.0)
18	I like the size of the device	5 (2.5)	11 (5.4)	21 (10.3)	62 (30.4)	105 (51.5)
19	The device is compact	3 (1.5)	13 (6.4)	23 (11.3)	53 (26.0)	112 (54.9)

Notes: Shown as n (%); ratings were based on a sample size of 204; ^a1, completely disagree; 2, somewhat disagree; 3, neutral; 4, somewhat agree; 5, completely agree.

Discussion

This study was designed to gain insight into participant perspective about the ease of use of the prototype single-dose autoinjector device. All participants were naïve to the use of the autoinjector. Participants rated the prototype on a 5-point Likert scale based on agreement or disagreement with 19 statements relating to ease-of-use, ability to self-inject, self-confidence in using the device, and look and feel. The prototype received high ratings from the majority of participants on ease-of-use, ability to self-inject, and self-confidence in using the device. These findings demonstrate that the prefilled autoinjector device for erenumab was well received. Following a one-on-one instructional session, participants felt confident in their ability to self-inject with the device.

The goal of this study was not to assess injection tolerability, as this has been thoroughly investigated in Phase 2 and Phase 3 clinical trials demonstrating that erenumab was well tolerated with an absence of dose-dependent injection-related events.^{14–16}

The prototype autoinjector device was well received among individuals with migraine. A limitation of the study included the subjective nature of participant ratings. Furthermore, the study was not designed to collect performance-based usability or clinical data on the prototype autoinjector. Another potential limitation is that the study took place in a controlled environment that differs from participants' home settings. In addition, participants were injection-naïve and only performed one injection. Thus, findings reported here are limited to first-time users and do not demonstrate if there is a learning curve. These study limitations are not expected to affect the utility of study data or the conclusions drawn from this study. The device was stable and easy to use in autoinjector-naïve participants. The high ratings of the autoinjector in this study indicate that the device is ideal for the administration of migraine therapy among individuals with migraines.

Conclusion

The SureClick[®] disposable autoinjector device was given high ease-of-use ratings, with an average rating of >4.5 on the 5-point Likert scale by study participants, suggesting that it provides an optimal method for the administration of erenumab. Ratings for study participants were uniformly positive across rating categories and three study centers, suggesting that the design of the device is suitable for and accessible to individuals with migraines.

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Author Contributions

All authors contributed to the study design, data collection and interpretation, data analysis, drafting or revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Disclosure

Jennifer Mead and Soeren Rasmussen are employees of Amgen Inc., and hold Amgen Inc., stock/stock options. Ryan Dammerman was an employee of Amgen Inc., at the time the study was conducted. The authors report no other conflicts of interest in this work.

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