

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AIMOVIG safely and effectively. See full prescribing information for AIMOVIG.

AIMOVIG® (erenumab-aooe) injection, for subcutaneous use
Initial U.S. Approval: 2018

RECENT MAJOR CHANGES

Dosage and Administration (2.2) 9/2022

INDICATIONS AND USAGE

AIMOVIG is a calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of migraine in adults. (1)

DOSAGE AND ADMINISTRATION

- For subcutaneous use only (2.1, 2.2)
- Recommended dosage is 70 mg once monthly; some patients may benefit from a dosage of 140 mg once monthly (2.1)
- Administer in the abdomen, thigh, or upper arm subcutaneously (2.2)
- See Dosage and Administration for important administration instructions (2.2)

DOSAGE FORMS AND STRENGTHS

- Injection: 70 mg/mL solution in a single-dose prefilled SureClick® autoinjector (3)
- Injection: 140 mg/mL solution in a single-dose prefilled SureClick® autoinjector (3)
- Injection: 70 mg/mL solution in a single-dose prefilled syringe (3)

- Injection: 140 mg/mL solution in a single-dose prefilled syringe (3)

CONTRAINDICATIONS

AIMOVIG is contraindicated in patients with serious hypersensitivity to erenumab-aooe or to any of the excipients. (4)

WARNINGS AND PRECAUTIONS

- Hypersensitivity Reactions: If a serious hypersensitivity reaction occurs, discontinue administration of AIMOVIG and initiate appropriate therapy. Hypersensitivity reactions can occur within hours to more than one week after administration. (5.1)
- Constipation with Serious Complications: Serious complications of constipation may occur. (5.2)
- Hypertension: New-onset or worsening of pre-existing hypertension may occur. (5.3)

ADVERSE REACTIONS

The most common adverse reactions in AIMOVIG clinical studies (occurring in at least 3% of treated patients and more often than placebo) are injection site reactions and constipation. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Amgen Medical Information at 1-800-77-AMGEN (1-800-772-6436) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved Patient Labeling.

Revised: 8/2024

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AIMOVIG is indicated for the preventive treatment of migraine in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

The recommended dosage of AIMOVIG is 70 mg injected subcutaneously once monthly. Some patients may benefit from a dosage of 140 mg injected subcutaneously once monthly.

If a dose of AIMOVIG is missed, administer as soon as possible. Thereafter, AIMOVIG can be scheduled monthly from the date of the last dose.

2.2 Important Administration Instructions

AIMOVIG is for subcutaneous use only.

AIMOVIG is intended for patient self-administration. Prior to use, provide proper training to patients and/or caregivers on how to prepare and administer AIMOVIG using the single-dose prefilled autoinjector or single-dose prefilled syringe, including aseptic technique [*see Instructions for Use*]:

- Prior to subcutaneous administration, allow AIMOVIG to sit at room temperature for at least 30 minutes protected from direct sunlight [*see How Supplied/Storage and Handling (16.2)*]. This is important for administering the entire dose and helps minimize discomfort. Do not warm by using a heat source such as hot water or a microwave.
- Do not shake the product.
- Inspect visually for particulate matter and discoloration prior to administration [*see Dosage Forms and Strengths (3)*]. Do not use if the solution is cloudy or discolored or contains flakes or particles.
- Administer AIMOVIG in the abdomen, thigh, or upper arm subcutaneously. Do not inject into areas where the skin is tender, bruised, red, or hard.
- Both prefilled autoinjector and prefilled syringe are single-dose and deliver the entire contents.

3 DOSAGE FORMS AND STRENGTHS

AIMOVIG is a sterile, clear to opalescent, colorless to light yellow solution available as follows:

- Injection: 70 mg/mL in a single-dose prefilled SureClick[®] autoinjector
- Injection: 140 mg/mL in a single-dose prefilled SureClick[®] autoinjector
- Injection: 70 mg/mL in a single-dose prefilled syringe
- Injection: 140 mg/mL in a single-dose prefilled syringe

4 CONTRAINDICATIONS

AIMOVIG is contraindicated in patients with serious hypersensitivity to erenumab-aooe or to any of the excipients. Reactions have included anaphylaxis and angioedema [*see Warnings and Precautions (5.1)*].

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions, including rash, angioedema, and anaphylaxis, have been reported with AIMOVIG in postmarketing experience. Most hypersensitivity reactions were not serious and occurred within hours of administration, although some occurred more than one week after administration. If a serious or severe hypersensitivity reaction occurs, discontinue administration of AIMOVIG and initiate appropriate therapy [*see Contraindications (4), and Patient Counseling Information (17)*].

5.2 Constipation with Serious Complications

Constipation with serious complications has been reported following the use of AIMOVIG in the postmarketing setting. There were cases that required hospitalization, including cases where surgery was necessary. In a majority of these cases, the onset of constipation was reported after the first dose of AIMOVIG; however, patients have also presented with constipation later on in treatment. AIMOVIG was discontinued in most reported cases of constipation with serious complications. Constipation was one of the most common (up to 3%) adverse reactions reported in clinical studies [*see Adverse Reactions (6.1)*].

Monitor patients treated with AIMOVIG for severe constipation and manage as clinically appropriate [*see Patient Counseling Information (17)*]. The concurrent use of medications associated with decreased gastrointestinal motility may increase the risk for more severe constipation and the potential for constipation-related complications.

5.3 Hypertension

Development of hypertension and worsening of pre-existing hypertension have been reported following the use of AIMOVIG in the postmarketing setting. Many of the patients had pre-existing hypertension or risk factors for hypertension. There were cases requiring pharmacological treatment and, in some cases, hospitalization. Hypertension may occur at any time during treatment but was most frequently reported within seven days of dose administration. In the majority of the cases, the onset or worsening of hypertension was reported after the first dose. AIMOVIG was discontinued in many of the reported cases.

Monitor patients treated with AIMOVIG for new-onset hypertension, or worsening of pre-existing hypertension, and consider whether discontinuation of AIMOVIG is warranted if evaluation fails to establish an alternative etiology.

6 ADVERSE REACTIONS

The following serious adverse reactions are described below and elsewhere in the labeling:

- Hypersensitivity Reactions [see *Warnings and Precautions (5.1)*]
- Constipation with Serious Complications [see *Warnings and Precautions (5.2)*]
- Hypertension [see *Warnings and Precautions (5.3)*]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety of AIMOVIG has been evaluated in 2537 patients with migraine who received at least one dose of AIMOVIG, representing 3040.2 patient-years of exposure. Of these, 2271 patients were exposed to 70 mg or 140 mg once monthly for at least 6 months, 1305 patients were exposed for at least 12 months, and 216 patients were exposed through 5 years.

In placebo-controlled clinical studies (Studies 1, 2, and 3) of 2184 patients, 787 patients received at least one dose of AIMOVIG 70 mg once monthly, 507 patients received at least one dose of AIMOVIG 140 mg once monthly, and 890 patients received placebo during 3 months or 6 months of double-blind treatment [see *Clinical Studies (14)*]. Approximately 84% were female, 91% were white, and the mean age was 42 years at study entry.

The most common adverse reactions (incidence $\geq 3\%$ and more often than placebo) in the migraine studies were injection site reactions and constipation. Table 1 summarizes the adverse reactions that occurred during the first 3 months in the migraine studies (Studies 1, 2, and 3).

Table 1: Adverse Reactions Occurring with an Incidence of at Least 2% for Either Dose of AIMOVIG and at Least 2% Greater than Placebo During the First 3 Months in Studies 1, 2, and 3

Adverse Reaction	AIMOVIG 70 mg Once Monthly N = 787 %	AIMOVIG 140 mg Once Monthly N = 507 %	Placebo N = 890 %
Injection site reactions ^{a,b}	6	5	3
Constipation	1	3	1
Cramps, muscle spasms	< 1	2	< 1

^a Injection site reactions include multiple adverse reactions related terms, such as injection site pain and injection site erythema.

^b The rate of injection site reactions reported in Table 1 is with the prefilled syringe.

In Studies 1, 2, and 3, 1.3% of patients treated with AIMOVIG 70 mg or 140 mg discontinued double-blind treatment because of adverse events. The most frequent injection site reactions were injection site pain, injection site erythema, and injection site pruritus.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of AIMOVIG. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune System Disorders: Hypersensitivity reactions, including rash, angioedema, and anaphylaxis [see *Warnings and Precautions (5.1)*].

Gastrointestinal Disorders: Constipation with serious complications [see *Warnings and Precautions (5.2)*], oral mucosal ulceration.

Skin and Subcutaneous Tissue Disorders: Rash, alopecia.

Vascular Disorders: Hypertension [see *Warnings and Precautions (5.3)*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to AIMOVIG during pregnancy. Patients should be encouraged to enroll by calling 1-833-244-4083 or visiting <https://www.genesispregnancyregistry.com/>.

Risk Summary

There are no adequate data on the developmental risk associated with the use of AIMOVIG in pregnant women. No adverse effects on offspring were observed when pregnant monkeys were administered erenumab-aooe throughout gestation [see *Data*]. Serum erenumab-aooe exposures in pregnant monkeys were greater than those in humans at clinical doses.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%-4% and 15%-20%, respectively. The estimated rate of major birth defects (2.2%-2.9%) and miscarriage (17%) among deliveries to women with migraine are similar to rates reported in women without migraine.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Published data have suggested that women with migraine may be at increased risk of preeclampsia and gestational hypertension during pregnancy.

Data

Animal Data

In a study in which female monkeys were administered erenumab-aooe (0 or 50 mg/kg) twice

weekly by subcutaneous injection throughout pregnancy (gestation day 20-22 to parturition), no adverse effects on offspring were observed. Serum erenumab-aooe exposures (AUC) in pregnant monkeys were approximately 20 times that in humans at a dose of 140 mg once monthly.

8.2 Lactation

Risk Summary

There are no data on the presence of erenumab-aooe in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for AIMOVIG and any potential adverse effects on the breastfed infant from AIMOVIG or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of AIMOVIG did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

11 DESCRIPTION

Erenumab-aooe is a human immunoglobulin G2 (IgG2) monoclonal antibody that has high affinity binding to the calcitonin gene-related peptide receptor. Erenumab-aooe is produced using recombinant DNA technology in Chinese hamster ovary (CHO) cells. It is composed of 2 heavy chains, each containing 456 amino acids, and 2 light chains of the lambda subclass, each containing 216 amino acids, with an approximate molecular weight of 150 kDa.

AIMOVIG (erenumab-aooe) injection is supplied as a sterile, preservative-free, clear to opalescent, colorless to light yellow solution for subcutaneous administration. Each 1 mL 70 mg single-dose prefilled autoinjector and 70 mg single-dose prefilled glass syringe contains 70 mg erenumab-aooe, acetate (1.5 mg), polysorbate 80 (0.10 mg), and sucrose (73 mg). Each 1 mL 140 mg single-dose prefilled autoinjector and 140 mg single-dose prefilled glass syringe contains 140 mg erenumab-aooe, acetate (2.0 mg), polysorbate 80 (0.10 mg), and sucrose (65 mg). Enclosed within the autoinjector is a single-dose, prefilled glass syringe. The solution of AIMOVIG has a pH of 5.2.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Erenumab-aooe is a human monoclonal antibody that binds to the calcitonin gene-related peptide (CGRP) receptor and antagonizes CGRP receptor function.

12.2 Pharmacodynamics

In a randomized, double-blind, placebo-controlled study in healthy volunteers, concomitant administration of erenumab-aooe (140 mg intravenous, single-dose) with sumatriptan (12 mg subcutaneous, given as two 6 mg doses separated by one hour) had no effect on resting blood pressure compared with sumatriptan alone. AIMOVIG is for subcutaneous use only.

12.3 Pharmacokinetics

Erenumab-aooe exhibits non-linear kinetics as a result of binding to the CGRP receptor. The C_{max} mean and AUC_{last} mean following subcutaneous administration of a 70 mg once monthly and a 140 mg once monthly dose in healthy volunteers or migraine patients are included in Table 2.

Less than 2-fold accumulation was observed in trough serum concentrations (C_{min}) for episodic and chronic migraine patients following subcutaneous administration of 70 mg once monthly and 140 mg once monthly doses (see Table 2). Serum trough concentrations approached steady state by 3 months of dosing. The effective half-life of erenumab-aooe is 28 days.

Table 2: Pharmacokinetic Parameters of AIMOVIG

	AIMOVIG 70 mg Subcutaneously Once Monthly	AIMOVIG 140 mg Subcutaneously Once Monthly
C_{max} mean (SD) ^{a,b}	6.1 (2.1) mcg/mL	15.8 (4.8) mcg/mL
AUC_{last} mean (SD) ^{a,b}	159 (58) day*mcg/mL	505 (139) day*mcg/mL
C_{min} (SD)		
Episodic migraine	5.7 (3.1) mcg/mL	12.8 (6.5) mcg/mL
Chronic migraine	6.2 (2.9) mcg/mL	14.9 (6.5) mcg/mL

^aSD = standard deviation

^bfrom a single-dose study

Absorption

Following a single subcutaneous dose of 70 mg or 140 mg erenumab-aooe administered to healthy adults, median peak serum concentrations were attained in approximately 6 days, and estimated absolute bioavailability was 82%.

Distribution

Following a single 140 mg intravenous dose, the mean (SD) volume of distribution during the terminal phase (V_z) was estimated to be 3.86 (0.77) L.

Metabolism and Excretion

Two elimination phases were observed for erenumab-aooe. At low concentrations, the elimination is predominantly through saturable binding to target (CGRP receptor), while at higher concentrations the elimination of erenumab-aooe is largely through a non-specific, non-saturable proteolytic pathway.

Specific Populations

The pharmacokinetics of erenumab-aooe were not affected by age, gender, race, or subtypes of migraine spectrum (episodic or chronic migraine) based on population pharmacokinetics analysis.

Patients with Renal or Hepatic Impairment

Population pharmacokinetic analysis of integrated data from the AIMOVIG clinical studies did not reveal a difference in the pharmacokinetics of erenumab-aooe in patients with mild or moderate renal impairment relative to those with normal renal function. Patients with severe renal impairment (eGFR < 30 mL/min/1.73 m²) have not been studied. No dedicated clinical studies were conducted to evaluate the effect of hepatic impairment or renal impairment on the pharmacokinetics of erenumab-aooe. Renal or hepatic impairment is not expected to affect pharmacokinetics of erenumab-aooe.

Drug Interaction Studies

P450 Enzymes

Erenumab-aooe is not metabolized by cytochrome P450 enzymes; therefore, interactions with concomitant medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely.

Oral Contraceptives

In an open-label drug interaction study in healthy female volunteers, erenumab-aooe (140 mg subcutaneous, single-dose) did not affect the pharmacokinetics of a combined oral contraceptive containing ethinyl estradiol and norgestimate.

Sumatriptan

In a study in healthy volunteers, concomitant administration of erenumab-aooe with sumatriptan had no effect on the pharmacokinetics of sumatriptan [see *Clinical Pharmacology (12.2)*].

12.6 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of erenumab-aooe.

The immunogenicity of AIMOVIG has been evaluated using an immunoassay for the detection of binding anti-erenumab-aooe antibodies. For patients whose sera tested positive in the screening immunoassay, an *in vitro* biological assay was performed to detect neutralizing antibodies.

In controlled studies with AIMOVIG [see *Clinical Studies (14)*], the incidence of anti-erenumab-aooe antibody development was 6.2% (48/778) in patients receiving AIMOVIG 70 mg once monthly (2 of whom had *in vitro* neutralizing activity) and 2.6% (13/504) in patients receiving AIMOVIG 140 mg once monthly (none of whom had *in vitro* neutralizing activity). In a long-term study, including 12 weeks of double-blind treatment and up to 256 weeks of open-label treatment, the incidence of anti-erenumab-aooe antibody development was 11.1% (25/225) among patients whose AIMOVIG dose was 70 mg or 140 mg (2 of whom had *in vitro*

neutralizing activity). The neutralizing anti-erenumab-aooe antibody positive rate may be underestimated because of limitations of the assay. Although these data do not demonstrate an impact of anti-erenumab-aooe antibody development on the efficacy or safety of AIMOVIG in these patients, the available data are too limited to make definitive conclusions.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

The carcinogenic potential of erenumab-aooe has not been assessed.

Mutagenesis

Genetic toxicology studies of erenumab-aooe have not been conducted.

Impairment of Fertility

Mating studies have not been conducted on erenumab-aooe. No histopathological changes in male or female reproductive organs were observed in monkeys administered erenumab-aooe (0, 25, or 150 mg/kg) by subcutaneous injection twice weekly for up to 6 months. Serum erenumab-aooe exposures (AUC) at the higher dose tested were more than 100 times that in humans at a dose of 140 mg once monthly.

14 CLINICAL STUDIES

The efficacy of AIMOVIG was evaluated as a preventive treatment of episodic or chronic migraine in three randomized, double-blind, placebo-controlled studies: two studies in patients with episodic migraine (4 to 14 migraine days per month) (Study 1 and Study 2) and one study in patients with chronic migraine (≥ 15 headache days per month with ≥ 8 migraine days per month) (Study 3). The studies enrolled patients with a history of migraine, with or without aura, according to the International Classification of Headache Disorders (ICHD-III) diagnostic criteria.

Episodic Migraine

Study 1 (NCT 02456740) was a randomized, multi-center, 6-month, placebo-controlled, double-blind study evaluating AIMOVIG for the preventive treatment of episodic migraine. A total of 955 patients with a history of episodic migraine were randomized to receive either AIMOVIG 70 mg (N = 317), AIMOVIG 140 mg (N = 319), or placebo (N = 319) by subcutaneous injection once monthly (QM) for 6 months. Patients were allowed to use acute headache treatments including migraine-specific medications (i.e., triptans, ergotamine derivatives) and NSAIDs during the study.

The study excluded patients with medication overuse headache as well as patients with myocardial infarction, stroke, transient ischemic attacks, unstable angina, coronary artery bypass surgery, or other revascularization procedures within 12 months prior to screening.

The primary efficacy endpoint was the change from baseline in mean monthly migraine days over months 4 to 6. Secondary endpoints included the achievement of a $\geq 50\%$ reduction from baseline in mean monthly migraine days over months 4 to 6 (“ $\geq 50\%$ MMD responders”), the change from baseline in mean monthly acute migraine-specific medication days over months 4 to 6, and the change from baseline in mean Migraine Physical Function Impact Diary (MPFID) over months 4 to 6. The MPFID measures the impact of migraine on everyday activities (EA) and physical impairment (PI) using an electronic diary administered daily. Monthly MPFID scores are averaged over 28 days, including days with and without migraine; scores are scaled from 0 to 100. Higher scores indicate worse impact on EA and PI. Reductions from baseline in MPFID scores indicate improvement.

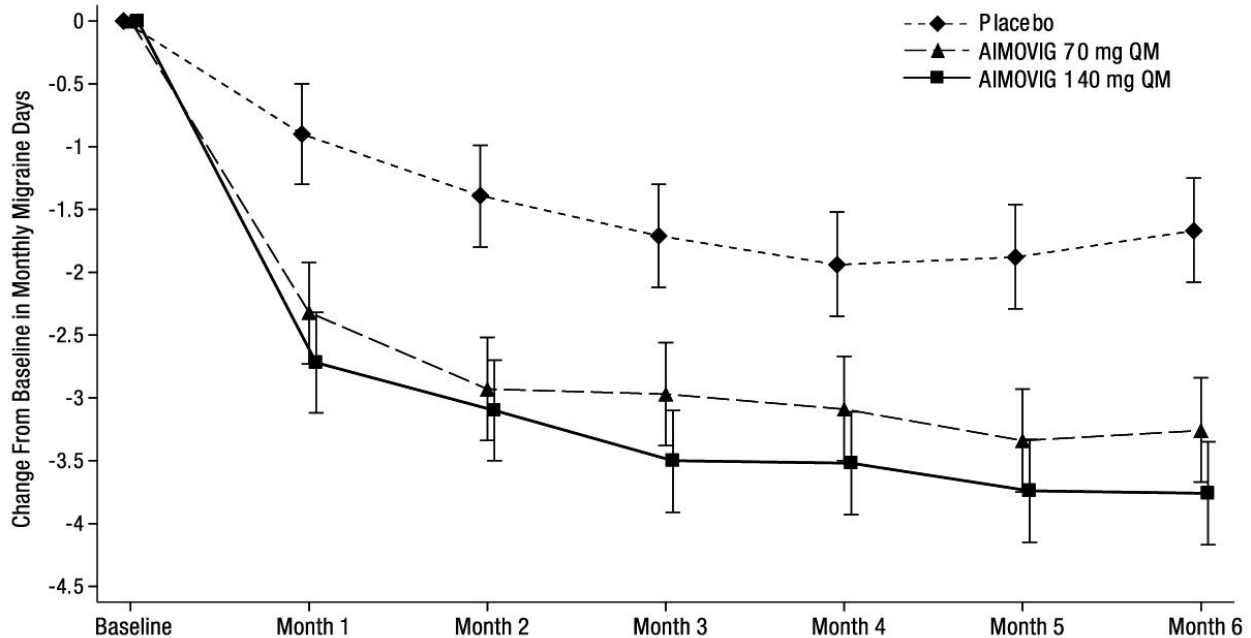
A total of 858 (90%) patients completed the 6-month double-blind study. Patients had a median age of 42 years (range: 18 to 65 years), 85% were female, and 89% were white. Three percent of patients were taking concomitant preventive treatments for migraine. The mean migraine frequency at baseline was approximately 8 migraine days per month and was similar across treatment groups.

AIMOVIG treatment demonstrated statistically significant improvements for key efficacy endpoints compared to placebo, as summarized in Table 3.

Table 3: Efficacy Endpoints Over Months 4 to 6 in Study 1

	AIMOVIG 70 mg Once Monthly N = 312	AIMOVIG 140 mg Once Monthly N = 318	Placebo N = 316
Monthly Migraine Days (MMD)			
Change from baseline	-3.2	-3.7	-1.8
Difference from placebo	-1.4	-1.9	
<i>p</i> -value	< 0.001	< 0.001	
$\geq 50\%$ MMD responders			
% Responders	43.3%	50.0%	26.6%
Difference from placebo	16.7%	23.4%	
Odds ratio relative to placebo	2.1	2.8	
<i>p</i> -value	< 0.001	< 0.001	
Monthly acute migraine-specific medication days			
Change from baseline	-1.1	-1.6	-0.2
Difference from placebo	-0.9	-1.4	
<i>p</i> -value	< 0.001	< 0.001	

Figure 1: Change from Baseline in Monthly Migraine Days in Study 1^a



^a Least-square means and 95% confidence intervals are presented.

Figure 2 shows the distribution of change from baseline in mean monthly migraine days over months 4 to 6 in bins of 2 days by treatment group. A treatment benefit over placebo for both doses of AIMOVIG is seen across a range of changes from baseline in monthly migraine days.

Figure 2: Distribution of Change from Baseline in Mean Monthly Migraine Days Over Months 4 to 6 by Treatment Group in Study 1

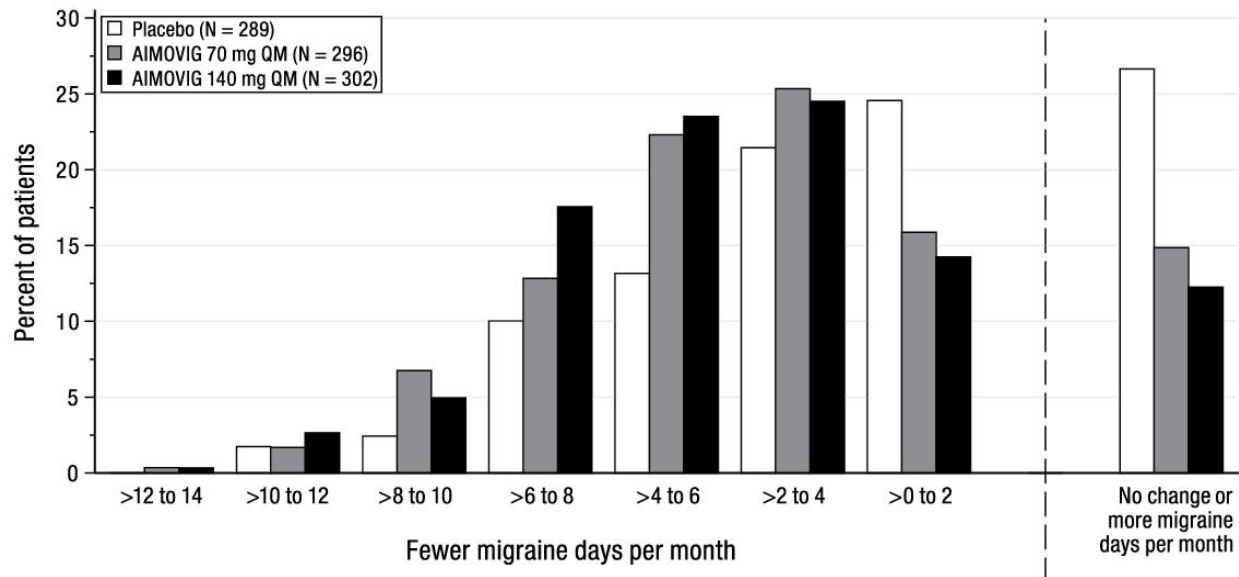


Figure excludes patients with missing data.

Compared to placebo, patients treated with AIMOVIG 70 mg once monthly and 140 mg once monthly showed greater reductions from baseline in mean monthly MPFID everyday activity scores averaged over months 4 to 6 [difference from placebo: -2.2 for AIMOVIG 70 mg and -2.6 for AIMOVIG 140 mg; p -value < 0.001 for both], and in mean monthly MPFID physical

impairment scores averaged over months 4 to 6 [difference from placebo: -1.9 for AIMOVIG 70 mg and -2.4 for AIMOVIG 140 mg; p -value < 0.001 for both].

Study 2 (NCT 02483585) was a randomized, multi-center, 3-month, placebo-controlled, double-blind study evaluating AIMOVIG for the preventive treatment of episodic migraine. A total of 577 patients with a history of episodic migraine were randomized to receive either AIMOVIG 70 mg (N = 286) or placebo (N = 291) by subcutaneous injection once monthly for 3 months. Patients were allowed to use acute headache treatments including migraine-specific medications (i.e., triptans, ergotamine derivatives) and NSAIDs during the study.

The study excluded patients with medication overuse headache as well as patients with myocardial infarction, stroke, transient ischemic attacks, unstable angina, coronary artery bypass surgery, or other revascularization procedures within 12 months prior to screening.

The primary efficacy endpoint was the change from baseline in monthly migraine days at month 3. Secondary endpoints included the achievement of a $\geq 50\%$ reduction from baseline in monthly migraine days (" $\geq 50\%$ MMD responders"), the change from baseline in monthly acute migraine-specific medication days at month 3, and the proportion of patients with at least a 5-point score reduction from baseline in MPFID at month 3.

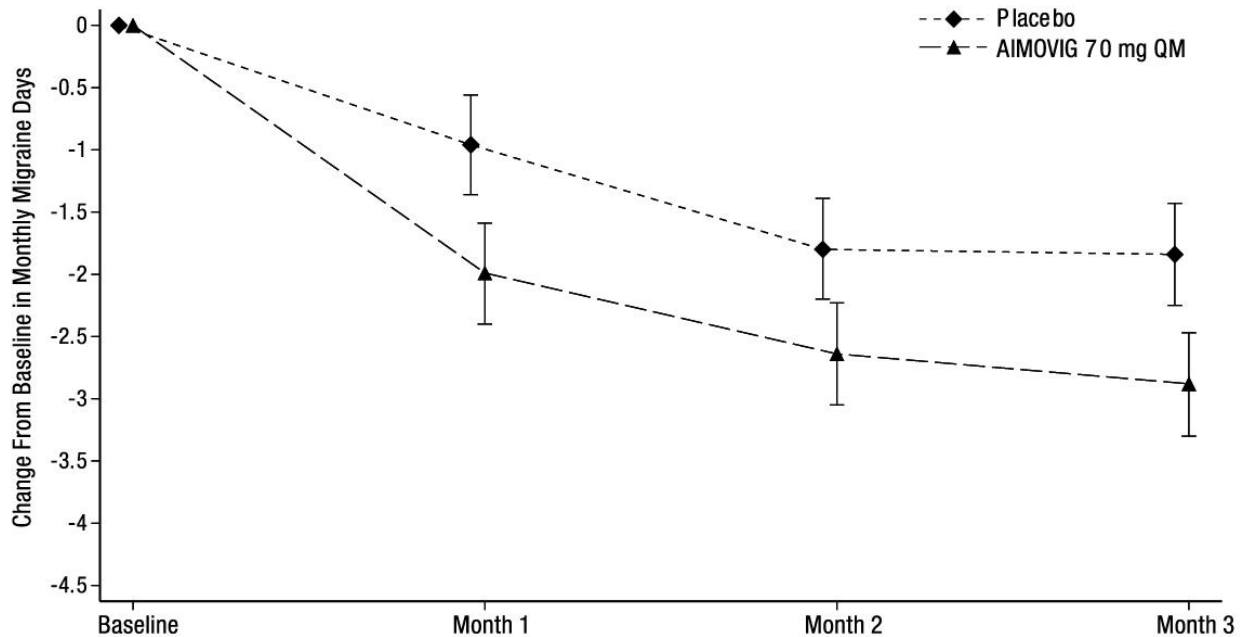
A total of 546 (95%) patients completed the 3-month double-blind study. Patients had a median age of 43 years (range: 18 to 65 years), 85% were female, and 90% were white. Six to seven percent of patients were taking concomitant preventive migraine treatment. The mean migraine frequency at baseline was approximately 8 migraine days per month and was similar between treatment groups.

AIMOVIG treatment demonstrated statistically significant improvements for key efficacy endpoints compared to placebo, as summarized in Table 4.

Table 4: Efficacy Endpoints at Month 3 for Study 2

	AIMOVIG 70 mg Once Monthly N = 282	Placebo N = 288
Monthly Migraine Days (MMD)		
Change from baseline	-2.9	-1.8
Difference from placebo	-1.0	
p -value	< 0.001	
$\geq 50\%$ MMD responders		
% Responders	39.7%	29.5%
Difference from placebo	10.2%	
Odds ratio relative to placebo	1.6	
p -value	0.010	
Monthly acute migraine-specific medication days		
Change from baseline	-1.2	-0.6
Difference from placebo	-0.6	
p -value	0.002	

Figure 3: Change from Baseline in Monthly Migraine Days in Study 2^a



^a Least-square means and 95% confidence intervals are presented.

Figure 4 shows the distribution of change from baseline in monthly migraine days at month 3 in bins of 2 days by treatment group. A treatment benefit over placebo for AIMOVIG is seen across a range of changes from baseline in monthly migraine days.

Figure 4: Distribution of Change from Baseline in Monthly Migraine Days at Month 3 by Treatment Group in Study 2

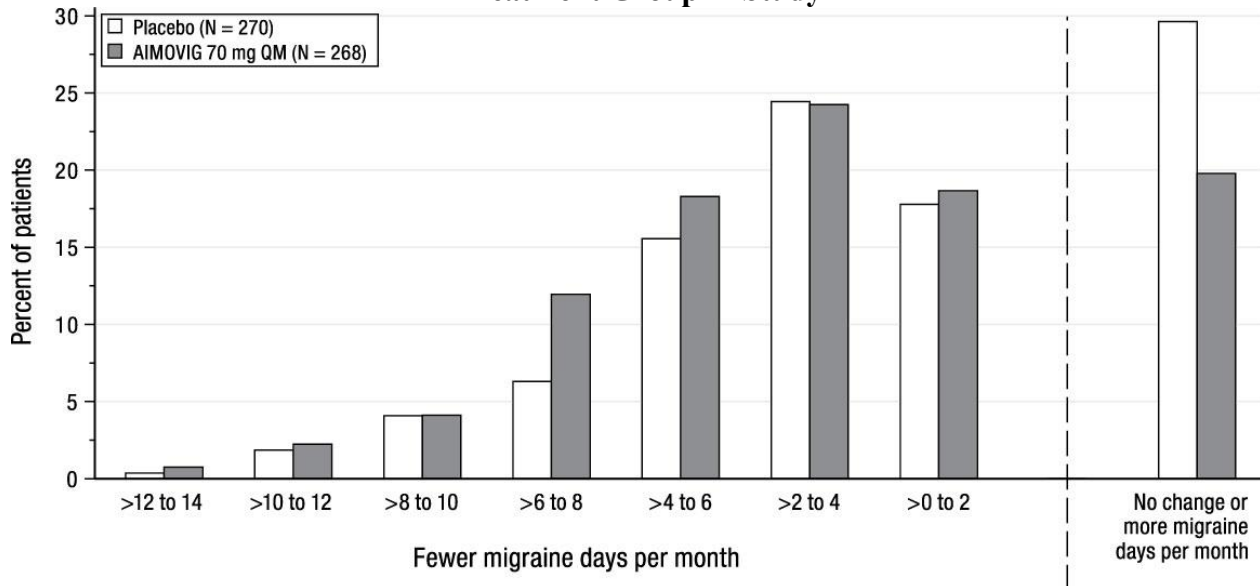


Figure excludes patients with missing data.

The pre-specified analysis for the MPFID was based on at least a 5-point reduction within-patient responder definition. AIMOVIG 70 mg once monthly was not significantly better than placebo for the proportion of responders for everyday activity [difference from placebo: 4.7%; odds ratio = 1.2; *p*-value = 0.26] and physical impairment [difference from placebo: 5.9%; odds

ratio = 1.3; p -value = 0.13]. In an exploratory analysis of the change from baseline in the mean MPFID scores at month 3, patients treated with AIMOVIG 70 mg, as compared to placebo, showed nominally greater reductions of physical impairment scores [difference from placebo: -1.3; p -value = 0.021], but not of everyday activities scores [difference from placebo: -1.1; p -value = 0.061].

Chronic Migraine

Study 3 (NCT 02066415) was a randomized, multi-center, 3-month, placebo-controlled, double-blind study evaluating AIMOVIG as a preventive treatment of chronic migraine. A total of 667 patients with a history of chronic migraine with or without aura were randomized to receive AIMOVIG 70 mg (N = 191), AIMOVIG 140 mg (N = 190), or placebo (N = 286) by subcutaneous injections once monthly for 3 months. Patients were allowed to use acute headache treatments including migraine-specific medications (i.e., triptans, ergotamine derivatives) and NSAIDs during the study.

The study excluded patients with medication overuse headache caused by opiate overuse and patients with concurrent use of migraine preventive treatments. Patients with myocardial infarction, stroke, transient ischemic attacks, unstable angina, coronary artery bypass surgery, or other revascularization procedures within 12 months prior to screening were also excluded.

The primary efficacy endpoint was the change from baseline in monthly migraine days at month 3. Secondary endpoints included the achievement of a $\geq 50\%$ reduction from baseline in monthly migraine days (" $\geq 50\%$ MMD responders") and change from baseline in monthly acute migraine-specific medication days at month 3.

A total of 631 (95%) patients completed the 3-month double-blind study. Patients had a median age of 43 years (range: 18 to 66 years), 83% were female, and 94% were white. The mean migraine frequency at baseline was approximately 18 migraine days per month and was similar across treatment groups.

AIMOVIG treatment demonstrated statistically significant improvements for key efficacy outcomes compared to placebo, as summarized in Table 5.

Table 5: Efficacy Endpoints at Month 3 in Study 3

	AIMOVIG 70 mg Once Monthly N = 188	AIMOVIG 140 mg Once Monthly N = 187	Placebo N = 281
Monthly Migraine Days (MMD)			
Change from baseline	-6.6	-6.6	-4.2
Difference from placebo	-2.5	-2.5	
p -value	< 0.001	< 0.001	
$\geq 50\%$ MMD responders			
% Responders	39.9%	41.2%	23.5%
Difference from placebo	16.4%	17.7%	
Odds ratio relative to placebo	2.2	2.3	
p -value	< 0.001	< 0.001	

	AIMOVIG 70 mg Once Monthly N = 188	AIMOVIG 140 mg Once Monthly N = 187	Placebo N = 281
Monthly acute migraine-specific medication days			
Change from baseline	-3.5	-4.1	-1.6
Difference from placebo	-1.9	-2.6	
<i>p</i> -value	< 0.001	< 0.001	

Figure 5: Change from Baseline in Monthly Migraine Days in Study 3^a

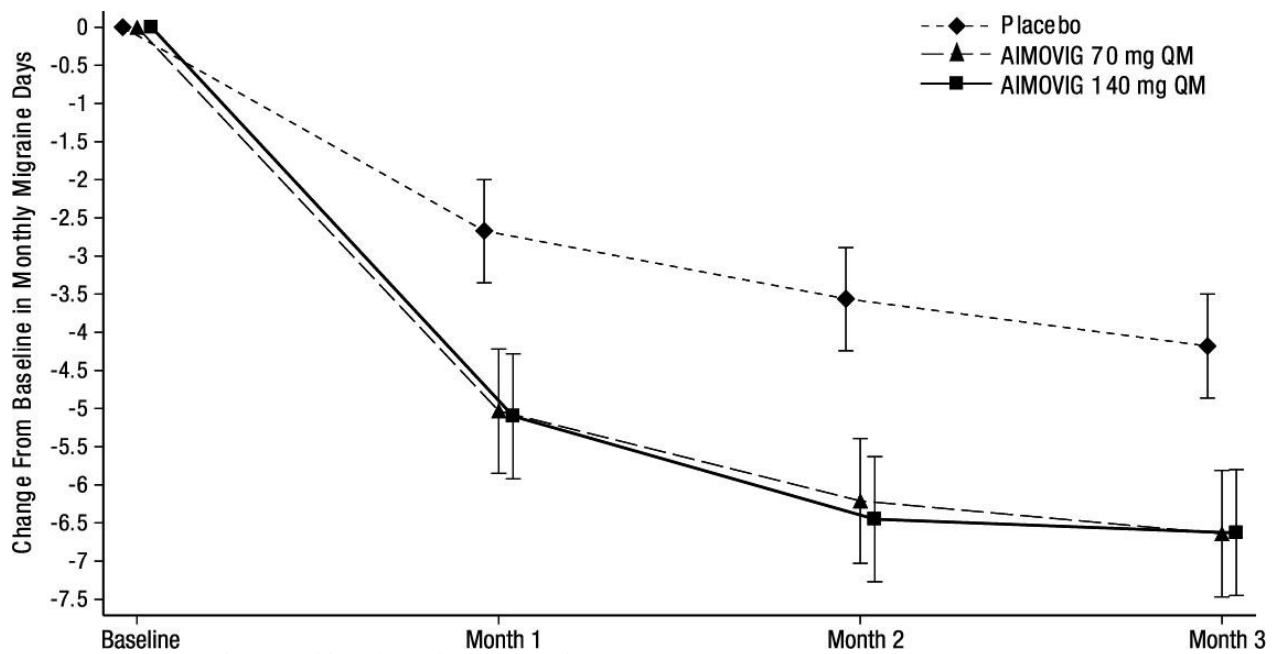


Figure 6 shows the distribution of change from baseline in monthly migraine days at month 3 in bins of 3 days by treatment group. A treatment benefit over placebo for both doses of AIMOVIG is seen across a range of changes from baseline in migraine days.

Figure 6: Distribution of Change from Baseline in Monthly Migraine Days at Month 3 by Treatment Group in Study 3

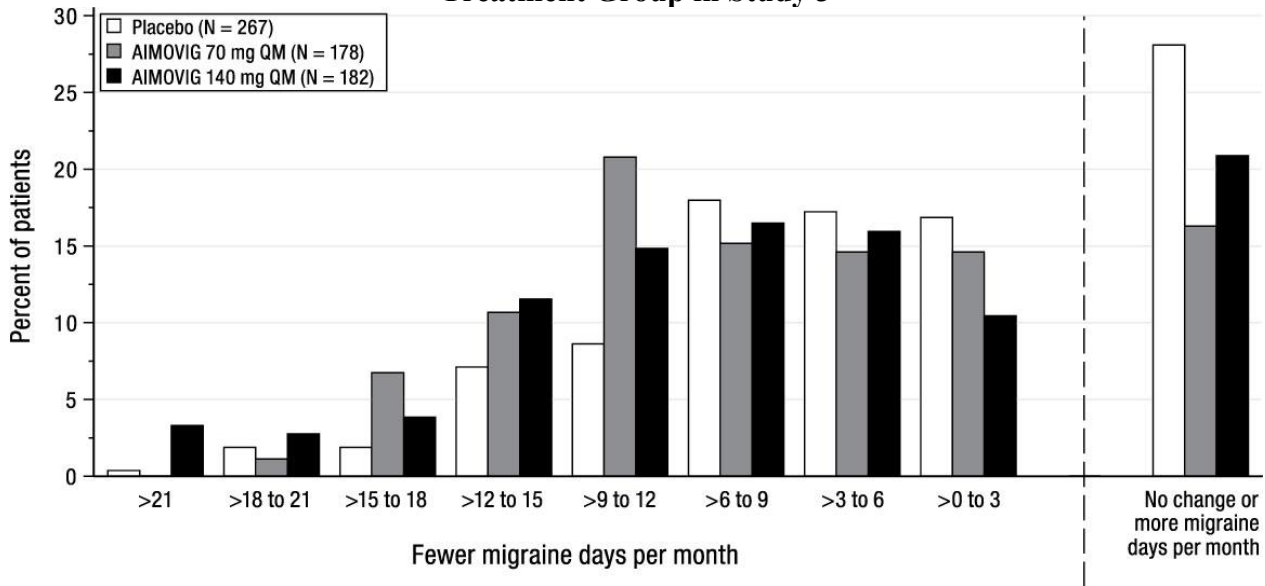


Figure excludes patients with missing data.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

AIMOVIG (erenumab-aooe) injection is a sterile, clear to opalescent, colorless to light yellow solution for subcutaneous administration.

AIMOVIG prefilled autoinjectors and prefilled syringes are not made with natural rubber latex. Each single-dose prefilled SureClick[®] autoinjector or single-dose prefilled syringe of AIMOVIG contains a Type 1 glass syringe and stainless steel needle and delivers 1 mL of 70 mg/mL or 140 mg/mL solution.

AIMOVIG is supplied as follows:

SureClick[®] Autoinjector

- Pack of 1 autoinjector: 70 mg/mL single-dose prefilled autoinjector
NDC 55513-841-01
- Pack of 1 autoinjector: 140 mg/mL single-dose prefilled autoinjector
NDC 55513-843-01

Syringe

- Pack of 1 syringe: 70 mg/mL single-dose prefilled syringe
NDC 55513-840-01
- Pack of 1 syringe: 140 mg/mL single-dose prefilled syringe
NDC 55513-842-01

16.2 Storage and Handling

- Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use.
- If removed from the refrigerator, AIMOVIG should be kept at room temperature (up to 25°C [77°F]) in the original carton and must be used within 7 days. Throw away AIMOVIG that has been left at room temperature for more than 7 days.
- Do not freeze.
- Do not shake.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Information on Preparation and Administration:

Provide guidance to patients and caregivers on proper subcutaneous administration technique, including aseptic technique, and how to use the single-dose prefilled autoinjector or single-dose prefilled syringe [see *Dosage and Administration (2.2)*]. Instruct patients and/or caregivers to read and follow the Instructions for Use each time they use AIMOVIG.

Advise patients to let AIMOVIG sit at room temperature for at least 30 minutes prior to administration [see *Dosage and Administration (2.2)*].

Hypersensitivity Reactions:

Advise patients to seek immediate medical attention if they experience any symptoms of serious or severe hypersensitivity reactions [see *Warnings and Precautions (5.1)*].

Constipation with Serious Complications:

Advise patients that constipation with serious complications can occur with AIMOVIG and that they should contact their healthcare providers if they experience severe constipation [see *Warnings and Precautions (5.2)*].

Hypertension:

Advise patients that development of hypertension and worsening of pre-existing hypertension can occur with AIMOVIG and that they should contact their healthcare providers if they experience elevation in their blood pressure [see *Warnings and Precautions (5.3)*].

Pregnancy:

Advise patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to AIMOVIG during pregnancy [see *Use in Specific Populations (8.1)*].

For more information, go to www.aimovig.com or call 1-800-77-AMGEN (1-800-772-6436).



AIMOVIG® (erenumab-aooe)

Manufactured by:

Amgen Inc.

One Amgen Center Drive

Thousand Oaks, CA 91320-1799 U.S.A.

U.S. License No. 1080

Patent: <http://pat.amgen.com/aimovig/>

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[part number] V11

Patient Information
AIMOVIG® (AIM-oh-vig) (erenumab-aooe)
injection, for subcutaneous use

What is AIMOVIG?

AIMOVIG is a prescription medicine used for the preventive treatment of migraine in adults. It is not known if AIMOVIG is safe and effective in children under 18 years of age.

Who should not use AIMOVIG?

Do not use AIMOVIG if you are allergic to erenumab-aooe or any of the ingredients in AIMOVIG. See the end of this Patient Information for a complete list of ingredients in AIMOVIG.

Before you start using AIMOVIG, tell your healthcare provider about all your medical conditions, including if you are:

- **Pregnant or plan to become pregnant.** It is not known if AIMOVIG will harm your unborn baby.
 - Pregnancy Registry: There is a pregnancy registry for women who take AIMOVIG. The purpose of this registry is to collect information about your health and your baby's health. You may enroll yourself by calling 1-833-244-4083 or visiting <https://www.genesispregnancyregistry.com/>. Or you may talk to your doctor about how you can take part in this registry.
- **Breastfeeding or plan to breastfeed.** It is not known if AIMOVIG passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using AIMOVIG.

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

How should I take AIMOVIG?

- **See the detailed “Instructions for Use” on complete information on how to take AIMOVIG.**
- Take AIMOVIG exactly as your healthcare provider tells you to take it.
- Before you inject, always check the label of your single-dose prefilled autoinjector or single-dose prefilled syringe to make sure you have the correct medicine and the correct dose of AIMOVIG.
- Also, before you inject, leave AIMOVIG at room temperature for at least 30 minutes protected from direct sunlight.
- AIMOVIG is injected under your skin (subcutaneously) 1 time each month.
- AIMOVIG comes in 2 different types of devices: a single-dose (1 time) prefilled autoinjector or a single-dose (1 time) prefilled syringe. Your healthcare provider will prescribe the type and dose that is best for you.
- If you forget to take AIMOVIG or are not able to take the dose at the regular time, take your missed dose as soon as you remember. After that, you can continue to take AIMOVIG 1 time each month from the date of your last dose.

What are possible side effects of AIMOVIG?

AIMOVIG may cause serious side effects, including:

- Allergic reactions. Allergic reactions, including rash or swelling can happen after receiving AIMOVIG. This can happen within hours to days after using AIMOVIG. Call your healthcare provider or get emergency medical help right away if you have any of the following symptoms of an allergic reaction:
 - swelling of the face, mouth, tongue, or throat
 - trouble breathing
- Constipation with serious complications. Severe constipation can happen after receiving AIMOVIG. In some cases, people have been hospitalized or needed surgery. Contact your healthcare provider if you have severe constipation or constipation associated with symptoms such as severe or constant belly pain, vomiting, swelling of belly or bloating.
- High blood pressure. High blood pressure or worsening of high blood pressure can happen after receiving AIMOVIG. Contact your healthcare provider if you have an increase in blood pressure.

The most common side effects of AIMOVIG include: pain, redness, or swelling at the injection site and constipation.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of AIMOVIG. Ask your pharmacist or healthcare provider for more information.

Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to Amgen at 1-800-77-AMGEN (1-800-772-6436).

How should I store AIMOVIG?

- Store AIMOVIG in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep AIMOVIG in the original carton. This will protect the medicine from light.
- 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.
- **Do not** shake.

Keep AIMOVIG and all medicines out of the reach of children.

General information about the safe and effective use of AIMOVIG.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **Do not** use AIMOVIG for a condition for which it is not prescribed. **Do not** give AIMOVIG to other people, even if they have the same symptoms that you have. It can harm them. You can ask your pharmacist or healthcare provider for information about AIMOVIG that is written for healthcare professionals.

What are the ingredients in AIMOVIG?

- **Active Ingredient:** erenumab-aooe
- **Inactive Ingredients:** acetate, polysorbate 80, and sucrose

AIMOVIG prefilled autoinjectors and prefilled syringes are not made with natural rubber latex.



AIMOVIG® (erenumab-aooe)

Manufactured by:

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799 U.S.A.
U.S. License No. 1080

Patent: <http://pat.amgen.com/aimovig/>

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For more information, go to www.aimovig.com or call 1-800-77-AMGEN (1-800-772-6436).

This Patient Information has been approved by the U.S. Food and Drug Administration.
[part number] v9

Revised: 8/2024

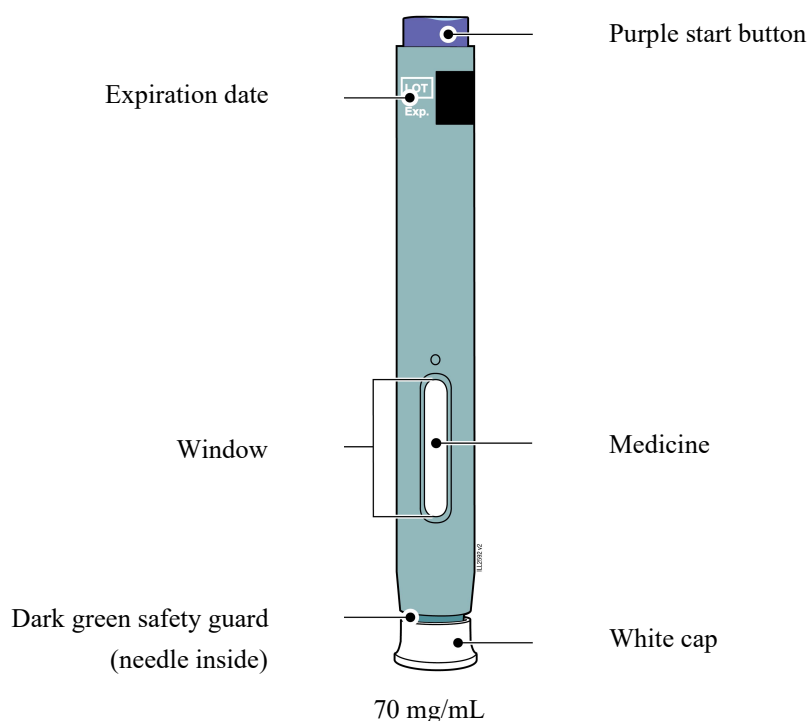
INSTRUCTIONS FOR USE
AIMOVIG® (AIM-oh-vig)
(erenumab-aooe)
injection, for subcutaneous use
70 mg/mL
single-dose prefilled SureClick® autoinjector

This Instructions for Use contains information on how to inject AIMOVIG with a SureClick autoinjector.

If your healthcare provider decides that you or a caregiver may be able to give your injections of AIMOVIG at home, you should receive training on the right way to prepare and inject AIMOVIG. Do not try to inject yourself until you have been shown the right way to give the injections by your healthcare provider or nurse.

The medicine in the AIMOVIG autoinjector is for injection under the skin (subcutaneous injection). See the AIMOVIG Patient Information for information about AIMOVIG.

Getting to know your prefilled autoinjector



1. Important Information You Need to Know Before Injecting AIMOVIG

- It is important that you do not try to give the injection until you have fully read and understood this Instructions for Use.
- **Do not** use the autoinjector if the carton is damaged or the seal is broken.
- **Do not** use the autoinjector after the expiration date on the label.
- **Do not** shake the autoinjector.
- **Do not** remove the white cap from the autoinjector until you are ready to inject.
- **Do not** 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).
- The autoinjector is not made with natural rubber latex.

Frequently asked questions:

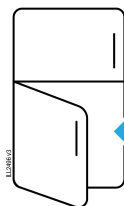
For additional information and answers to frequently asked questions, visit www.aimovig.com.

Where to get help:

If you want more information or help using AIMOVIG:

- Contact your healthcare provider,
- Visit www.aimovig.com, or
- Call 1-800-77-AMGEN (1-800-772-6436)

2. Storing and Preparing to Inject AIMOVIG



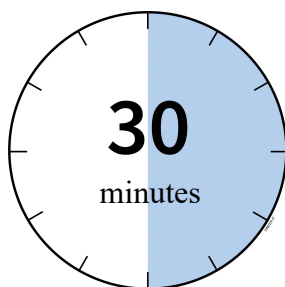
Refrigerate in carton until ready to use

2a Refrigerate the autoinjector carton until you are ready to use it.

- Keep the autoinjector in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the autoinjector in the original carton to protect it from light or physical damage.
- **Do not** freeze the autoinjector.
- **Do not** store the autoinjector in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.

Important: Keep the autoinjector and all medicines out of the sight and reach of children.

WAIT



2b Wait 30 minutes for the autoinjector to reach room temperature.

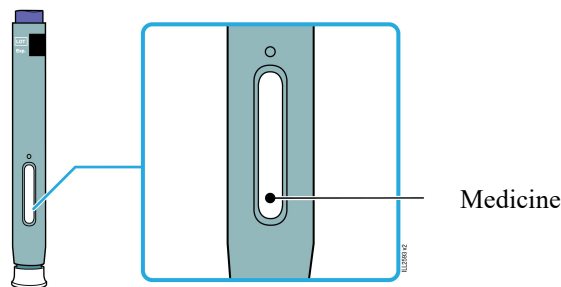
- Let the autoinjector warm up naturally.
- **Do not** heat the autoinjector with hot water, a microwave, or direct sunlight.
- **Do not** shake the autoinjector at any time.
- Using the autoinjector at room temperature makes sure the full dose is delivered and allows for a more comfortable injection.



2c You may keep AIMOVIG at room temperature for up to 7 days, if needed.

- For example, when you are traveling, you may keep AIMOVIG at room temperature.
 - Keep it at room temperature between 68°F to 77°F (20°C to 25°C).
 - **Do not** put it back in the refrigerator.
 - Record the date you removed it from the refrigerator and use it within 7 days.

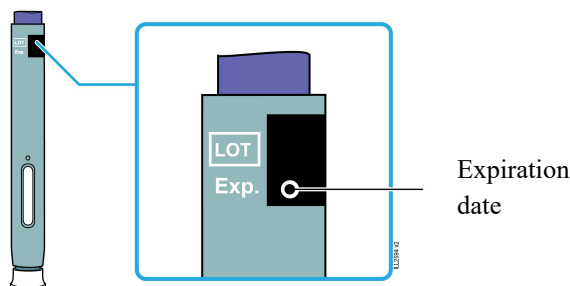
Important: Place the autoinjector in a sharps disposal container if it has reached room temperature and has not been used within 7 days.



2d Inspect the medicine. It should be clear and colorless to slightly yellow.

- It is okay to see air bubbles in the autoinjector.
- **Do not** use AIMOVIG if the medicine is cloudy, discolored, or has flakes or particles.

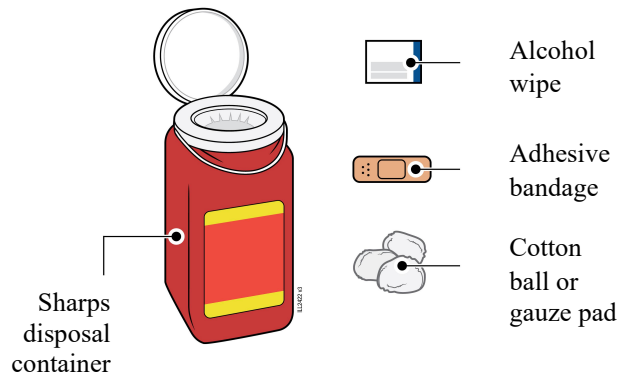
Important: If the medicine is cloudy, discolored, or has flakes or particles, or if the autoinjector is damaged or expired, call 1-800-77-AMGEN (1-800-772-6436).



2e Check the expiration date (Exp.) and inspect the autoinjector for damage.

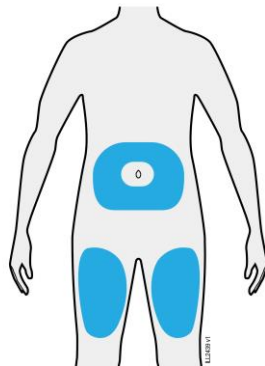
- **Do not** use the autoinjector if the expiration date has passed.
- **Do not** use the autoinjector if:
 - the white cap is missing or loose.
 - it has cracks or broken parts.
 - it has been dropped on a hard surface.
- Make sure you have the right medicine and dose.

3. Getting Ready for Your Injection



3a Gather and place the following items for your injection on a clean, flat, and well-lit surface:

- AIMOVIG autoinjector (room temperature)
- Sharps disposal container [see Disposing of AIMOVIG and Checking the Injection Site]
- Alcohol wipe
- Adhesive bandage
- Cotton ball or gauze pad



3b Inject into 1 of these sites.

- Inject into the front of your thigh or stomach (except for 2 inches around your belly button).
- Someone else can inject in your thigh, stomach, or back of the upper arm.

Important: Avoid areas with scars or stretch marks, or where the skin is tender, bruised, red, hard, raised, thick or scaly skin patch or lesion.



3c Wash hands thoroughly with soap and water.

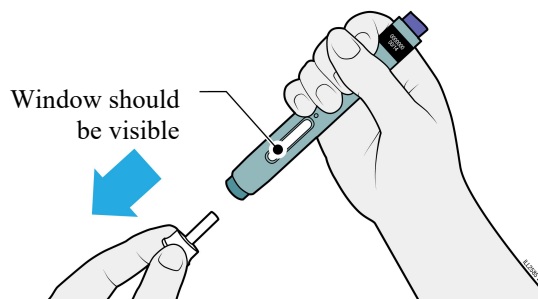


3d Clean the injection site with an alcohol wipe.

- Let the skin dry on its own.
 - **Do not** touch this area again before injecting.
-

4. Injecting AIMOVIG

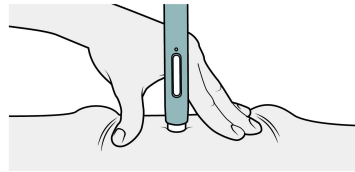
Important: Only remove the white cap when you can inject right away (within 5 minutes) because the medicine can dry out. **Do not** recap.



4a Grasp the autoinjector so you can see the window. Pull the white cap straight off. You may need to pull hard.

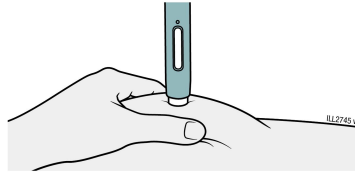
- **Do not** twist, bend or wiggle the white cap to pull it off.
 - **Never** put the white cap back on. It may damage the needle.
 - **Do not** put your finger inside the dark green safety guard.
 - It is normal to see a drop of medicine at the end of the needle or dark green safety guard.
-

STRETCH



OR

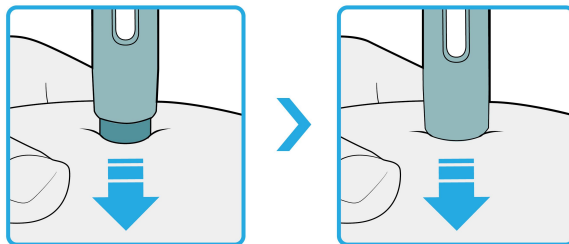
PINCH



4b Stretch or pinch the skin to create a firm surface at the injection site. Place the dark green safety guard straight against the skin.

- Keep the skin **stretched or pinched** until the injection is finished.
- Make sure you can see the window.
- Make sure the autoinjector is positioned straight on the injection site (at a 90-degree angle).

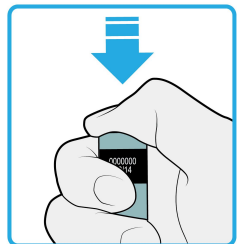
PUSH
and hold against skin



4c Firmly push the autoinjector down until the dark green safety guard stops moving. Hold the autoinjector down, do not lift.

- The dark green safety guard pushes in and unlocks the purple start button.

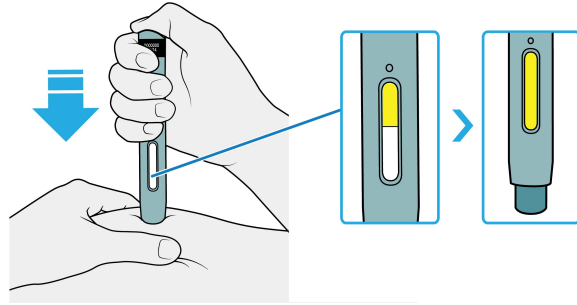
PRESS
purple start button



4d Keep pushing the autoinjector down and press the purple start button to start the injection.

- You may hear or feel a click.
- The window starts to turn yellow.
- It is okay to let go of the purple start button.

WATCH and CONFIRM
that the window turns fully yellow

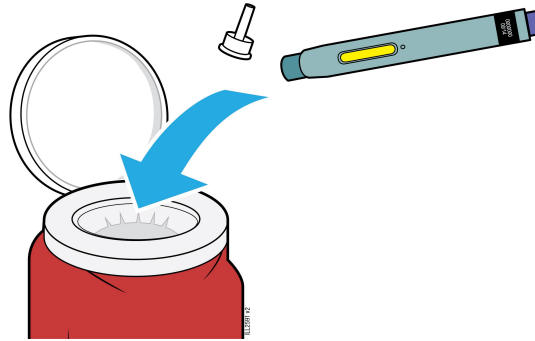


4e Keep pushing the autoinjector down. When the window is fully yellow, the injection is complete.

- The injection may take up to **15** seconds to complete.
- You may hear or feel a click.
- Lift the autoinjector away from your skin.
- The dark green safety guard locks around the needle.

Important: If the window has not turned fully yellow, or it looks like the medicine is still coming out, you have not received a full dose. Call your healthcare provider right away.

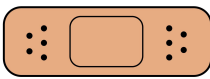
5. Disposing of AIMOVIG and Checking the Injection Site



5a Place the used autoinjector and white cap in an FDA-cleared sharps disposal container right away after use.

Important: Do not throw away the autoinjector in your household trash.

- **Do not** reuse the autoinjector.
- **Do not** touch the dark green safety guard.



5b Check the injection site.

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

Additional information about your sharps disposal container

If you do not have an 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, and
- properly labeled to warn of hazardous waste inside the container.

Disposing of sharps disposal containers:

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 dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

Do not recycle your used sharps disposal container.

Important: Keep the autoinjector and sharps disposal container out of the sight and reach of children.

For more information or help call 1-800-77-AMGEN (1-800-772-6436).

AIMOVIG® (AIM-oh-vig)

AMGEN

Manufactured by:

Amgen Inc.

One Amgen Center Drive

Thousand Oaks, California 91320-1799

US License Number 1080

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Revised: 8/2024

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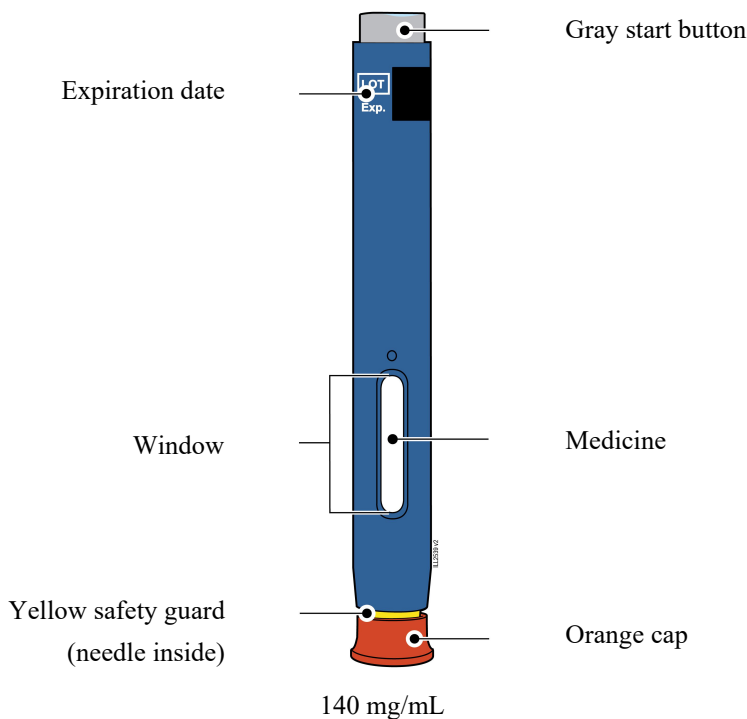
INSTRUCTIONS FOR USE
AIMOVIG® (AIM-oh-vig)
(erenumab-aooe)
injection, for subcutaneous use
140 mg/mL
single-dose prefilled SureClick® autoinjector

This Instructions for Use contains information on how to inject AIMOVIG with a SureClick autoinjector.

If your healthcare provider decides that you or a caregiver may be able to give your injections of AIMOVIG at home, you should receive training on the right way to prepare and inject AIMOVIG. Do not try to inject yourself until you have been shown the right way to give the injections by your healthcare provider or nurse.

The medicine in the AIMOVIG autoinjector is for injection under the skin (subcutaneous injection). See the AIMOVIG Patient Information for information about AIMOVIG.

Getting to know your prefilled autoinjector



1. Important Information You Need to Know Before Injecting AIMOVIG

- It is important that you do not try to give the injection until you have fully read and understood this Instructions for Use.
- **Do not** use the autoinjector if the carton is damaged or the seal is broken.
- **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** 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).
- The autoinjector is not made with natural rubber latex.

Frequently asked questions:

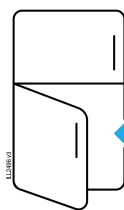
For additional information and answers to frequently asked questions, visit www.aimovig.com.

Where to get help:

If you want more information or help using AIMOVIG:

- Contact your healthcare provider,
- Visit www.aimovig.com, or
- Call 1-800-77-AMGEN (1-800-772-6436)

2. Storing and Preparing to Inject AIMOVIG



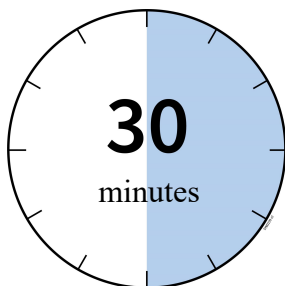
Refrigerate in carton until ready to use

2a Refrigerate the autoinjector carton until you are ready to use it.

- Keep the autoinjector in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the autoinjector in the original carton to protect it from light or physical damage.
- **Do not** freeze the autoinjector.
- **Do not** store the autoinjector in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.

Important: Keep the autoinjector and all medicines out of the sight and reach of children.

WAIT



2b Wait 30 minutes for the autoinjector to reach room temperature.

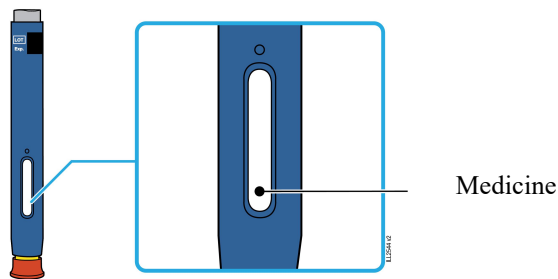
- Let the autoinjector warm up naturally.
 - **Do not** heat the autoinjector with hot water, a microwave, or direct sunlight.
 - **Do not** shake the autoinjector at any time.
 - Using the autoinjector at room temperature makes sure the full dose is delivered and allows for a more comfortable injection.
-



2c You may keep AIMOVIG at room temperature for up to 7 days, if needed.

- For example, when you are traveling, you may keep AIMOVIG at room temperature.
 - Keep it at room temperature between 68°F to 77°F (20°C to 25°C).
 - **Do not** put it back in the refrigerator.
 - Record the date you removed it from the refrigerator and use it within 7 days.

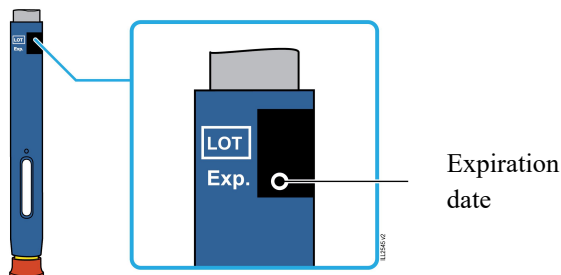
Important: Place the autoinjector in a sharps disposal container if it has reached room temperature and has not been used within 7 days.



2d Inspect the medicine. It should be clear and colorless to slightly yellow.

- It is okay to see air bubbles in the autoinjector.
- **Do not** use AIMOVIG if the medicine is cloudy, discolored, or has flakes or particles.

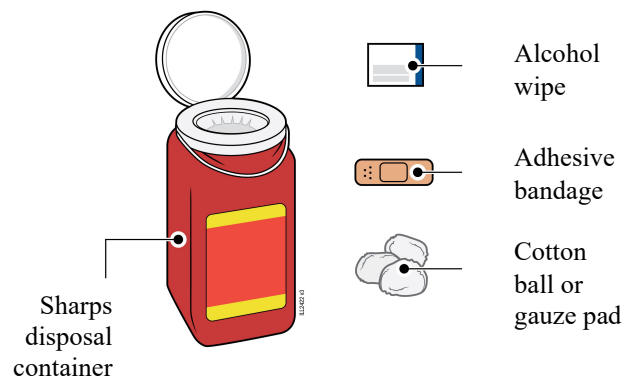
Important: If the medicine is cloudy, discolored, or has flakes or particles, or if the autoinjector is damaged or expired, call 1-800-77-AMGEN (1-800-772-6436).



2e Check the expiration date (Exp.) and inspect the autoinjector for damage.

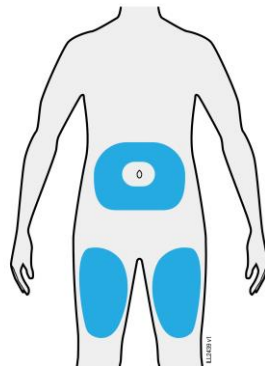
- **Do not** use the autoinjector if the expiration date has passed.
- **Do not** use the autoinjector if:
 - the orange cap is missing or loose.
 - it has cracks or broken parts.
 - it has been dropped on a hard surface.
- Make sure you have the right medicine and dose.

3. Getting Ready for Your Injection



3a Gather and place the following items for your injection on a clean, flat, and well-lit surface:

- AIMOVIG autoinjector (room temperature)
- Sharps disposal container [see Disposing of AIMOVIG and Checking the Injection Site]
- Alcohol wipe
- Adhesive bandage
- Cotton ball or gauze pad



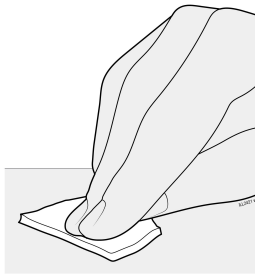
3b Inject into 1 of these sites.

- Inject into the front of your thigh or stomach (except for 2 inches around your belly button).
- Someone else can inject in your thigh, stomach, or back of the upper arm.

Important: Avoid areas with scars or stretch marks, or where the skin is tender, bruised, red, hard, raised, thick or scaly skin patch or lesion.



3c Wash hands thoroughly with soap and water.

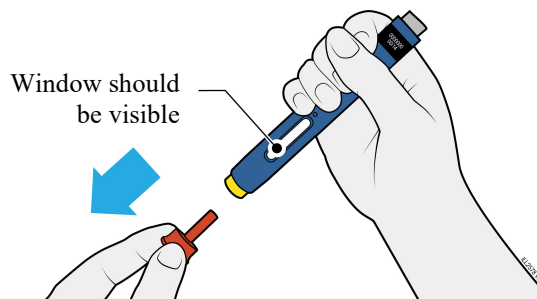


3d Clean the injection site with an alcohol wipe.

- Let the skin dry on its own.
 - **Do not** touch this area again before injecting.
-

4. Injecting AIMOVIG

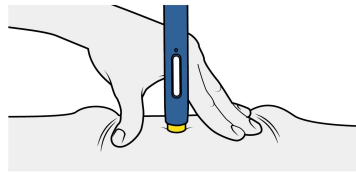
Important: Only remove the orange cap when you can inject right away (within 5 minutes) because the medicine can dry out. **Do not** recap.



4a Grasp the autoinjector so you can see the window. Pull the orange cap straight off. You may need to pull hard.

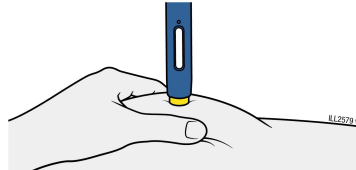
- **Do not** twist, bend or wiggle the orange cap to pull it off.
 - **Never** put the orange cap back on. It may damage the needle.
 - **Do not** put your finger inside the yellow safety guard.
 - It is normal to see a drop of medicine at the end of the needle or yellow safety guard.
-

STRETCH



OR

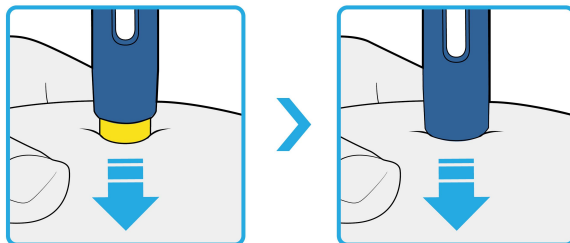
PINCH



4b Stretch or pinch the skin to create a firm surface at the injection site. Place the yellow safety guard straight against the skin.

- Keep the skin **stretched or pinched** until the injection is finished.
- Make sure you can see the window.
- Make sure the autoinjector is positioned straight on the injection site (at a 90-degree angle).

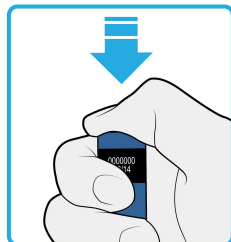
PUSH
and hold against skin



4c Firmly push the autoinjector down until the yellow safety guard stops moving. Hold the autoinjector down, do not lift.

- The yellow safety guard pushes in and unlocks the gray start button.

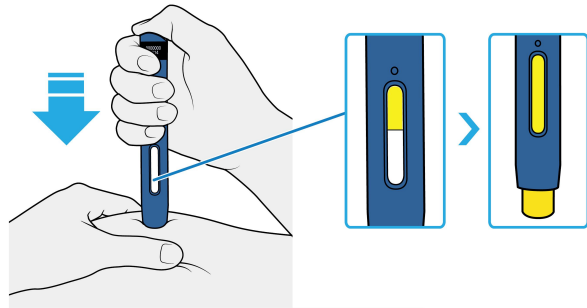
PRESS
gray start button



4d Keep pushing the autoinjector down and press the gray start button to start the injection.

- You may hear or feel a click.
- The window starts to turn yellow.
- It is okay to let go of the gray start button.

WATCH and CONFIRM
that the window turns fully yellow



4e Keep pushing the autoinjector down. When the window is fully yellow, the injection is complete.

- The injection may take up to **15** seconds to complete.
- You may hear or feel a click.
- Lift the autoinjector away from your skin.
- The yellow safety guard locks around the needle.

Important: If the window has not turned fully yellow, or it looks like the medicine is still coming out, you have not received a full dose. Call your healthcare provider right away.

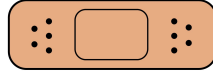
5. Disposing of AIMOVIG and Checking the Injection Site



5a Place the used autoinjector and orange cap in an FDA-cleared sharps disposal container right away after use.

Important: Do not throw away the autoinjector in your household trash.

- **Do not** reuse the autoinjector.
- **Do not** touch the yellow safety guard.



5b Check the injection site.

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

Additional information about your sharps disposal container

If you do not have an 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, and
- properly labeled to warn of hazardous waste inside the container.

Disposing of sharps disposal containers:

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 dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

Do not recycle your used sharps disposal container.

Important: Keep the autoinjector and sharps disposal container out of the sight and reach of children.

For more information or help call 1-800-77-AMGEN (1-800-772-6436).

AIMOVIG® (AIM-oh-vig)

AMGEN

Manufactured by:

Amgen Inc.

One Amgen Center Drive

Thousand Oaks, California 91320-1799

U.S. License Number 1080

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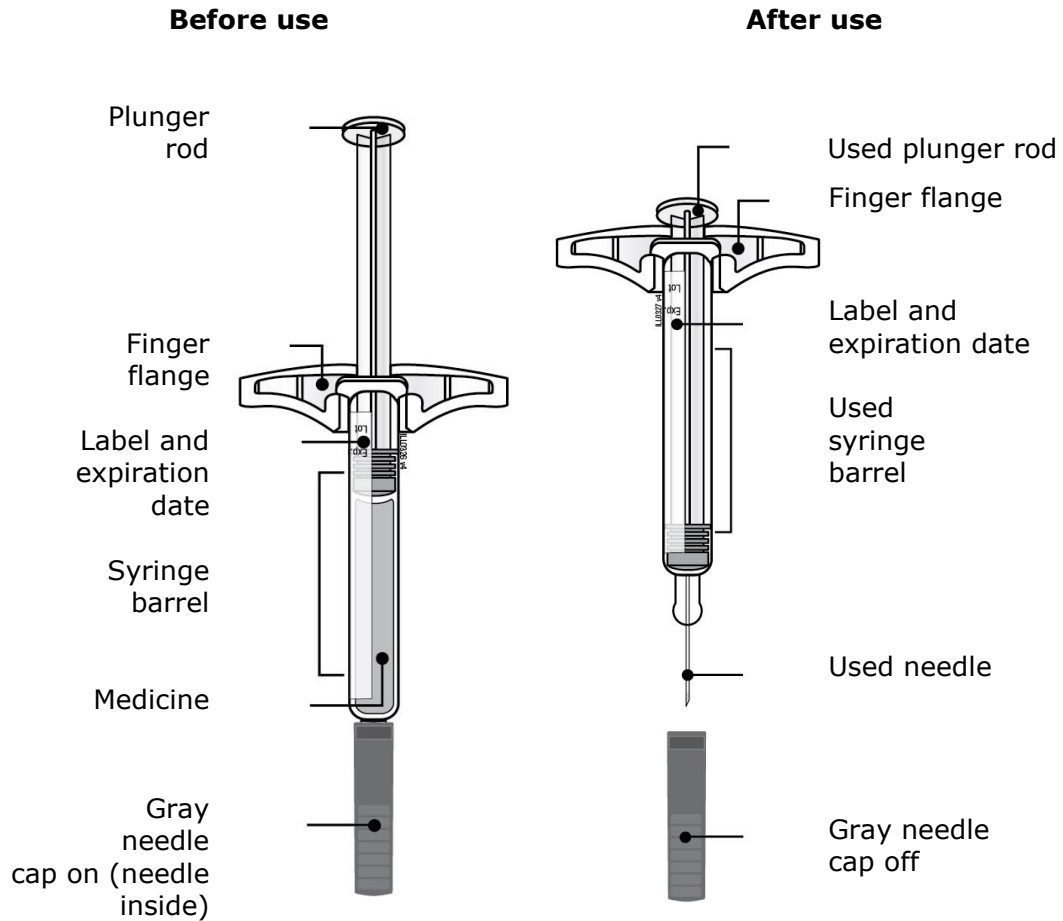
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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Revised: 8/2024
v10

Instructions for Use
AIMOVIG® (AIM-oh-vig) (erenumab-aooe)
Injection, For Subcutaneous Use
Single-Dose Prefilled Syringe
70 mg/mL and 140 mg/mL

Guide to parts



Important: Needle is inside the gray needle cap.

Important

Before you use AIMOVIG prefilled syringe, read this important information:

Storing your AIMOVIG prefilled syringe

- Keep the syringe out of the reach of children.
- Keep the syringe in the original carton to protect from light.
- The syringe 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 prefilled syringe

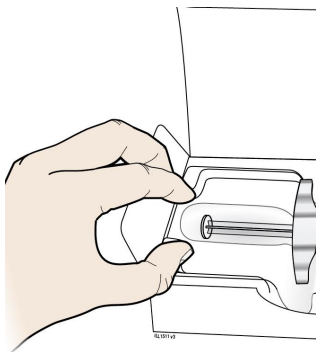
- It is important that you do not try to give the injection unless you or your caregiver has received training from your healthcare provider.
- **Do not** use a syringe after the expiration date on the label.
- **Do not** shake the syringe.
- **Do not** remove the gray needle cap from the syringe until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

Step 1: Prepare

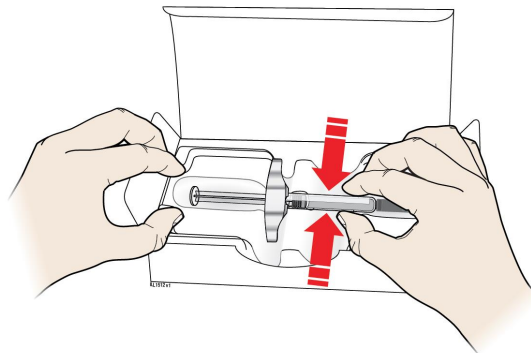
AIMOVIG comes as a single-dose (1 time) prefilled syringe. Your healthcare provider will prescribe the dose that is best for you.

Before you inject, always check the label of your single-dose prefilled syringe to make sure you have the correct medicine and the correct dose of AIMOVIG.

- A** Remove AIMOVIG prefilled syringe from the carton.
Grab the syringe barrel to remove the syringe from the tray.



Place finger or thumb on edge of tray to secure it while you remove the syringe.



Grab Here

For safety reasons:

- **Do not** grab the plunger rod.
- **Do not** grab the gray needle cap.
- **Do not** remove the gray needle cap until you are ready to inject.

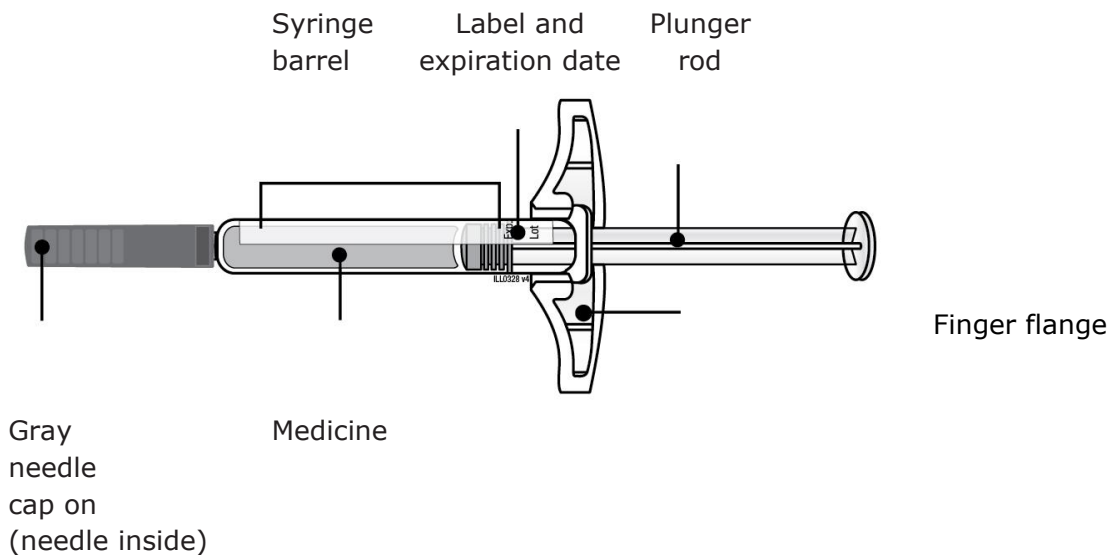
- **Do not** remove the finger flange. This is part of the syringe.

Leave the syringe at room temperature for at least **30** minutes before injecting.

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

Important: Always hold the prefilled syringe by the syringe barrel.

B Inspect the AIMOVIG prefilled syringe.



Always hold the syringe by the syringe barrel.

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

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

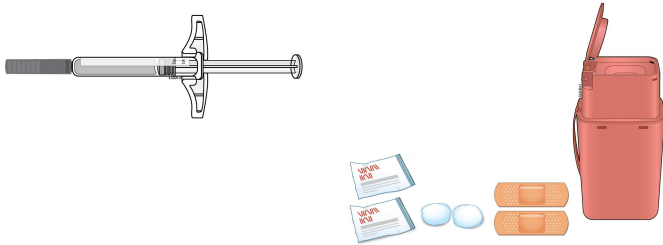
In all cases, use a new syringe, and call 1-800-77-AMGEN (1-800-772-6436).

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



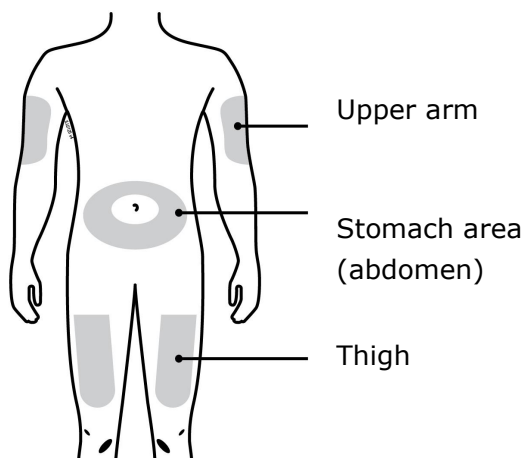
D Prepare and clean your injection site.

Only use these injection sites:

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

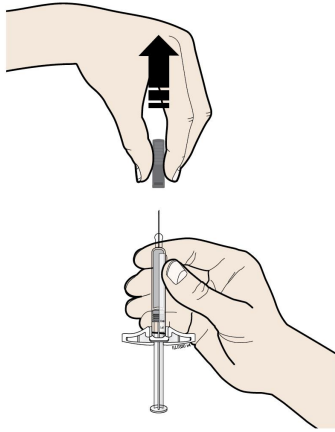
Clean your injection site with an alcohol wipe. Let your skin dry.

- **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 patch or lesion, or areas with scars or stretch marks.



Step 2: Get ready

E Pull gray needle cap straight out and away from your body, only when you are ready to inject. **Do not** leave the gray needle cap off for more than **five minutes**. This can dry out the medicine.

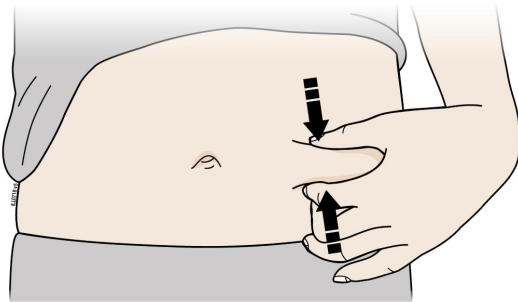


It is normal to see a drop of liquid at the end of the needle.

- **Do not** twist or bend the gray needle cap.
- **Do not** put the gray needle cap back onto the syringe.
- **Do not** remove the gray needle cap from the syringe until you are ready to inject.

Important: Throw the gray needle cap into the sharps disposal container.

F Pinch your injection site to create a firm surface.

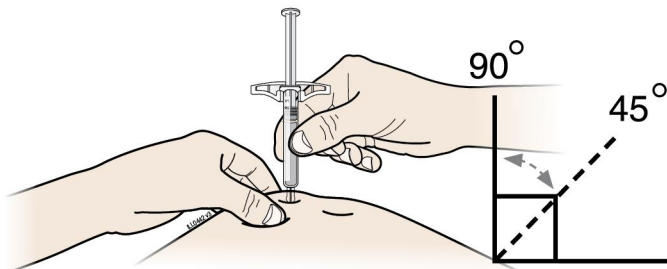


Pinch skin firmly between your thumb and fingers, creating an area about **two** inches wide.

Important: Keep skin pinched while injecting.

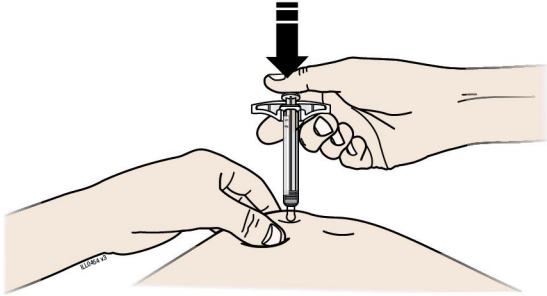
Step 3: Inject

G Hold the pinch. With the gray needle cap off, insert the syringe into your skin at 45 to 90 degrees.

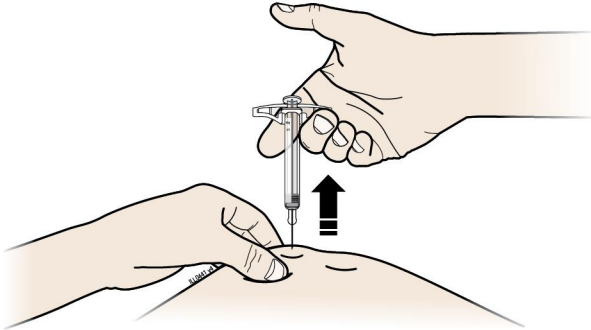


Do not place your finger on the plunger rod while inserting the needle.

H Place your finger on the plunger rod. Using slow and constant pressure, push the plunger rod all the way down until the prefilled syringe stops moving.



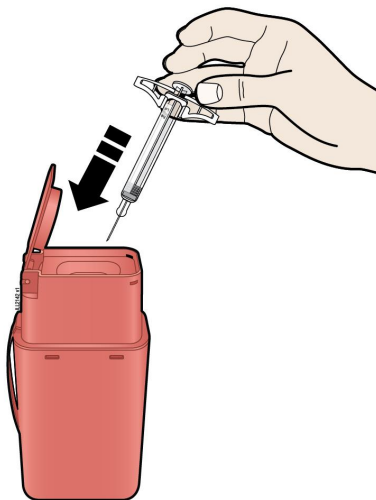
I When done, release your thumb, and gently lift the syringe off of your skin.



Important: When you remove the syringe, if it looks like the medicine is still in the syringe barrel, this means you have not received a full dose. Call your healthcare provider immediately.

Step 4: Finish

J Discard the used syringe and the gray needle cap.



Put the used AIMOVIG syringe and gray needle cap in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the syringe 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 syringe.
- **Do not** recycle the syringe or sharps disposal container or throw them into household trash.

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

K 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.

For more information, go to www.aimovig.com or call 1-800-77-AMGEN (1-800-772-6436).



AIMOVIG® (ereenumab-aooe)

Manufactured by:




Amgen Inc.

One Amgen Center Drive

Thousand Oaks, CA 91320-1799 USA

U.S. License No. 1080

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Symbol table		
 Do not reuse	 CAUTION, Prior to use, read the enclosed Instructions For Use for administration information and see package insert for full Prescribing Information	 Lot number

This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Approved: 8/2024
[partnumber] v7