HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use KLYGEFA safely and effectively. See full prescribing information for KLYGEFA.

KLYGEFA™ (gefurulimab-gaks) injection, for subcutaneous use
Initial U.S. Approval: 2026

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS
See full prescribing information for complete boxed warning.

KLYGEFA increases the risk of serious and life-threatening infections caused by *Neisseria meningitidis*.
- **Complete or update meningococcal vaccination at least 2 weeks prior to the first dose of KLYGEFA, unless the risks of delaying therapy with KLYGEFA outweigh the risks of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients receiving a complement inhibitor. (5.1)**
- **Patients receiving KLYGEFA are at increased risk for invasive disease caused by *N. meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of meningococcal infections and evaluate immediately if infection is suspected. (5.1)**

KLYGEFA is available only through a restricted program called KLYGEFA REMS. (5.2)

---------- **INDICATIONS AND USAGE** ----------
KLYGEFA is a complement inhibitor indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. (1)

---------- **DOSAGE AND ADMINISTRATION** ----------
- Vaccinate patients against meningococcal infection (serogroups A, C, W, Y and B) according to current ACIP recommendations at least 2 weeks prior to initiation of KLYGEFA. (2.1)
- Administer only by subcutaneous injection. (2.2)
- The recommended dosage is based on body weight, as shown below (2.2):

Body Weight	Loading Dose (Day 1)	Maintenance Dosage (starting on Day 8)
Less than 80 kg	600 mg (two 300 mg injections)	300 mg once weekly
80 kg or more	900 mg (three 300 mg injections)	600 mg (two 300 mg injections) once weekly

- See Full Prescribing Information for instructions on preparation and administration. (2.3)

---------- **DOSAGE FORMS AND STRENGTHS** ----------
- Injection: 300 mg/2 mL solution in a single-dose prefilled autoinjector. (3)
- Injection: 300 mg/2 mL solution in a single-dose prefilled syringe with safety device. (3)

---------- **CONTRAINDICATIONS** ----------
KLYGEFA is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection. (4)

---------- **WARNINGS AND PRECAUTIONS** ----------
Other Serious Infections: Serious, including life-threatening and fatal infections, have occurred in patients treated with complement inhibitors, including KLYGEFA If administered to a patient with active systemic infection, monitor closely for signs and symptoms of worsening infection. If the patient's infection worsens, consider whether to discontinue KLYGEFA. (5.3)

---------- **ADVERSE REACTIONS** ----------
The most common adverse reactions in the gMG placebo-controlled clinical study (at least 10%) were injection site reactions. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Alexion Pharmaceuticals, Inc. at 1-844-259-6783 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------- **DRUG INTERACTIONS** ----------
- Plasma Exchange or Plasmapheresis: concomitant use requires supplemental dose of KLYGEFA. (7.1)
- Neonatal Fc Receptor Inhibitors that cause reductions in serum albumin. Monitor for reduced effectiveness of KLYGEFA with concomitant use. (7.2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 11/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

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FULL PRESCRIBING INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

KLYGEFA, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis* [see Warnings and Precautions (5.1)]. Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of KLYGEFA, unless the risks of delaying therapy with KLYGEFA outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients receiving a complement inhibitor. See Warnings and Precautions (5.1) for additional guidance on the management of the risk of serious infections caused by meningococcal bacteria.**
- **Patients receiving KLYGEFA are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of meningococcal infections and evaluate immediately if infection is suspected.**

Because of the risk of serious meningococcal infections, KLYGEFA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called KLYGEFA REMS *[see Warnings and Precautions (5.2)]*.

1 INDICATIONS AND USAGE

KLYGEFA is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Vaccination and Prophylaxis for Meningococcal Infection

Vaccinate patients against meningococcal infection (serogroups A, C, W, Y and B) according to current ACIP recommendations at least 2 weeks prior to initiation of KLYGEFA *[see Warnings and Precautions (5.1)]*.

If urgent KLYGEFA therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer these vaccines as soon as possible *[see Warnings and Precautions (5.1)]*.

Healthcare providers who prescribe KLYGEFA must enroll in the KLYGEFA REMS *[see Warnings and Precautions (5.2)]*.

2.2 Recommended Dosage for Adult Patients with gMG

The recommended dosage of KLYGEFA is dependent on body weight and administered as a subcutaneous injection as shown in Table 1.

Table 1: KLYGEFA Recommended Dosage

Body Weight	Loading Dose* (Day 1)	Maintenance Dosage* ± (starting on Day 8)
Less than 80 kg	600 mg (two 300 mg injections)	300 mg once weekly
80 kg or more	900 mg (three 300 mg injections)	600 mg (two 300 mg injections) once weekly

* Administered as subcutaneous injections

± The weekly maintenance dosage of KLYGEFA may be administered 1 day before the scheduled dose.

Missed dose

If a weekly maintenance dose has been missed, administer KLYGEFA as soon as possible, up to 6 days after the missed dose, and then administer the next dose on the regularly scheduled treatment day. Thereafter, resume the original dosing schedule. Do not double doses on the same day.

Supplemental Dosage of KLYGEFA

Plasma exchange (PE) and plasmapheresis (PP) reduce KLYGEFA serum levels. See Table 2 for supplemental dosage recommendations in the setting of PE or PP.

Table 2: KLYGEFA Supplemental Dosage After Plasma Exchange (PE) or Plasmapheresis (PP)

Body Weight	Supplemental Dose	Frequency*
Less than 80 kg	300 mg	After every other PE or PP session
80 kg or more	300 mg	After every PE or PP session

* Administer within 4 hours after PE or PP session completion.

2.3 Preparation and Administration Instructions

KLYGEFA is for subcutaneous use only.

KLYGEFA is intended to be self-administered by the patient or injected by a caregiver. For detailed instructions on the preparation and administration of KLYGEFA, *see Instructions for Use.*

Preparation

Visually inspect KLYGEFA for particulate matter and discoloration prior to administration, whenever solution and container permit. KLYGEFA is a clear to moderately opalescent, slightly yellow to yellow solution. Do not use if the solution is discolored or cloudy or if the solution contains visible particles or foreign particulate matter.

Allow KLYGEFA to remain at room temperature at 20ºC to 25ºC (68ºF to 77ºF) for at least 45 minutes before use. Protect from light during this time. Do not use an external heat source to heat KLYGEFA.

Administration

Administer KLYGEFA by subcutaneous injection in the lower abdomen or front of thighs. The back of the upper arm can also be used as an injection site if a healthcare provider or caregiver administers KLYGEFA.

Rotate injection sites and administer at least 1 inch from the previous injection.

Do not inject into sites that are itchy, hard or tender, painful, bruised, red or scarred.

3 DOSAGE FORMS AND STRENGTHS

Injection: KLYGEFA (gefurulimab-gaks) is a clear to moderately opalescent, slightly yellow to yellow solution.

300 mg/2 mL solution in a single-dose prefilled autoinjector.

300 mg/2 mL solution in a single-dose prefilled syringe with safety device.

4 CONTRAINDICATIONS

KLYGEFA is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection *[see Warnings and Precautions (5.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Serious Meningococcal Infections

KLYGEFA, a complement inhibitor, increases the patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains. Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors. The initiation of KLYGEFA treatment is contraindicated in patients with unresolved serious *Neisseria meningitidis* infection.

Complete or update meningococcal vaccination (for serogroups A, C, W, Y and B) at least 2 weeks prior to administration of the first dose of KLYGEFA, according to current ACIP recommendations for patients receiving a complement inhibitor. Revaccinate patients in accordance with ACIP recommendations considering the duration of KLYGEFA therapy. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. If urgent KLYGEFA therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible. Various durations and regimens of antibacterial drug prophylaxis have been considered, but the optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including KLYGEFA. The benefits and risks of treatment with KLYGEFA, as well as the benefits and risks of antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by *Neisseria meningitidis*.

Vaccination does not eliminate the risk of meningococcal infections, despite development of antibodies following vaccination.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if these signs and symptoms occur. Promptly treat known infections. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of KLYGEFA in patients who are undergoing treatment for serious meningococcal infection, depending on the risks of interrupting treatment.

KLYGEFA is available only through a restricted program under a REMS *[see Warnings and Precautions (5.2)]*.

5.2 KLYGEFA REMS

KLYGEFA is available only through a restricted program under a REMS called KLYGEFA REMS, because of the risk of serious meningococcal infections *[see Warnings and Precautions (5.1)]*.

Notable requirements of the KLYGEFA REMS include the following:

- Prescribers must enroll in the REMS.
- Prescribers must counsel patients about the risk of serious meningococcal infection.
- Prescribers must provide the patients with the REMS educational materials.
- Prescribers must assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y, and B) and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of KLYGEFA.
- Prescribers must provide a prescription for antibacterial drug prophylaxis if treatment must be started urgently and the patient is not up to date with meningococcal vaccines according to current ACIP recommendations at least two weeks prior to the first dose of KLYGEFA.
- Healthcare settings and pharmacies that dispense KLYGEFA must be certified in the REMS and must verify prescribers are certified.
- Patients must receive counseling from the prescriber about the need to receive meningococcal vaccines per ACIP recommendations, the need to take antibiotics as directed by the prescriber, and the signs and symptoms of meningococcal infection.
- Patients must be instructed to carry the Patient Safety Card with them at all times during and for 3 months following treatment with KLYGEFA.

Further information is available at www.KlygefaREMS.com or 1-888-765-4747.

5.3 Other Serious Infections

KLYGEFA blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections caused by *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*. Serious infections with Neisseria species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported in patients treated with complement inhibitors.

Administer vaccinations for the prevention of Streptococcus pneumoniae infection according to ACIP recommendations. Patients receiving KLYGEFA are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

Serious infections, including fatal events, have been observed in Study 1 and its extension study *[see Adverse Reactions (6.1)]*.

If KLYGEFA is administered to patients with active systemic infections, monitor closely for signs and symptoms of worsening infection. If the patient's infection worsens, consider whether to discontinue KLYGEFA.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling:

- Serious Meningococcal Infections *[see Warnings and Precautions (5.1)]*
- Other Serious Infections *[see Warnings and Precautions (5.3)]*

6.1 Clinical Trial 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 practice.

In clinical studies, the safety of KLYGEFA has been evaluated in 253 adult patients with gMG who received at least one dose of KLYGEFA. Of those, 240 patients were exposed to KLYGEFA for at least 6 months, and 182 patients were exposed for at least 12 months.

In a 26-week randomized, double-blind, placebo-controlled treatment period (Study 1), 131 patients with gMG received KLYGEFA weekly, at the recommended weight-based dosing, and 129 patients received placebo *[see Dosage and Administration (2.2), Clinical Studies (14)]*.

Adverse reactions reported in at least 5% of patients treated with KLYGEFA and more frequently than placebo are summarized in Table 3. The most common adverse reactions (reported in at least 10% of patients treated with KLYGEFA) were injection site reactions.

Table 3: Adverse Reactions Reported in at Least 5% of Patients Treated with KLYGEFA and More Frequently Than in Patients who Received Placebo in Study 1

Adverse Reactions	KLYGEFA (N = 131) %	Placebo (N = 129) %
Injection site reactions[a,b]	12	3
Back pain	8	2
Vomiting	5	1

[a] Injection site reactions reported with the prefilled syringe with safety device.
[b] Injection site reactions include multiple injection reaction terms.

Injection Site Reactions

In Study 1 and its extension study, out of 253 patients treated with KLYGEFA, 36 (14%) patients experienced injection site reactions. In Study 1, injection site reactions observed in patients treated with KLYGEFA, including rash, erythema, and pruritus, were non-serious, and none led to discontinuation of KLYGEFA. In the open-label extension, one patient experienced an injection site reaction that required discontinuation of KLYGEFA. Most injection site reactions occurred within 24 hours to 72 hours post-injection relative to the most recent administration of KLYGEFA.

Hypersensitivity Reactions

Across Study 1 and its extension study, patients treated with KLYGEFA experienced hypersensitivity reactions, including rash and urticaria, none of which resulted in treatment discontinuation. The majority of these reactions occurred within 24 hours to 72 hours post-injection relative to the most recent administration of KLYGEFA.

Serious Infections

Serious infections occurred in Study 1 and its extension study. There were two fatal infections in patients treated with KLYGEFA, including one case of dengue fever and one case of sepsis from a tooth infection associated with a dental procedure. There was a serious event of sepsis due to *Mycoplasma pneumoniae*, which resulted in discontinuation of KLYGEFA. There were three serious cases of diverticulitis (two with abscesses) leading to intestinal perforation in patients treated with KLYGEFA. Two of these patients had prior medical history of diverticulitis.

7 DRUG INTERACTIONS

7.1 Use with PE or PP

Use of KLYGEFA with PE or PP in patients with gMG has been shown to reduce serum gefurulimab concentrations. Administer a supplemental dose of KLYGEFA with concomitant use of PE or PP *[see Dosage and Administration (2.2)]*.

7.2 Use with Neonatal Fc Receptor (FcRn) Inhibitors

Concomitant use of KLYGEFA with FcRn inhibitors that cause reductions in serum albumin may lower systemic exposure to gefurulimab-gaks and reduce its effectiveness. Monitor for reduced effectiveness of KLYGEFA during concomitant use.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on KLYGEFA use in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In an enhanced pre- and postnatal development study, no adverse developmental outcomes were observed when monkeys were exposed to gefurulimab-gaks during the period of organogenesis through parturition at doses that produced maternal exposures 10-times the exposures at the maximum recommended human dose (MRHD) (see animal data). Treatment of pregnant women with KLYGEFA should only be considered if the clinical benefit outweighs the risks.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background rate of major birth defects and miscarriage in the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Report pregnancies to the Alexion Pharmaceuticals, Inc. adverse event reporting line at 1-844-259-6783.

Data

Animal Data

In an enhanced pre and postnatal development toxicity study in cynomolgus monkeys, gefurulimab-gaks was administered once weekly via SC injection at the dose levels of 100 or 300 mg/kg/week to pregnant cynomolgus monkeys, beginning on gestation day 20 through delivery (approximately 21 doses in total). Overall, there were no gefurulimab-related toxicities noted in maternal animals or their offspring, and no gefurulimab-related effects on pregnancy and parturition, embryo-fetal development, and infant survival, growth, and postnatal development, at doses providing at least 10-fold exposure margins over the recommended human doses.

8.2 Lactation

Risk Summary

There are no data on the presence of gefurulimab-gaks 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 KLYGEFA and any potential adverse effects on the breastfed infant from KLYGEFA 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 KLYGEFA did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger adult patients.

11 DESCRIPTION

Gefurulimab-gaks, a complement inhibitor, is a humanized bispecific single variable domain on a heavy chain (VHH) antibody produced in Chinese hamster ovary (CHO) cells by recombinant deoxyribonucleic acid (DNA) technology and has an approximate molecular weight of 28 kDa.

KLYGEFA (gefurulimab-gaks) injection is a sterile, preservative-free, clear to moderately opalescent, and slightly yellow to yellow solution for subcutaneous use with a pH of 6.7.

Autoinjector

The autoinjector consists of a 2 mL Type I glass syringe with a staked 27-gauge ½-inch stainless steel needle with a rigid needle shield. The syringe is integrated within the autoinjector. Each autoinjector contains 2 mL solution of 300 mg (150 mg/mL) gefurulimab-gaks, histidine (5.1 mg), L-histidine hydrochloride monohydrate (1.5 mg), glycine (15 mg), sucrose (136.9 mg), polysorbate 80 (1.6 mg) and Water for Injection.

Prefilled Syringe with Safety Device

The prefilled syringe consists of a 2 mL Type I glass syringe with a staked 27-gauge ½-inch stainless steel needle with a rigid needle shield. Each prefilled syringe is pre-assembled with a needle safety device, add-on finger flange and plunger rod. Each prefilled syringe contains 2 mL solution of 300 mg (150 mg/mL) gefurulimab-gaks, histidine (5.1 mg), L-histidine hydrochloride monohydrate (1.5 mg), glycine (15 mg), sucrose (136.9 mg), polysorbate 80 (1.6 mg) and Water for Injection.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Gefurulimab-gaks is a terminal complement inhibitor that specifically binds both complement protein C5 and serum albumin. Gefurulimab-gaks binding to C5 inhibits its cleavage to C5a and C5b thus preventing the formation and deposition of membrane attack complex (MAC or C5b-9) at the neuromuscular junction.

The precise mechanism by which gefurulimab exerts its therapeutic effect in gMG is unknown but is presumed to involve reduction of terminal complement complex C5b-9 deposition at the neuromuscular junction.

12.2 Pharmacodynamics

Following treatment with KLYGEFA in adult patients with gMG, complete inhibition of serum free C5 (concentration of less than 0.5 mcg/mL) was observed after the loading dose and sustained during the 26-week treatment period in the majority (99.2%) of patients.

12.3 Pharmacokinetics

Gefurulimab-gaks pharmacokinetics were characterized in healthy volunteers and patients with gMG. Dose-proportional increases in C_{max} and AUC were observed following single doses ranging from 30 mg to 1700 mg *[see Dosage and Administration (2.2)]*. Following multiple weekly doses, gefurulimab-gaks accumulated with a C_{max} accumulation ratio of 2.2 and an AUC accumulation ratio of 2.5.

Absorption

The bioavailability of subcutaneously administered gefurulimab-gaks is approximately 96%. There were no clinically relevant differences in bioavailability observed across devices (autoinjector or prefilled syringe) or injection sites (abdomen, thigh, or upper arm) *[see Dosage and Administration (2.3)]*. The median time to maximum observed concentration (t_{max}) was 24 to 48 hours post-dose.

Distribution

The mean (standard deviation [SD]) volume of distribution of gefurulimab-gaks was 3.64 L (4.43).

Elimination

The mean (SD) clearance and terminal elimination half-life of gefurulimab-gaks were 0.0116 L/h (0.00369) and 14 days (7.51), respectively.

Specific Populations

No clinically relevant impact of sex, age, race, mild to moderate renal impairment, or mild to moderate hepatic impairment on gefurulimab-gaks pharmacokinetics was identified in adult patients with gMG. No data are available in patients with severe hepatic or severe renal impairment (including patients on dialysis).

Drug Interactions

No drug-drug interaction studies have been performed.

Concomitant use of PE or PP has been shown to reduce serum gefurulimab-gaks concentrations *[see Dosage and Administration (2.2) and Drug Interactions (7.1)]*.

Administration of IVIg or SCIg with KLYGEFA does not impact gefurulimab-gaks serum levels.

Concomitant use of KLYGEFA with FcRn inhibitors that cause reductions in serum albumin may lower systemic exposure to gefurulimab-gaks and reduce the effectiveness of gefurulimab-gaks *[see Drug Interactions (7.2)]*.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies (ADA) is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of ADA in the studies described below with the incidence of ADA in other studies, including those of KLYGEFA or other gefurulimab products.

During 26 weeks of treatment in Study 1, 13/131 (9.9%) of patients treated with KLYGEFA developed treatment-emergent anti-gefurulimab-gaks antibodies. None of the ADA-positive patients developed neutralizing antibodies. The available data are too limited to make definitive conclusions regarding immunogenicity and its effect on pharmacokinetics, pharmacodynamics, safety, or efficacy of KLYGEFA.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

No carcinogenicity studies have been conducted.

Mutagenesis

No genotoxicity studies have been conducted.

Impairment of Fertility

No dedicated fertility studies have been conducted with gefurulimab-gaks. In a 13-week repeat-dose toxicity study, no treatment-related histopathological changes were observed in male or female reproductive organs following repeated administration in sexually mature cynomolgus monkeys at exposures greater than 10-fold to those achieved at the recommended human dose.

14 CLINICAL STUDIES

The efficacy of KLYGEFA for the treatment of gMG in adult patients who are anti-AChR antibody-positive was established in a randomized, double-blind, placebo-controlled, parallel, multicenter study (Study 1; NCT05556096). Patients were randomized 1:1 to either receive KLYGEFA (n=131) or placebo (n=129) for 26 weeks. KLYGEFA was administered subcutaneously according to the recommended weight-based dosage *[see Dosage and Administration (2.2)]*.

Study 1 enrolled patients who met the following criteria at screening:

- Patients with gMG and a positive serological test for anti-AChR antibodies.
- Myasthenia Gravis Foundation of America (MGFA) clinical classification Class II to IV.
- Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score of ≥ 5.
- On stable dose of MG therapy prior to screening (including acetylcholinesterase (AChE) inhibitors, corticosteroids, or non-steroidal immunosuppressive therapies (NSISTs), intravenous or subcutaneous immunoglobulin (IVIg/SCIg) either in combination or alone).

Baseline demographics and disease characteristics were similar between treatment groups. Mean age at first dose was 53 years of age; 60% of the patients were female; 55% were White, 31% were Asian, and 2% were Black. The duration of MG since diagnosis was a mean of 9 years, ranging from 0.3 to 51 years. At baseline the mean MG-ADL total score was 9, ranging from 5 to 18 points.

Of the 131 patients treated with KLYGEFA, 66% of patients received corticosteroids, 60% received NSISTs, and 92% received AChE inhibitor, at stable doses. In addition, 3.5% of patients received stable doses of IVIg/SCIg for gMG treatment for ≥ 6 months. Patients on concomitant medications for the treatment of gMG were permitted to continue therapy at stable doses throughout the course of the study.

The efficacy of KLYGEFA was measured using the MG-ADL scale, which assesses the impact of gMG on daily function of 8 signs and symptoms that are typically affected in gMG. Each item is assessed on a 4-point scale, where a score of 0 represents normal function and a score of 3 represents loss of ability to perform that function. A total score ranges from 0 to 24, with higher scores indicating more impairment.

The primary efficacy endpoint was the change from baseline between treatment groups in the MG-ADL total score at Week 26.

The efficacy of KLYGEFA was also measured using the Quantitative MG (QMG) total score, which is a 13-item categorical grading system that assesses muscle weakness. Each item is assessed on a 4-point scale, where

a score of 0 represents no weakness, and a score of 3 represents severe weakness. A total possible score ranges from 0 to 39, where higher scores indicate more severe impairment.

Key secondary endpoint was the change from baseline between treatment groups in the QMG total score at Week 26.

Treatment with KLYGEFA demonstrated a statistically significant change in the MG-ADL and QMG total scores from baseline to Week 26, as compared to placebo (see Table 4 and Figure 1).

Table 4: Least Squares Mean Change from Baseline to Week 26 in MG-ADL and QMG Total Scores in Study 1

Efficacy Endpoints Change from Baseline at Week 26	**KLYGEFA (N = 131)** LS Mean (SE)	**Placebo (N = 129)** LS Mean (SE)	**Treatment Effect (95% CI)**	**p-value***
Primary Endpoint				
MG-ADL	−4.2 (0.29)	−2.6 (0.27)	−1.6 (−2.4, −0.8)	< 0.001
Secondary Endpoint				
QMG	−4.5 (0.37)	−2.4 (0.34)	−2.1 (−3.1, −1.1)	< 0.001

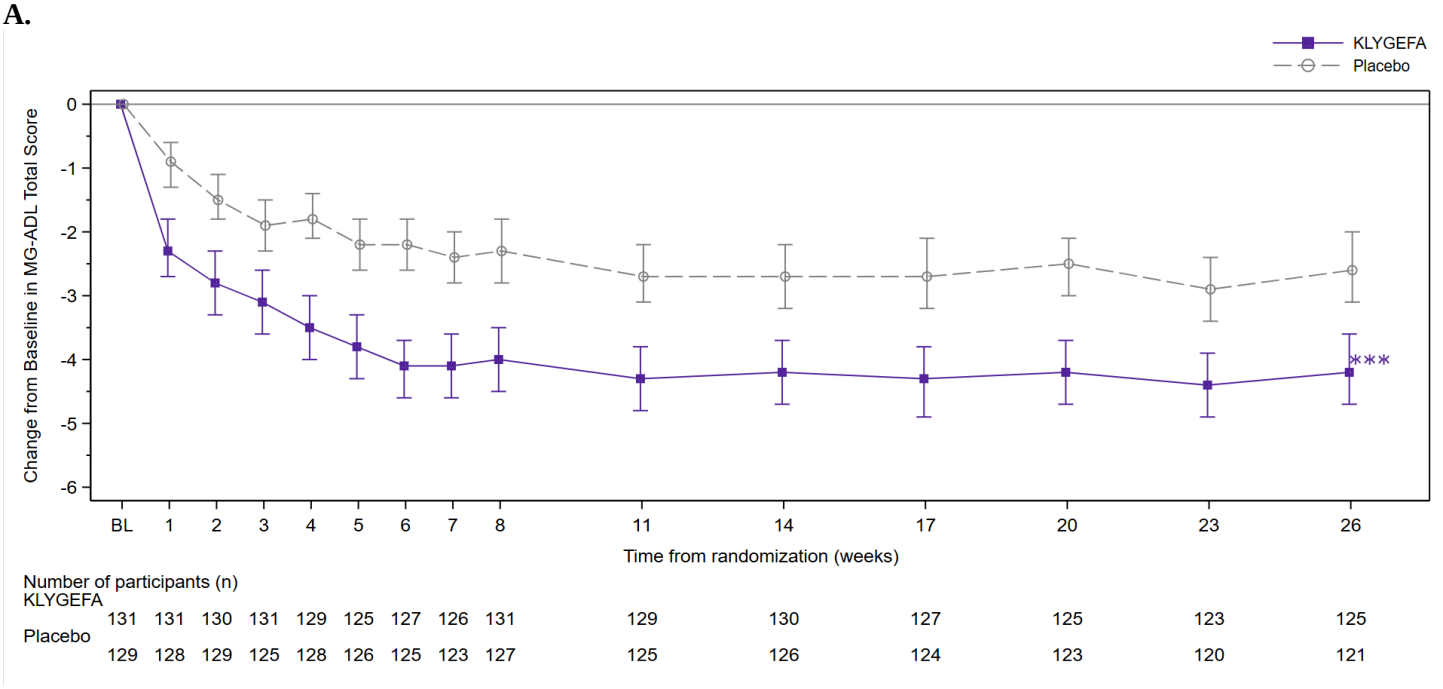
*The p-value was calculated using an MMRM model that included treatment group, region, baseline body weight category, the corresponding baseline total score (MG-ADL or QMG), study visit, and study visit-by-treatment group interaction.
Abbreviations: CI = confidence interval, LS = least squares; MG-ADL = Myasthenia Gravis-Activities of Daily Living profile; MMRM = mixed model repeated measures; QMG = Quantitative Myasthenia Gravis score for disease severity; SE = standard error

Other secondary endpoints included the proportion of patients with improvements of at least 5 and 3 points in the QMG and MG-ADL total scores, respectively.

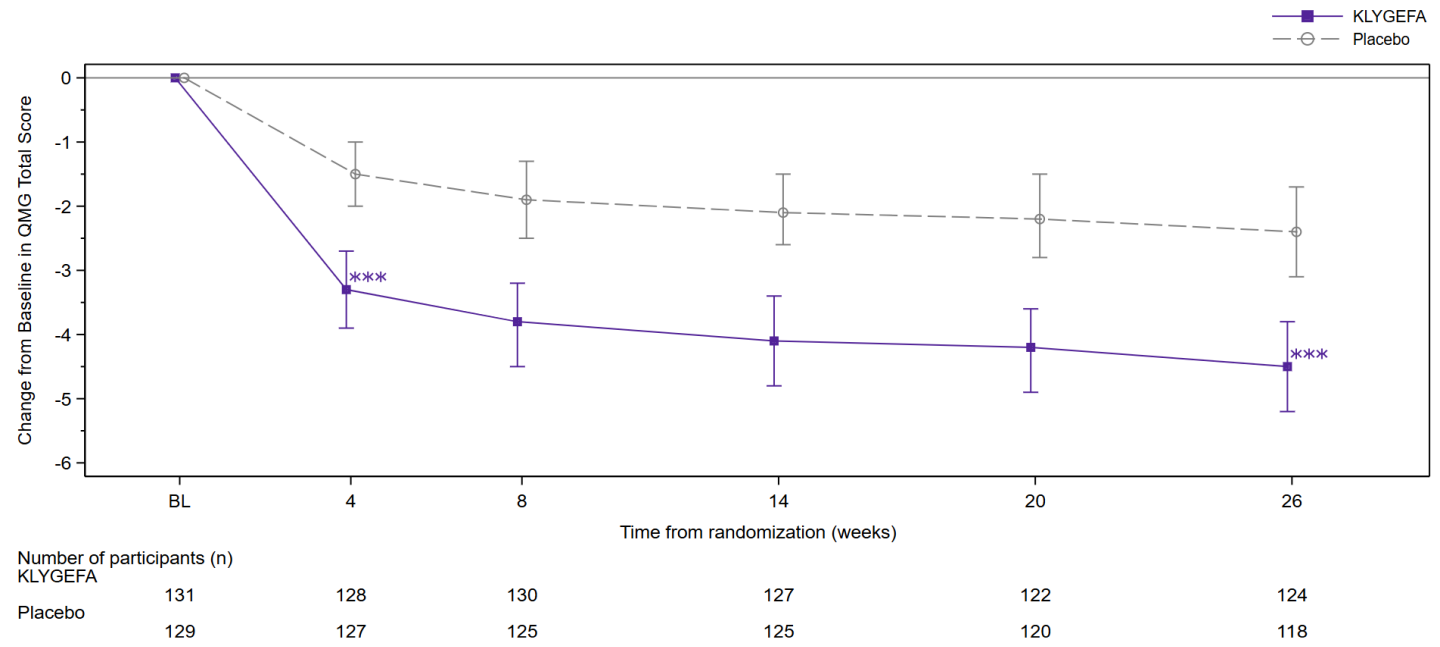
The proportion of MG-ADL responders with at least a 3-point improvement at Week 26 was greater for KLYGEFA (65.5%) compared to placebo (52.2%), p = 0.037. The proportion of QMG responders with at least a 5-point improvement at Week 26 was greater for KLYGEFA (46.3%) compared to placebo (25.2%), p = 0.002.

Figure 1: Least Squares Mean Change from Baseline in MG-ADL Total Score (A) and QMG Total Score (B) Through Week 26 in Study 1

A.



B.



***p<0.001 versus placebo and significant according to the pre-specified multiplicity-adjusted testing procedure. The p-value was calculated using an MMRM Model that included treatment group, region, baseline body weight category, MG-ADL total score at baseline (Figure 1A) or QMG total score at baseline (Figure 1B), study visit, and study visit by treatment group interaction.
Error bars represent 95% CI
Abbreviations: BL = baseline; CI = confidence interval; MG-ADL = Myasthenia Gravis-Activities of Daily Living, QMG = Quantitative Myasthenia Gravis

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

KLYGEFA (gefurulimab-gaks) subcutaneous injection is a sterile, preservative-free, clear to moderately opalescent, and slightly yellow to yellow solution with a pH of 6.7.

Prefilled Autoinjector

KLYGEFA prefilled autoinjector is available as follows:

Strength	**Pack Size**	**NDC**
Injection: 300 mg/2 mL	Carton of 1 single-dose prefilled autoinjector	25682-067-01
Injection: 300 mg/2 mL	Carton of 2 single-dose prefilled autoinjectors	25682-067-02

Prefilled Syringe with Safety Device

KLYGEFA prefilled syringe is available as follows:

Strength	**Pack Size**	**NDC**
Injection: 300 mg/2 mL	Carton of 1 single-dose prefilled syringe	25682-070-01
Injection: 300 mg/2 mL	Carton of 2 single-dose prefilled syringes	25682-070-02

16.2 Storage and Handling

Store KLYGEFA refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light.

KLYGEFA can be removed from and placed back in the refrigerator one time if needed. The total combined time out of the refrigerator may not be more than 24 hours. Protect from light when stored at room temperature.

Discard if stored at room temperature for more than 24 hours.

Do not freeze. Do not shake. Do not expose to heat.

Dispense in the original sealed carton with the enclosed Instructions for Use.

17 PATIENT COUNSELING INFORMATION

Advise the patients and caregivers to read the FDA-approved patient labeling (Medication Guide and Instructions for Use).

Serious Meningococcal Infection

Advise patients of the risk of serious meningococcal infection *[see Warnings and Precautions (5.1)]*. Inform patients of the need to complete or update meningococcal vaccinations at least 2 weeks prior to receiving the first dose of KLYGEFA or receive antibacterial drug prophylaxis if KLYGEFA treatment must be initiated immediately and they have not been previously vaccinated. Inform patients of the requirement to be revaccinated according to current ACIP recommendations for meningococcal infection while on KLYGEFA therapy.

Inform patients that vaccination may not prevent serious meningococcal infection and to seek immediate medical attention if the following signs or symptoms occur:

- fever
- fever and a rash

- fever with high heart rate
- headache with nausea or vomiting
- headache and a fever
- headache with a stiff neck or stiff back
- confusion
- muscle aches with flu-like symptoms
- eyes sensitive to light

Inform patients that they will be given a Patient Safety Card for KLYGEFA that they should carry with them at all times during and for 3 months following treatment with KLYGEFA. This card describes symptoms which, if experienced, should prompt the patient to immediately seek medical evaluation.

KLYGEFA REMS

KLYGEFA is available only through a restricted program called KLYGEFA REMS *[see Warnings and Precautions (5.2)]*.

Inform the patient of the following notable requirements:

- Patients must receive counseling about the risk of serious meningococcal infections.
- Patients must receive written educational materials about this risk.
- Patients must be instructed to carry the Patient Safety Card with them at all times during and for 3 months following treatment with KLYGEFA.
- Patients must be instructed to complete or update meningococcal vaccines for serogroups A, C, W, Y, and B per ACIP recommendations as directed by the prescriber prior to treatment with KLYGEFA.
- Patients must receive antibiotics as directed by the prescriber if they are not up to date with meningococcal vaccines and have to start KLYGEFA right away.

Other Serious Infections

Counsel patients of the increased risk of infections, particularly those due to encapsulated bacteria, especially *Neisseria* species. Advise patients of the need for vaccination against meningococcal infections according to current medical guidelines *[see Warnings and Precautions (5.3)]*. Counsel patients about gonorrhea prevention and advise regular testing for patients at risk. Advise patients to report any new signs and symptoms of infection.

Manufactured by:

Alexion Pharmaceuticals, Inc.
121 Seaport Boulevard
Boston, MA 02210 USA

U.S. License Number 1743

This product, or its use, may be covered by one or more US patents, including US Patent No. 11,498,960 and 12,221,473 in addition to others including patents pending.

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MEDICATION GUIDE

KLYGEFA™ (klahy-gef-uh)

(gefurulimab-gaks)

injection, for subcutaneous use

What is the most important information I should know about KLYGEFA?

KLYGEFA is a medicine that affects your immune system. KLYGEFA may lower the ability of your immune system to fight infections.

- KLYGEFA increases your chance of getting serious meningococcal infections caused by Neisseria meningitidis bacteria. Meningococcal infections may quickly become life-threatening or cause death if not recognized and treated early.
  - You must complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of KLYGEFA.
  - If you have not completed your meningococcal vaccines and KLYGEFA must be started right away, you should receive the required vaccine(s) as soon as possible.
  - If you have not been vaccinated and KLYGEFA must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.
  - If you had a meningococcal vaccine in the past, you might need additional vaccines before starting KLYGEFA. Your healthcare provider will decide if you need additional meningococcal vaccines.
  - Meningococcal vaccines do not prevent all meningococcal infections. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:**
    - fever
    - fever with high heart rate
    - headache and fever
    - confusion
    - muscle aches with flu-like symptoms
    - fever and a rash
    - headache with nausea or vomiting
    - headache with a stiff neck or stiff back
    - eyes sensitive to light

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 3 months after your last KLYGEFA dose. Your risk of meningococcal infection may continue for several weeks after your last dose of KLYGEFA. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

KLYGEFA is only available through a program called the KLYGEFA Risk Evaluation and Mitigation Strategy (REMS). Before you can receive KLYGEFA, your healthcare provider must:

- enroll in the KLYGEFA REMS program.
- counsel you about the risk of serious meningococcal infections.
- give you the **Patient Guide**, including information about the signs and symptoms of meningococcal infection.
- give you a **Patient Safety Card** about your risk of meningococcal infection, as discussed above**.**
- make sure that you are vaccinated against serious infections caused by meningococcal bacteria and that you receive antibiotics if you need to start KLYGEFA right away and you are not up to date on your vaccines.

KLYGEFA may also increase the risk of other types of serious infections caused by encapsulated bacteria, including Streptococcus pneumoniae, Haemophilus influenzae, and Neisseria gonorrhoeae.

- Certain people may be at risk of serious infections with gonorrhea. Talk to your healthcare provider about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and regular testing.

Call your healthcare provider right away if you have new signs or symptoms of infection.

What is KLYGEFA?

- KLYGEFA is a prescription medicine used to treat a disease called generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) antibody positive.
- It is not known if KLYGEFA is safe and effective in children.

Do not use KLYGEFA if you:

- have a serious meningococcal infection when you are starting KLYGEFA treatment.

Before you use KLYGEFA, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or fever.
- are pregnant or plan to become pregnant. It is not known if **KLYGEFA** will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if **KLYGEFA** passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use KLYGEFA.

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

Know the medicines you take and the vaccines you receive. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use KLYGEFA?

See the detailed Instructions for Use that comes with KLYGEFA for information on how to prepare and inject a dose of KLYGEFA, and how to properly throw away (dispose of) used KLYGEFA autoinjectors and prefilled syringes.

- Use KLYGEFA exactly as prescribed by your healthcare provider.
- KLYGEFA is given as an injection under the skin (for subcutaneous use) in an autoinjector or prefilled syringe.
- After proper training on how to prepare and inject KLYGEFA, you or your caregiver will inject KLYGEFA weekly.
- Your recommended dose is dependent upon your body weight. Your first dose will be 600 mg or 900 mg. Then you will take 300 mg or 600 mg 1 time weekly, starting 1 week after the initial dose.
- Inject KLYGEFA under the skin (subcutaneously) of your stomach (abdomen) or thigh. If another person gives your injection, you can choose the back of your upper arm.
- Change (rotate) your injection site with each injection. You may use the same area of your body but be sure to choose a different injection site in that area. Do not use the same site for each injection.
- Each autoinjector or prefilled syringe is for single-use only. Throw away the autoinjector or prefilled syringe after each use. Do not reuse.
- If you use too much KLYGEFA, call your healthcare provider or go to the nearest emergency room right away.

If you miss taking your KLYGEFA dose, inject a dose as soon as possible up to 6 days after the missed dose. Then, inject your next dose on your regularly scheduled day. Do not inject more than 1 dose each day. Call your healthcare provider if you are not sure what to do. Take KLYGEFA exactly as your healthcare provider tells you to take it.

What are the possible side effects of KLYGEFA?

KLYGEFA may cause side effects, including:

- See **"What is the most important information I should know about KLYGEFA?"**

The most common side effect of KLYGEFA includes:

- Injection site reactions

These are not all of the possible side effects of KLYGEFA. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store KLYGEFA?

- Store KLYGEFA in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton to protect from light.
- KYLGEFA can be taken out of the refrigerator and placed back in the refrigerator 1 time, if needed. Do not keep KLYGEFA out of the refrigerator for more than 24 hours. Protect from light when stored at room temperature.
- Throw away KLYGEFA if stored at room temperature for more than 24 hours.
- Do not freeze KLYGEFA.
- Do not shake KLYGEFA.
- Do not expose KLYGEFA to heat.

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

General information about the safe and effective use of KLYGEFA.

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

What are the ingredients in KLYGEFA?

Active ingredient: gefurulimab-gaks

Inactive ingredients: histidine, L-histidine-hydrochloride monohydrate, glycine, sucrose, polysorbate 80 and Water for Injection.

Manufactured by: Alexion Pharmaceuticals, Inc., 121 Seaport Boulevard, Boston, MA 02210 USA

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For more information, go to www.KLYGEFA.com or call 1-888-765-4747.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Approved: 11/2026

INSTRUCTIONS FOR USE
KLYGEFA™ (klahy-gef-uh)
(gefurulimab-gaks)
injection, for subcutaneous use
Single-dose prefilled autoinjector

This Instructions for Use contains information on how to inject KLYGEFA using the prefilled autoinjector.



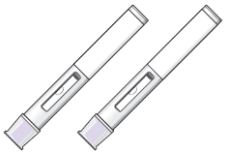
Your healthcare provider should show you or your caregiver how to use the prefilled autoinjector the right way. If you or your caregiver have any questions, talk to your healthcare provider.

For subcutaneous injection only (inject directly under the skin).

Check your prescription

If you were prescribed:

600 mg
Use **2 prefilled autoinjectors** to give 2 injections.



Second injection is given immediately after the first injection.

or

300 mg
Use **1 prefilled autoinjector** to give 1 injection.



Your first dose is different from your weekly dose and will require 2 or 3 injections, depending on your body weight.

Unsure of your dose? Call your healthcare provider or pharmacist.

Important Information Before Injecting KLYGEFA

Storing KLYGEFA

- Store KLYGEFA in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton to protect from light.
- KLYGEFA can be taken out of the refrigerator and placed back in the refrigerator 1 time, if needed. Do not keep KLYGEFA out of the refrigerator for more than 24 hours. Protect from light when stored at room temperature.
- Throw away (discard) the autoinjector if it has been left out at room temperature for more than 24 hours.
- Do not freeze KLYGEFA.
- Do not shake KLYGEFA.
- Do not expose KLYGEFA to heat.
- Keep KLYGEFA and all medicines out of the reach of children.

Handling KLYGEFA

- **Do not** remove needle cap until you are ready to inject to prevent the medicine from drying out.
- Grip the autoinjector body and keep hands away from the needle end to prevent a needle stick.
- **Do not** touch the purple needle end. This could cause the autoinjector to activate early.
- **Do not** re-cap as you may stick yourself or damage the needle.
- **Do not** use KLYGEFA if it has been previously used.
- **Do not** use KLYGEFA if it was dropped, damaged, or appears to be tampered with.

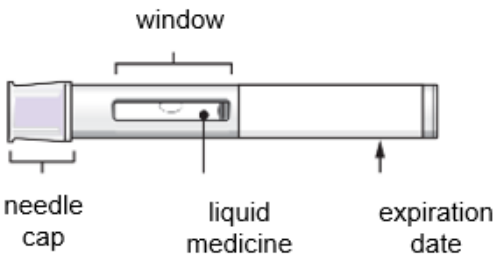
- **Do not** use KLYGEFA if it is past the expiration date (EXP).
- **Do not** use KLYGEFA if it contains particles.
- **Do not** use KLYGEFA if the needle has touched any surface after cap removal.

If any of these apply, throw away (dispose of) the autoinjector in a puncture-resistant sharps disposal container and use a new autoinjector.

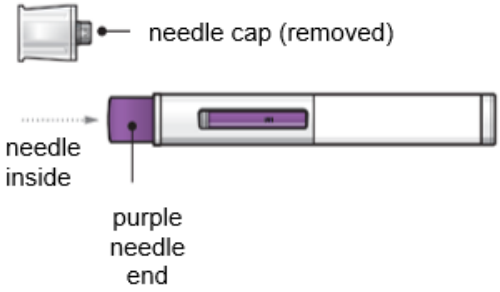
KLYGEFA autoinjector

After the injection is complete, the purple needle end will lock in place over the needle.

Before use:



After use:



Prepare KLYGEFA

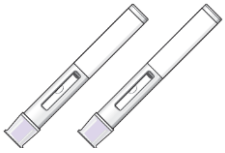
1. Confirm your dose

Check your prescription to confirm the dose your healthcare provider has prescribed.

If you were prescribed:

600 mg

Use **2 prefilled autoinjectors** to give 2 injections.



or

300 mg

Use **1 prefilled autoinjector** to give 1 injection.



Your first dose is different from your weekly dose and will require 2 or 3 injections, depending on your body weight.

2. Gather supplies

Gather the following supplies on a clean, flat workspace:

(See Figure A)

- Alcohol swabs
- Cotton balls
- Bandages
- Sharps disposal container

Note: Supplies listed are not included with autoinjector.



Figure A

3. Remove cartons needed from the refrigerator

Remove the number of cartons needed for your dose from the refrigerator. (See Figure B)

Inspect the cartons for any damage.

Check the expiration date.

4. Remove autoinjectors from the carton

Open the cartons.

Grip the autoinjector body and remove the autoinjector from the carton. (See Figure B)

Return extra autoinjectors back into the refrigerator in their carton.

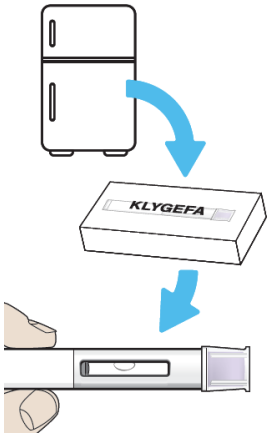


Figure B

5. Inspect autoinjector

Check the autoinjector for any damage.

Check the expiration date. (See Figure C)

- **Do not** touch the purple needle end. This may cause the autoinjector to activate early.
- **Do not** use if the expiration date has passed or there are signs of damage.

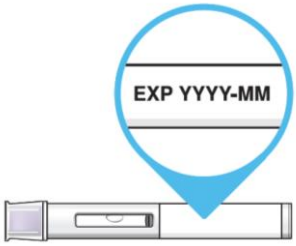


Figure C

6. Inspect medicine

Check the medicine to make sure the liquid is clear and slightly yellow to yellow.

(See Figure D)

Confirm there are no particles in the liquid. Do not use the autoinjector if the liquid is cloudy, discolored, or has flakes or particles in it.

It is normal to see air bubbles.

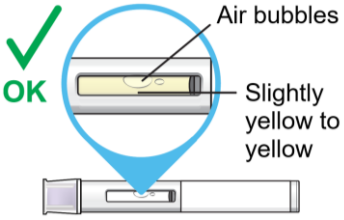


Figure D

7. Allow autoinjector to warm

Let the autoinjector sit at room temperature for 45 minutes before use. Protect from light. (See Figure E)

This will make the injection more comfortable.

- **Do not** use external heat sources such as a microwave or hot water to warm the autoinjector.
- **Do not** use the autoinjector if it has been out of the refrigerator for more than **24 hours** or previously frozen. Safely throw away (dispose of) the autoinjector and use a new one.



Figure E

8. Wash your hands

Wash your hands well with soap and water. (See Figure F)

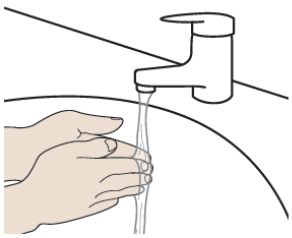


Figure F

9. Choose injection site

Use a different injection site from your previous injection. If your prescribed dose requires more than 1 injection, leave a 1-inch (2.5 cm) space between injection sites. Do not inject into the exact same spot.

Choose from the following areas for your injection:

(See Figure G)

- Lower stomach area (lower abdomen), except the 2-inch (5 cm) area around your belly button (navel)
- Front of thighs
- Back of upper arms (injection by caregiver only)

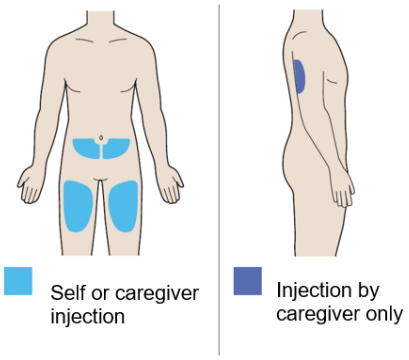


Figure G

10. Clean injection site

Clean any injection site with an alcohol swab and allow the skin to air dry. (See Figure H)

- **Do not** inject into itchy, hard, tender, painful, bruised, red or scarred skin.
- **Do not** touch the injection site again or blow on it before the injection.

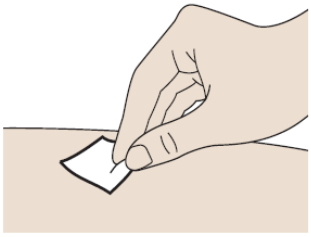


Figure H

Inject KLYGEFA

Things to know before you inject:

- **Do not** remove needle cap until you are ready to inject to prevent the medicine from drying out.
- **Do not** use the autoinjector if it has been dropped.
- **Do not** re-cap as you may stick yourself or damage the needle.
- **Do not** touch the purple needle end as this may cause the autoinjector to activate early.

11. Remove needle cap

Hold the autoinjector by its body and pull the needle cap straight off.

(See Figure I)

Throw away (dispose of) the needle cap right away.

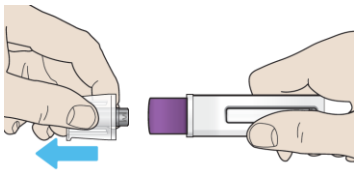


Figure I

12. Position the autoinjector

Grip the autoinjector firmly. Be careful not to cover the window.

Position the purple needle end flat against your skin with the window facing you. (See Figure J)

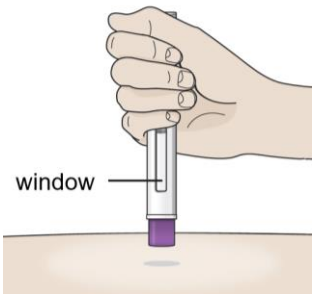
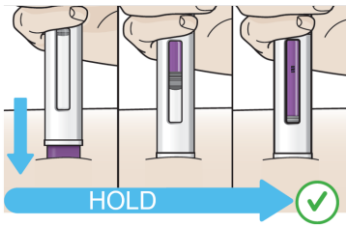


Figure J

13. Push down firmly

Push down to start the injection and hold firmly.

Count out loud slowly to 15, making sure you hold the autoinjector down to deliver all the medicine.



You may hear clicks before you get to 15 but keep holding the autoinjector down. (See Figure K)

Figure K

14. Confirm injection is complete

Before lifting the autoinjector up, make sure the window is all purple.

Then lift the autoinjector straight up. (See Figure L)

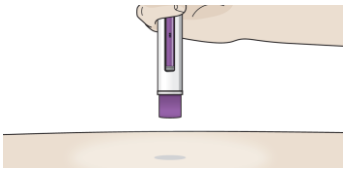
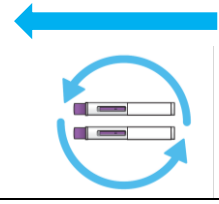


Figure L

If your dose is 600 mg
With a second autoinjector, repeat injection starting at step 5. Inject into a spot 1 inch away from first injection.

or

If your dose is 300 mg
Continue to step 15.



15. Check injection site

Check the injection site. If you see blood, press a cotton ball or gauze on the injection site. (See Figure M)

Apply a bandage if necessary. **Do not** rub the injection site.

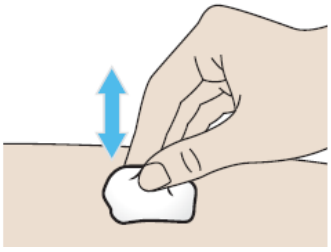


Figure M

Throw away (dispose of) KLYGEFA

16. Throw away (dispose of) used autoinjector

Put your used autoinjectors in an FDA-cleared sharps disposal container right away after injection. (See Figure N)

- **Do not** throw away your autoinjector in your household trash.

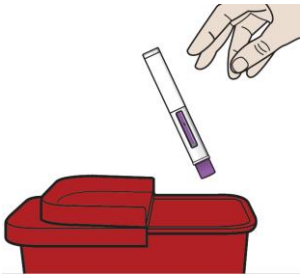


Figure N

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.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the correct way to dispose of your sharps disposal container.

There may be state or local laws about how you should throw away used needles and autoinjectors. 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.

Need help?

For additional assistance call 1-888-765-4747.

Frequently Asked Questions

Why do I need to allow the autoinjector to warm up at room temperature for 45 minutes prior to injecting?

- This step is primarily for your comfort. Never try to speed up the warming process in any way, like using the microwave or placing the autoinjector in warm water.

How many autoinjectors do I need for my prescribed dose?

- Check your prescription to confirm the dose your healthcare provider has prescribed. If you are prescribed a 600 mg dose, use 2 autoinjectors to administer the full dose. If you are prescribed a 300 mg dose, use 1 autoinjector to administer the full dose.

Can I perform my second injection in the same location?

- You can inject in the same area but leave 1 inch (2.5 cm) space between injection sites.

What if my autoinjector appears to be broken or damaged?

- Do not use the autoinjector. Contact your healthcare provider or pharmacist for further instructions.

What if I see air bubbles in my autoinjector?

- Air bubbles are normal.

What if my medicine is yellowish?

- The medicine is safe to use if the liquid is clear and slightly yellow to yellow.

Why do I need to hold the autoinjector down for 15 seconds during the injection?

- This is necessary to make sure that you receive the full dose.

Where should I dispose of the needle cap?

- You can dispose of the needle cap in your household trash.

Manufactured by:

Alexion Pharmaceuticals, Inc.
Boston, MA 02210 USA

U.S. License Number 1743

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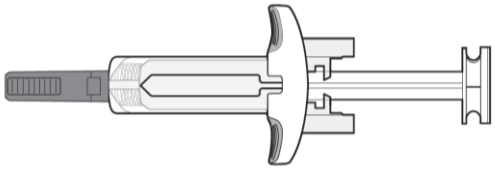
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For more information, go to www.KLYGEFA.com or call 1-888-765-4747. If you still have questions, contact your healthcare provider.

This Instructions for Use has been approved by the U.S. Food and Drug Administration. Issued: 11/2026

INSTRUCTIONS FOR USE
KLYGEFA™ (klahy-gef-uh)
(gefurulimab-gaks)
injection, for subcutaneous use
Single-dose prefilled syringe

This Instructions for Use contains information on how to inject KLYGEFA using the prefilled syringe.



Your healthcare provider should show you or your caregiver how to use the prefilled syringe the right way. If you or your caregiver have any questions, talk to your healthcare provider.

For subcutaneous injection only (inject directly under the skin).

Check your prescription

If you were prescribed:

600 mg
Use **2 prefilled syringes**
to give 2 injections.



Second injection is given immediately after the first injection.

or

300 mg
Use **1 prefilled syringe**
to give 1 injection.



Your first dose is different from your weekly dose and will require 2 or 3 injections, depending on your body weight.

Unsure of your dose? Call your healthcare provider or pharmacist.

Important Information Before Injecting KLYGEFA

Storing KLYGEFA

- Store KLYGEFA in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton to protect from light.
- KLYGEFA can be taken out of the refrigerator and placed back in the refrigerator 1 time, if needed. Do not keep KLYGEFA out of the refrigerator for more than 24 hours. Protect from light when stored at room temperature.
- Throw away (discard) the syringe if it has been left out at room temperature for more than 24 hours.
- Do not freeze KLYGEFA.
- Do not shake KLYGEFA.
- Do not expose KLYGEFA to heat.
- Keep KLYGEFA and all medicines out of the reach of children.

Handling KLYGEFA

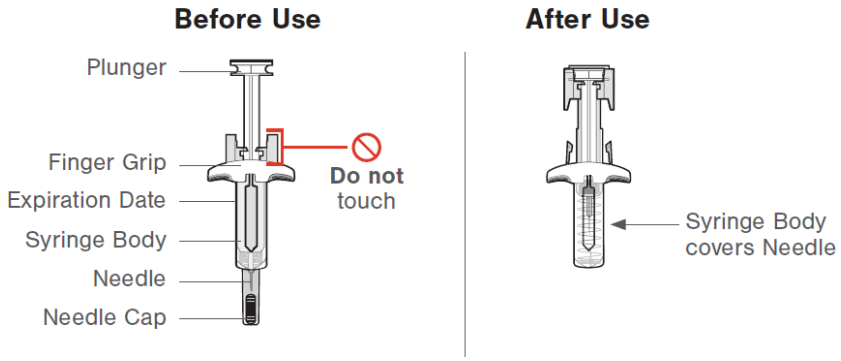
- **Do not** remove needle cap until you are ready to inject to prevent the medicine from drying out.
- Grip the syringe body and keep hands away from the needle area to prevent a needle stick.
- **Do not** touch the plunger or the area above the finger grip. **Do not** hold the plunger while removing the needle cap. This could cause the needle safety guard to activate early.
- **Do not** use KLYGEFA if it has been previously used.

- **Do not** use KLYGEFA if it was dropped, damaged, or appears to be tampered with.
- **Do not** use KLYGEFA if it is past the expiration date (EXP).
- **Do not** use KLYGEFA if it contains particles.
- **Do not** use KLYGEFA if the needle has touched any surface after cap removal.

If any of these apply, throw away (dispose of) the syringe in a puncture-resistant sharps disposal container and use a new syringe.

KLYGEFA prefilled syringe

After the injection is complete, the needle will be locked inside the syringe body.



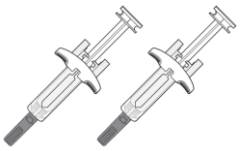
Prepare KLYGEFA

1. Confirm your dose

Check your prescription to confirm the dose your healthcare provider has prescribed.

If you were prescribed:

600 mg
Use **2 prefilled syringes**
to give 2 injections.



or

300 mg
Use **1 prefilled syringe**
to give 1 injection.



Your first dose is different from your weekly dose and will require 2 or 3 injections, depending on your body weight.

2. Gather supplies

Gather the following supplies on a clean, flat workspace:

(See Figure A)

- Alcohol swabs
- Cotton balls
- Bandages
- Sharps disposal container

Note: Supplies listed are not included with prefilled syringe.



Figure A

3. Remove cartons needed from the refrigerator

Remove the number of cartons needed for your dose from the refrigerator. (See Figure B)

Inspect the cartons for any damage.

Check the expiration date.

4. Remove syringes from the carton

Open the carton.

Grip the syringe body and remove the syringe from the carton.

(See Figure B)

Return extra syringes back into the refrigerator in their carton.

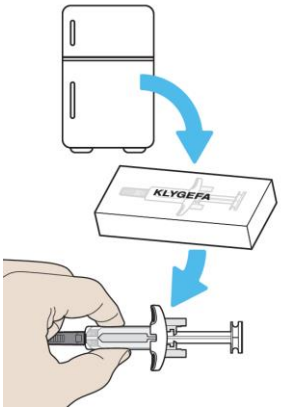


Figure B

5. Inspect syringe

Check the syringe for any damage.

Check the expiration date. (See Figure C)

- **Do not** touch the area above finger grip. This may cause the needle safety guard to activate early.
- **Do not** use if the expiration date has passed or there are signs of damage.
- **Do not** touch the plunger or the needle cap.

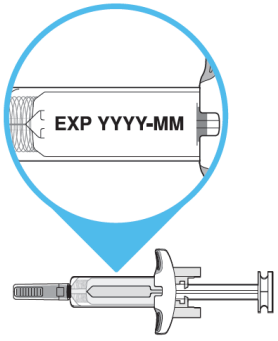


Figure C

6. Inspect medicine

Check the medicine to make sure the liquid is clear and slightly yellow to yellow.

(See Figure D)

Confirm there are no particles in the liquid. Do not use the prefilled syringe if the liquid is cloudy, discolored, or has flakes or particles in it.

It is normal to see air bubbles.

- **Do not** try to remove air bubbles from the syringe.

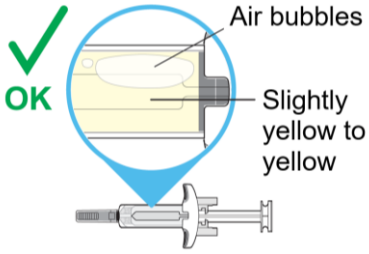


Figure D

7. Allow prefilled syringe to warm

Let the syringe sit at room temperature for 45 minutes before use. Protect from light. (See Figure E)

This will make the injection more comfortable.

- **Do not** use external heat sources such as a microwave or hot water to warm the prefilled syringe.
- **Do not** use the prefilled syringe if it has been out of the refrigerator for more than **24 hours** or previously frozen. Safely throw away (dispose of) the prefilled syringe and use a new one.



Figure E

8. Wash your hands

Wash your hands well with soap and water. (See Figure F)

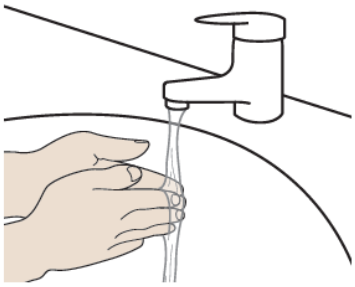


Figure F

9. Choose injection site

Use a different injection site from your previous injection. If your prescribed dose requires more than 1 injection, leave a 1-inch (2.5 cm) space between injection sites. Do not inject into the exact same spot.

Choose from the following areas for your injection:

(See Figure G)

- Lower stomach area (lower abdomen), except the 2-inch (5 cm) area around your belly button (navel)
- Front of thighs
- Back of upper arms (injection by caregiver only)

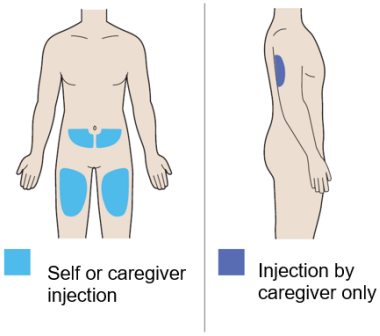


Figure G

10. Clean injection site

Clean any injection site with an alcohol swab and allow the skin to air dry. (See Figure H)

- **Do not** inject into itchy, hard, tender, painful, bruised, red or scarred skin.
- **Do not** touch the injection site again or blow on it before the injection.

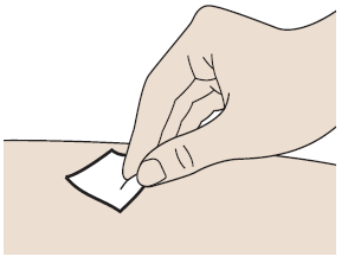


Figure H

Inject KLYGEFA

Things to know before you inject:

- **Do not** remove needle cap until you are ready to inject to prevent the medicine from drying out.
- **Do not** hold the plunger while removing the needle cap.
- **Do not** use the syringe if the needle is bent or the syringe has been dropped.
- **Do not** re-cap as you may stick yourself or damage the needle.
- **Do not** touch the needle or let it touch any surface.
- **Do not** touch the plunger or area above finger grip as this may cause the needle safety guard to activate early.

11. Remove needle cap

Hold the prefilled syringe by its body and pull the needle cap straight off.

(See Figure I)

Throw away (dispose of) the needle cap right away.

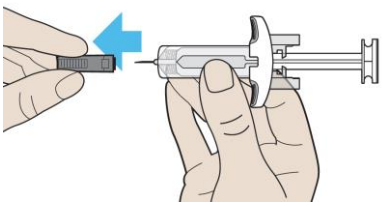


Figure I

12. Pinch skin

With one hand, pinch the skin at the injection site. (See Figure J)

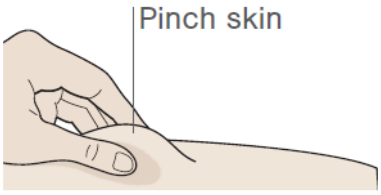


Figure J

13. Insert needle

With your other hand, position the syringe at about a 45º angle.

Gently insert the entire needle into the pinched skin. (See Figure K)

Let go of pinched skin.

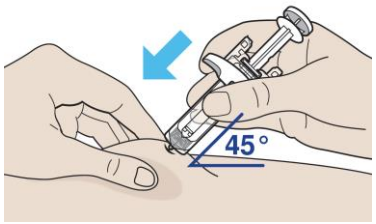


Figure K

14. Press plunger

Slowly press the plunger all the way down until you cannot push any further. (See Figure L)

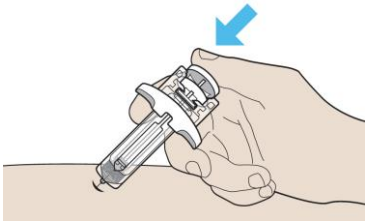


Figure L

15. Release plunger to activate safety

When the plunger is pressed all the way down, lift your thumb from the plunger. The needle will move into the syringe body for safety.

(See Figure M)

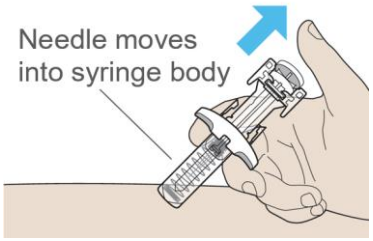
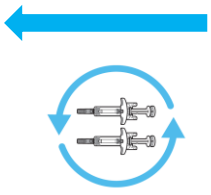


Figure M

If your dose is 600 mg

With a second syringe, repeat injection starting at step 5. Inject into a spot 1 inch away from first injection.



or

If your dose is 300 mg

Continue to step 16.



16. Check injection site

Check the injection site. If you see blood, press a cotton ball or gauze on the injection site. (See Figure N)

Apply a bandage if necessary. **Do not** rub the injection site.

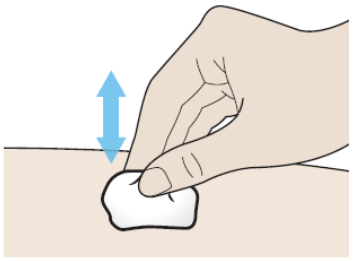


Figure N

Throw Away (dispose of) KLYGEFA

17. Throw away (dispose of) used syringe

Put your used syringes in an FDA-cleared sharps disposal container right away after injection. (See Figure O)

- **Do not** throw away your syringe in your household trash.

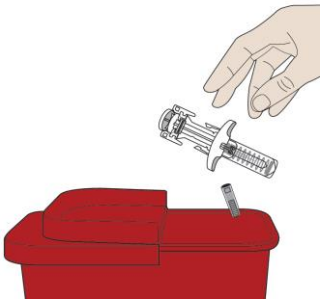


Figure O

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.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the correct 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.

Need help?

For additional assistance call 1-888-765-4747.

Frequently Asked Questions

Why do I need to allow the prefilled syringe to warm up at room temperature for 45 minutes prior to injecting?

- This step is primarily for your comfort. Never try to speed up the warming process in any way, like using the microwave or placing the syringe in warm water.

How many prefilled syringes do I need for my prescribed dose?

- Check your prescription to confirm the dose your healthcare provider has prescribed. If you are prescribed a 600 mg dose, use 2 prefilled syringes to administer the full dose. If you are prescribed a 300 mg dose, use 1 prefilled syringe to administer the full dose.

Can I perform my second injection in the same location?

- You can inject in the same area but leave 1 inch (2.5 cm) space between injection sites.

Where should I dispose of the needle cap?

- You can dispose of the needle cap in your household trash.

What if my prefilled syringe appears to be broken or damaged?

- Do not use the prefilled syringe. Contact your healthcare provider or pharmacist for further instructions.

What if I see air bubbles in my prefilled syringe?

- Air bubbles are normal.

What if my medicine is yellowish?

- The medicine is safe to use if the liquid is clear and slightly yellow to yellow.

What if there is a drop of liquid on the tip of the needle when I remove the needle cap?

- A drop of liquid on the tip of the needle is normal.

Manufactured by:
Alexion Pharmaceuticals, Inc.
Boston, MA 02210 USA
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