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.

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