

**MEDICATION GUIDE**  
**PIASKY (pea-UH-sky)**  
**(crovalimab-akkz)**

**injection, for intravenous or subcutaneous use**

**What is the most important information I should know about PIASKY?**

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

- **PIASKY increases your chance of getting serious infections caused by *Neisseria meningitidis*. Meningococcal infections may quickly become life-threatening or cause death if not recognized and treated early.**
  - You must complete or update your meningococcal vaccines at least 2 weeks before your first dose of PIASKY.
  - If you have not completed your meningococcal vaccines and PIASKY must be started right away, you should receive the required vaccines as soon as possible.
  - If you have not been vaccinated and PIASKY must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you to.
  - If you had a meningococcal vaccine in the past, you might need additional vaccines before starting PIASKY. 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 serious meningococcal infection:**
    - fever
    - fever and a rash
    - fever with a high heart rate
    - fever with a headache
    - headache with nausea or vomiting
    - headache with a stiff neck or stiff back
    - confusion
    - muscle aches, with flu-like symptoms
    - 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 11 months after your last dose of PIASKY. Your risk of meningococcal infection may continue for several months after your last dose of PIASKY. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

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

- enroll in the PIASKY REMS program
- counsel you about the risk of serious meningococcal infection
- give you information about the signs and symptoms of serious meningococcal infection
- make sure that you are vaccinated against serious infections caused by meningococcal bacteria and that you receive antibiotics if you need to start PIASKY right away and you are not up to date on your vaccines
- give you a **Patient Safety Card** about your risk of meningococcal infection, as discussed above
- **Immune system reactions** called Type III hypersensitivity reactions are common during treatment with PIASKY and can also be serious. If you are currently being treated with or have been treated with another C5 inhibitor medicine **and you switch to PIASKY**, PIASKY may cause Type III hypersensitivity reactions. People may also develop Type III hypersensitivity reactions when they switch from PIASKY to another C5 inhibitor medicine. **If you have been treated with another C5 inhibitor medicine and you switch to PIASKY, or if you have been treated with PIASKY and you switch to another C5 inhibitor medicine, your healthcare provider should monitor you for 30 days after you switch medicines.** Call your healthcare provider or go to the nearest emergency room right away if you develop any signs and symptoms of Type III hypersensitivity reactions, including:
  - joint pain
  - muscle or bone pain
  - rash or skin problems
  - itching
  - headache
  - kidney problems
  - numbness and tingling or a feeling of pins and needles, especially of the hands and feet
  - fever
  - weakness, tiredness, or lack of energy
  - stomach trouble or pain
- **PIASKY may also increase the risk of other types of serious infections** caused by encapsulated bacteria, including infections caused by *Neisseria* spp., *Streptococcus pneumoniae*, and *Haemophilus influenzae* and *Neisseria gonorrhoeae*.
  - If you receive treatment with PIASKY, you should receive vaccines against *Streptococcus pneumoniae*.

- If your child receives treatment with PIASKY, your child should receive vaccines against *Streptococcus pneumoniae* and may receive vaccines against *Haemophilus influenzae*, depending on their age.

Call your healthcare provider right away if you have any new signs or symptoms of infection such as:

- fever of 100.4°F (38°C) or higher
- cough
- chest pain
- tiredness
- feeling short of breath
- painful rash
- sore throat
- burning pain when passing urine
- feeling weak or generally unwell

For more information about side effects, see “**What are the possible side effects of PIASKY?**”

### **What is PIASKY?**

PIASKY is a prescription medicine used to treat a disease called paroxysmal nocturnal hemoglobinuria (PNH) in adults and children 13 years of age and older who weigh at least 88 pounds (40 kg).

It is not known if PIASKY is safe and effective in children under 13 years of age and in people who weigh less than 88 pounds (40 kg).

### **Who should not receive PIASKY?**

#### **Do not receive PIASKY if you:**

- have a serious meningococcal infection caused by *Neisseria meningitidis* when you are starting PIASKY treatment.
- are allergic to crovalimab or any of the ingredients in PIASKY. See the end of this Medication Guide for a complete list of ingredients in PIASKY.

#### **Before receiving PIASKY 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 PIASKY will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if PIASKY passes into your breast milk. You should not breastfeed during treatment with PIASKY and for 9 months after your final dose.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. PIASKY and other medicines can affect each other, causing side effects.

**Especially tell your healthcare provider** if you are currently being treated with or have ever been treated with any other complement C5 inhibitor (C5 inhibitor) medicine. PIASKY is a C5 inhibitor medicine. Ask your healthcare provider if you are not sure if you have been treated with a C5 inhibitor medicine. See “**What are the possible side effects of PIASKY?**”

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 receive PIASKY?**

- Your healthcare provider will give you your PIASKY treatment.
- Your first dose will be given through a vein by intravenous (IV) infusion over 60 to 90 minutes on Day 1 by your healthcare provider. This is the first loading dose.
- Another loading dose will be given as an injection under the skin (subcutaneous) on Days 2, 8, 15, and 22.
- Your maintenance doses will begin on Day 29 and then will be given every 4 weeks as a subcutaneous injection.
- Your healthcare provider will prescribe the dose based on your weight. If your weight changes, tell your healthcare provider.
- Talk to your healthcare provider if you miss receiving an entire dose or part of your dose of PIASKY.
- **If you are changing treatment from another C5 inhibitor such as eculizumab or ravulizumab to PIASKY**, you should receive your first loading dose of PIASKY no sooner than the time you would have received your next scheduled dose of eculizumab or ravulizumab.
- **If you stop taking PIASKY** and do not switch to another treatment for your PNH, your healthcare provider will need to monitor you closely for at least 20 weeks after stopping PIASKY. **Stopping treatment with PIASKY may cause a breakdown of red blood cells due to PNH.**

#### **Symptoms or problems that can happen due to red blood cell breakdown include:**

- a lower number of red blood cells (anemia)
- blood in your urine or dark urine
- feeling short of breath
- feeling tired or low energy (fatigue)
- stomach pain
- blood clotting (thrombosis)
- difficulty swallowing
- difficulty getting or keeping an erection (erectile dysfunction)
- kidneys not working properly

### **What are the possible side effects of PIASKY?**

**PIASKY may cause serious side effects including:**

- See “**What is the most important information I should know about PIASKY?**”
- **Infusion- and injection-related reactions.** Infusion- or injection-related reactions may happen during or after your PIASKY infusion or injection. Symptoms may include headache, pain at the infusion or injection site or pain in other parts of your body, swelling, bruising or bleeding, red skin, itching and rash. **PIASKY can also cause serious allergic reactions.** If you have an infusion-related reaction, your healthcare provider may need to infuse PIASKY more slowly, temporarily stop your infusion, or completely stop PIASKY if you develop a serious allergic reaction. Call your healthcare provider right away or go to the nearest emergency room if you develop any signs or symptoms of a serious allergic reaction, including:
  - shortness of breath or trouble breathing
  - swelling of the throat, lips, tongue, or face
  - pain or tightness in your chest
  - skin itching, hives, or rash
  - wheezing
  - fever or chills
  - feeling dizzy or lightheaded

**The most common side effects of PIASKY include:**

- infusion-related reactions
- respiratory tract infections including infections of the lungs, cold symptoms, and pain or swelling of the nose or throat
- viral infections
- Type III hypersensitivity reactions

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

These are not all of the possible side effects of PIASKY. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of PIASKY.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PIASKY for a condition for which it was not prescribed. You can ask your pharmacist or healthcare provider for information about PIASKY that is written for health professionals.

**What are the ingredients in PIASKY?**

**Active ingredient:** crovalimab-akkz

**Inactive ingredients:** arginine hydrochloride, histidine, poloxamer 188, and Water for Injection. Aspartic acid may be added to adjust the pH.

Manufactured by: **Genentech, Inc.**, A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990

U.S. License No.: 1048

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This Medication Guide has been approved by the U.S. Food and Drug Administration

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