

# Givosiran

Care Team Contact Information: \_\_\_\_\_

Pharmacy Contact Information: \_\_\_\_\_

Diagnosis: \_\_\_\_\_

- This treatment is often used for acute hepatic porphyria (AHP).
- It may also be used for other reasons.

Goal of Treatment: \_\_\_\_\_

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

## Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Givosiran (giv-oh-SIR-an): Givlaari (giv-LAH-ree)	Works by lowering the level of an enzyme in the liver that acts like a "start switch" for making toxins. By turning down this switch, givosiran prevents the buildup of harmful chemicals that cause painful porphyria attacks.	Injection under the skin (subcutaneous injection) into the stomach area (abdomen), thigh, or upper arm.

## Treatment Administration and Schedule

Treatment is typically repeated every 4 weeks. This length of time is sometimes called a "cycle".

Treatment Name	Cycle 1								Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	...	Day 28	Day 1
Givosiran	✓								✓

## Appointments

Appointments may include regular check-ups with your care team, treatment appointments, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

## Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
To help prevent or treat nausea and vomiting	_____ _____	_____ _____
Other	_____ _____	_____ _____

**Common Side Effects**

Side Effect	Important Information
<p>Nausea</p>	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Eat smaller, more frequent meals.</li> <li>• Avoid fatty, fried, spicy, or highly sweet foods.</li> <li>• Eat bland foods at room temperature and drink clear liquids.</li> <li>• If you vomit, start with small sips of water, broth, or other clear liquids. If these stay down, try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and gradually return to solid foods.</li> <li>• Your care team may prescribe medicine for these symptoms.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Vomiting for more than 24 hours</li> <li>• Nonstop vomiting</li> <li>• Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine)</li> <li>• Blood or coffee-ground-like appearance in your vomit</li> <li>• Severe stomach pain that does not go away after vomiting</li> </ul>
<p>Injection-Site Reactions</p>	<p>Description: An injection-site reaction is a local skin reaction where the medicine is given under the skin (subcutaneous injection). It can cause pain, redness, swelling, itching, or a lump at the injection site.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Keep the area clean and dry. Gently wash with mild soap and water.</li> <li>• Apply a cool, clean compress for 10–15 minutes to reduce pain and swelling.</li> <li>• Avoid rubbing or massaging the site, and avoid tight clothing over the area.</li> <li>• Rotate injection sites if instructed by your care team.</li> <li>• Use over-the-counter pain relievers or topical creams only if your care team says they are safe.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Increasing redness, swelling, warmth, or pain at the site</li> <li>• A growing lump or hard area that does not get better</li> <li>• Drainage of pus or fluid from the site</li> <li>• Heavy or prolonged bleeding or new bruising at the site</li> <li>• Fever or chills with the injection-site reaction</li> </ul>

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Allergic Reactions, Including Anaphylaxis	<p>Get emergency medical help right away if you develop any of the following signs or symptoms:</p> <ul style="list-style-type: none"> <li>• Swelling of your lips, mouth, tongue, or throat</li> <li>• Trouble breathing or swallowing</li> <li>• Raised red areas on your skin (hives)</li> <li>• A very fast heartbeat</li> <li>• You feel dizzy or faint</li> </ul>
Liver Problems	<ul style="list-style-type: none"> <li>• Yellowing of your skin or the white part of your eyes (jaundice)</li> <li>• Severe nausea or vomiting</li> <li>• Pain on the right side of your stomach area (abdomen)</li> <li>• Dark, tea-colored urine</li> <li>• Bleeding or bruising more easily than normal</li> </ul>
Kidney Problems	<ul style="list-style-type: none"> <li>• Decrease in your amount of urine</li> <li>• Blood in your urine</li> <li>• Swelling of your ankles</li> <li>• Loss of appetite</li> </ul>
High Blood Homocysteine Levels	<p>Givosiran may cause increased levels of homocysteine (a type of amino acid) in your blood. Your care team will check your homocysteine levels before and during treatment by doing blood tests. If your levels are increased, your care team may check your folate, vitamins B12 and B6, and tell you to take a vitamin B6 supplement.</p> <ul style="list-style-type: none"> <li>• Dizziness</li> <li>• Fatigue</li> <li>• Irregular heartbeat</li> <li>• Muscle weakness</li> <li>• Skin color changes</li> <li>• Tingling in your feet, arms, or hands</li> <li>• Tongue or mouth sore</li> </ul>
Inflammation of the Pancreas (Pancreatitis)	<ul style="list-style-type: none"> <li>• Nausea or vomiting</li> <li>• Fast heart rate</li> <li>• Fast, shallow breathing</li> <li>• Fever</li> </ul>

**Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help. If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.**



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