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LIPOSORBER®

Provides Hope When Drug Therapy Fails™

12
Treatments
Over
9 Weeks

For Adult & Pediatric Primary FSGS Patients



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Welcome!

If you have been diagnosed with primary Focal Segmental Glomerulosclerosis (FSGS) and your doctor has recommended LIPOSORBER®, then this guide is for you. You should be proud that you are taking the right steps to educate yourself about this rare disease! We know you're here because you care about your kidney health. This guide is designed to help you understand what FSGS is, how it affects you and your family, and how LIPOSORBER may help.

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About Focal Segmental Glomerulosclerosis (FSGS)

FSGS is a rare, scarring disease of the kidney that generally causes excess protein in the urine, nephrotic syndrome, and progressive kidney failure.

There are four types of FSGS:^{1*}

- **Primary FSGS:** This type of FSGS means that the disease happened on its own without a known or obvious cause.
- **Secondary FSGS:** This type is caused by another source, such as an infection, drug toxicity, diabetes, sickle cell disease, obesity, or even other kidney diseases.
- **Genetic (familial) FSGS:** This rare form of FSGS is caused by genetic mutations. It's suspected when several members of a family show signs of FSGS. Familial FSGS can also occur when neither parent has the disease, but each carries one copy of an abnormal gene that can be passed onto the next generation.
- **Unknown FSGS:** The underlying cause of FSGS cannot be determined despite the evaluation of clinical symptoms and extensive testing.

FSGS Signs and Symptoms

Early stages of FSGS may not cause any noticeable symptoms. You may only see some signs on your own, while others may be found by your healthcare provider.

Signs and symptoms of FSGS include:²

- **Swelling in body parts**, such as your legs, ankles and around your eyes.
- **Weight gain** due to extra fluid building in your body.
- **Foamy urine** caused by high protein levels in the urine or proteinuria.
- **High fat levels** in the blood (high cholesterol).
- **Low levels of protein** in the blood.

Please consult with your healthcare provider if you exhibit any signs or symptoms of kidney problems for a proper diagnosis.

*LIPOSORBER® is only indicated for use in primary FSGS.



Prevalence of FSGS

FSGS is currently the most common primary glomerular disease causing kidney failure in the United States and the leading cause of kidney disease worldwide.¹



Over **5,400 FSGS patients** are diagnosed in the U.S. annually.¹



In adults, **FSGS is more common in males**, with an approximate 1.5-fold increased incidence compared to females.³



The incidence of FSGS is around **4x higher in black patients** compared to white patients.⁴

Both adults and children can be affected by FSGS, but it is most common in people over 45 years old. It occurs more often in men than in women and in African Americans than other ethnicities.

FSGS is estimated to be responsible for **40% of adult nephrotic syndromes and 20% of pediatric nephrotic syndromes**.⁵

Diagnosis of FSGS

There are several tests that doctors use to diagnose FSGS. These can include:²

- **Blood test:** Taking a sample of blood to measure levels of protein and fat.
- **Glomerular filtration rate (GFR):** Checking a blood sample to measure how well your kidneys work.
- **Urine test:** Measuring the levels of blood and protein in your urine. However, a definitive diagnosis of FSGS can only be made with a kidney biopsy.
- **Kidney biopsy:** Using a needle to take a small sample of tissue from the kidney for a lab to study for signs of FSGS under a microscope.
- **Genetic testing**

Management and Treatment of FSGS

Treatment for FSGS depends on the type and cause, your age, and whether you have other health conditions. Doctors aim to control symptoms to help patients maintain a good quality of life and slow or prevent progressive scarring so that FSGS does not lead to kidney failure.

In general, treatments for FSGS may include:^{2,1}

- **Angiotensin-converting enzyme (ACE) inhibitors:** Drugs that treat high blood pressure.
- **Antibiotics**
- **Diuretics:** Medications that lower blood pressure and rid the body of excess fluids.
- **Immunosuppressive drugs:** Drugs that manage the immune system response, such as cyclosporine and tacrolimus.
- **Corticosteroid (e.g. Prednisone):** An anti-inflammatory drug that lowers levels of protein in the urine.
- **Plasma Apheresis:** A process in which the liquid part of the blood (plasma) is separated from the blood cells.
- **Lipoprotein-Apheresis:** A process in which cholesterol-rich lipoproteins are removed from the plasma.*



*Indicated for use only in patients with nephrotic syndrome associated with primary FSGS when standard drug therapy has been unsuccessful or the patient is post transplant.

FSGS Patient's Journey: Exploring Treatment Options

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FAMILY HEALTH ASSESSMENT

Some people with FSGS have no symptoms. When symptoms do appear, the patient may be experiencing the following:²

- **Swelling** in legs, ankles and/or around the eyes (edema)
- **Weight gain** due to extra fluid building in body
- **Foamy urine** (proteinuria) caused by high protein levels in the urine
- **High fat levels** in the blood (high cholesterol)
- **High blood pressure**
- **Low levels of protein** in the blood

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TACKLING SYMPTOMS

The patient goes to their physician. If FSGS is suspected, the doctor will review patient's medical history and order a series of tests:²

- **Blood test:** to measure levels of protein and fat.
- **Glomerular filtration rate (GFR):** blood sample to measure how well the kidneys work.
- **Urine test:** to measure blood and protein levels in urine.
- **Kidney biopsy:** a small tissue sample is taken from the kidney, sent to lab and studied for signs of FSGS. A definitive diagnosis can only be made with a kidney biopsy.
- **Genetic testing:** may be done to see if patient was born with genes that caused the kidney disease. This information may help the doctor decide what treatment option is best.

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DIAGNOSIS

The test comes back and confirms that the patient has Focal Segmental Glomerulosclerosis (FSGS).

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TREATMENT RECOMMENDATION



In cases where the patient has primary FSGS and drug therapies are unsuccessful, or the patient is post transplant, the physician may recommend lipoprotein-apheresis and connect you with the nearest treatment center.

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Unfortunately, 50% of patients diagnosed with FSGS may not respond to the recommended drug therapies.⁷ Depending on the patient's health status, the physician may recommend dialysis, kidney transplant, plasma apheresis or **lipoprotein-apheresis (LA)**.

DRUG THERAPY & LIFESTYLE CHANGES

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The physician talks to the patient about lifestyle changes to help support kidney functioning:

- Follow a low sodium / low protein diet
- Be active and maintain a healthy weight
- Avoid medications that can harm kidneys (i.e., NSAIDs)
- Take daily vitamins (i.e., vitamin D)

The physician then talks about treatment options:²

- Corticosteroids (steroids)
- Angiotensin Converting Enzyme (ACE) Inhibitors or Angiotensin II Receptor Blockers (ARB)
- Cholesterol medication
- Anticoagulants
- Diuretics

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ONBOARDING



The patient will meet with the LA team to see what they need to do before the first treatment (such as a switch or addition of medication, vascular access discussion, etc.).

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ADHERENCE: MANAGING LEVELS



The patient starts treatment and should expect to be there for **2-4 hours**, per session. The physician will check the patient's kidney function (filtration rate, proteinuria, etc.) and compare with future sessions to make sure treatment goals are being met. The patient can bring items to help pass the time and relax (book, tablet, headphones, etc.).

FOLLOW UP

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Patients typically receive LA treatments **2x a week for 3 weeks** followed by **1x a week for 6 weeks**, for a total of 12 sessions. Patients should talk with their doctor about recommended treatment frequency, medications, and follow up care.*

PATIENT CAN ENJOY A FULL LIFE

*While individual results vary, clinical studies demonstrate benefits to FSGS patients, measured at 2, 4 and 5 years following treatment.

About LIPOSORBER®

LIPOSORBER LA-15 is a lipoprotein-apheresis procedure that separates plasma from whole blood and selectively removes the bad cholesterol, such as LDL-C and Lp(a).

The FDA has approved LIPOSORBER based on a finding of probable benefit. Studies have shown that LIPOSORBER may help patients that have glomerulus toxicity of persistent high cholesterol in refractory nephrotic syndrome, and protect against glomerular injury. In addition, preliminary evidence suggests that, in some patients, lipoprotein-apheresis may promote complete or partial remission of nephrotic syndrome.*

The main symptom of primary FSGS is protein found in the patient's urine. Although the LIPOSORBER System primarily reduces the level of serum LDL-cholesterol, it also appears to reduce the urine protein (proteinuria).

Your physician can help you understand the benefits and risks of LIPOSORBER treatment and whether the procedure may benefit you or your child.

Indications For Use:


LIPOSORBER is indicated for adult and pediatric patients with nephrotic syndrome associated with primary FSGS when:


- standard treatment options, including corticosteroid and/or calcineurin inhibitor drugs, are unsuccessful or not well tolerated, and the patient's glomerular filtration rate (GFR) is $\geq 60\text{ml/min/1.73m}^2$
- or-
- FSGS recurs post kidney transplant.⁶

LIPOSORBER is an FDA authorized Humanitarian Use Device for the treatment of certain patients with nephrotic syndrome associated with primary FSGS.

***Measured at 2, 4 and 5 years post treatment.
Effectiveness for this condition has not been established.**

LIPOSORBER Safety Profile

 **ADVERSE EVENTS:** The most common adverse events are hypotension (0.8%), nausea/vomiting (0.5%), and flushing/blotching (0.4%). Other adverse reactions may occur, including angina/chest pain, shortness of breath, fainting, lightheadedness and anemia.⁶

 **CONTRAINDICATION:** Angiotensin converting enzyme [ACEI(s)] inhibitors are contraindicated with LIPOSORBER® due to possible bradykinin reaction. ACEI(s) should be replaced with angiotensin II receptor blockers (ARBs) or any other antihypertensive agent as determined by the prescribing physician.⁶

For complete safety information and contraindications, please refer to the Instructions For Use manual: bit.ly/liposorberifu

Talk to your doctor to see whether LIPOSORBER is an option for you.



Tips for Successful Treatment Sessions

- 1. Do not take ACE inhibitor medication.** Talk to your doctor about other medications, such as ARBs (angiotensin receptor blockers).
- 2. Do not take other anti-hypertensive (for high blood pressure) medications on the day of treatment.** You can resume following your LIPOSORBER® treatment. Again, talk to your doctor before stopping your medication.
- 3. Eat a low fat, low salt meal before your treatment.*** Also, avoid drinking alcohol 24 hours prior.
- 4. Do not perform strenuous exercise** on the day of your procedure.
- 5. Avoid activities that could increase the risk of physical injury** for 24 hours after your treatment because of the blood thinning medication being used.
- 6. Come to treatment wearing comfortable clothes** and bring items to help pass the time (book, tablet, headphones, etc.)

*Consult with your doctor for specific dietary recommendations.

Reimbursement & Resources

Most insurance plans, including Medicare and Medicaid, cover the cost of LIPOSORBER treatment. Make sure to talk to your doctor about your insurance coverage options prior to starting treatment.

To learn more about FSGS and LIPOSORBER, please scan the resources below.



Find a Treatment Center Near You

There are 50+ locations across the US and Canada that offer LIPOSORBER treatment with new facilities being added regularly.



Kidney Health Gateway

Brought to you by NephCure, Kidney Health Gateway is your resource for helping you find clinical trials and specialists in your area.



Connect on Social Media

Follow LIPOSORBER and get updates delivered to your social media channels.



Definitions Index

ACEIs - Angiotensin-Converting Enzyme Inhibitors: medications used to treat and manage hypertension, which is a significant risk factor for coronary disease, heart failure, stroke, and a host of other cardiovascular conditions.

BUN - Blood Urea Nitrogen: a test used to determine how well the kidneys are working.

Cholesterol: a waxy, fatlike substance that travels through the blood on proteins called lipoproteins.

ESKD - End Stage Kidney Disease: Also known as kidney failure, occurs when chronic kidney disease (the gradual loss of kidney function) reaches an advanced state.

FSGS - Focal Segmental Glomerulosclerosis: a disease in which scar tissue develops on the parts of the kidneys that filter waste out of the blood (glomeruli).

Glomerular Disease: Diseases that affect the filtering units of the kidney (the glomeruli). Symptoms include foamy urine, pink urine, high blood pressure and swelling in your face, hands, ankles or feet.

Glomerulus Toxicity (glomerulonephritis): inflammation of the tiny filters in the kidneys (glomeruli).

HDL-C - High-Density Lipoprotein Cholesterol: “good” cholesterol, consists primarily of protein. HDL absorbs cholesterol in the blood and carries it back to the liver.

LDL-C - Low-Density Lipoprotein Cholesterol: “bad” cholesterol that collects in the walls of your blood vessels, raising your chances of health problems like a heart attack or stroke.

Lipoprotein-Apheresis (or LDL-apheresis): nonsurgical therapy that removes low-density lipoprotein (LDL) cholesterol and Lipoprotein(a) from the blood that may induce complete or partial remission of proteinuria in up to 50% of patients with both drug-resistant and recurrent FSGS.⁸

Lp(a) - Lipoprotein(a): a type of protein that transports cholesterol (a fatty substance) in the blood.

Nephrotic Syndrome: a kidney disorder that causes your body to pass too much protein into your urine (proteinuria).

Plasma: the liquid part of the blood (about 55%) containing 92% water, 7% vital proteins and 1% mineral salts, sugars, fats, hormones and vitamins.

Proteinuria: high levels of protein in the urine.

