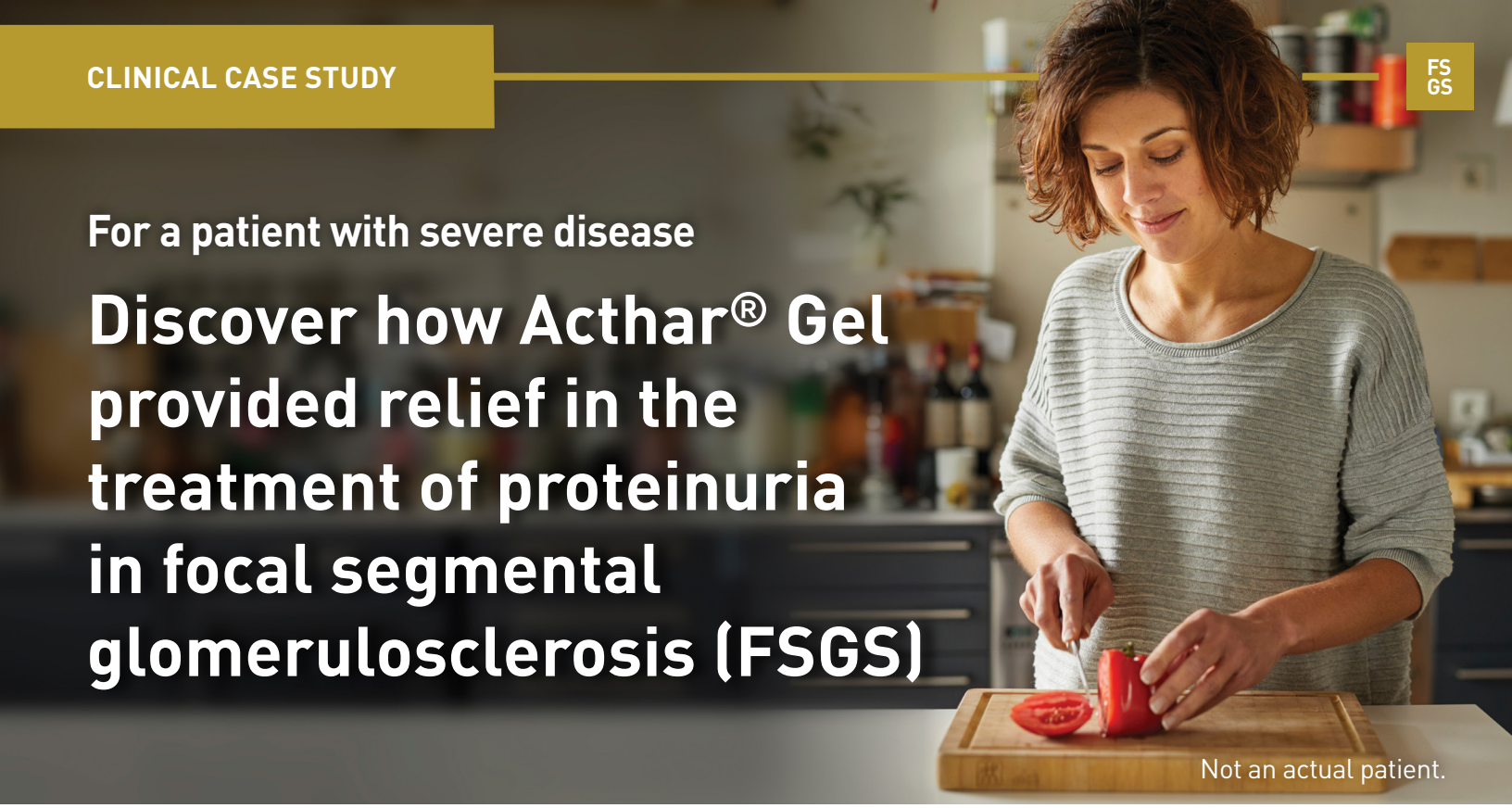
CLINICAL CASE STUDY

FS
GS



For a patient with severe disease

Discover how Acthar® Gel provided relief in the treatment of proteinuria in focal segmental glomerulosclerosis (FSGS)

Diagnosis: FSGS

Patient profile: A 36-year-old woman presenting with edema and fatigue for the last 6 weeks.

Case study provided by:

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This case study is provided for general medical education purposes only and is not a substitute for independent clinical medical judgment. The intent of this case study is to present the experience of an individual patient, which may not represent outcomes in the overall patient population. Response to treatment may vary from patient to patient.

INDICATION

Acthar Gel is indicated to induce a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

Acthar is contraindicated:

- For intravenous administration
- In infants under 2 years of age who have suspected congenital infections
- With concomitant administration of live or live attenuated vaccines in patients receiving immunosuppressive doses of Acthar
- In patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins of porcine origin

Please see additional Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit ActharHCP.com.

Acthar® GEL
(repository corticotropin injection) 80 U/mL

Patient had severe disease and demonstrated a need for an effective treatment option to reduce proteinuria

Assessment and diagnosis

- Patient presented with fatigue and grade 2 lower extremity edema
- Laboratory results showed hyperkalemia, iron deficiency anemia, and elevated creatinine level
- Renal ultrasound was normal
- Biopsy was consistent with FSGS

Treatment history

- Patient had no prior treatments for FSGS and was not taking any medications

Decision to treat with Acthar Gel

- Patient declined prednisone
- Initiated treatment with amlodipine and torsemide
- Initiated 40 units of Acthar Gel twice weekly
- Initiated 20 mg of lisinopril
- Amlodipine stopped and lisinopril dosage increased

40 units
2X A WEEK
subcutaneous injection
for **6 MONTHS**

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Warnings and Precautions

- The adverse effects of Acthar are related primarily to its steroidogenic effects
- Acthar may increase susceptibility to new infection or reactivation of latent infections
- Suppression of the hypothalamic-pituitary-adrenal (HPA) axis may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by tapering of the dose when discontinuing treatment. During recovery of the adrenal gland patients should be protected from the stress (e.g., trauma or surgery) by the use of corticosteroids. Monitor patients for effects of HPA axis suppression after stopping treatment
- Cushing's syndrome may occur during therapy but generally resolves after therapy is stopped. Monitor patients for signs and symptoms
- Acthar can cause elevation of blood pressure, salt and water retention, and hypokalemia. Monitor blood pressure and sodium and potassium levels
- Acthar often acts by masking symptoms of other diseases/disorders. Monitor patients carefully during and for a period following discontinuation of therapy

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Patient experienced sustained relief after **6 months** of treatment with a regimen including Acthar® Gel

Results after a 6-month treatment regimen that included Acthar Gel*

- Edema improved
- Patient's energy level was adequate
- No adverse events were observed

85% UPCR (g/g) **DECREASE** after 6 months of treatment regimen*

5.8 (g/g) Before Acthar Gel — 0.85 (g/g) After Acthar Gel

30% Creatinine (mg/dL) **DECREASE** after 6 months of treatment regimen*

1.68 (mg/dL) Before Acthar Gel — 1.18 (mg/dL) After Acthar Gel

Additional improvements in lab test results*

	Before Acthar Gel	After 6 months of treatment
Blood pressure (mmHg)	168/110	108/80
Potassium (mmol/L)	5.8	5.4
Albumin (g/dL)	3.6	4
Hemoglobin (g/dL)	9.1	10

UPCR=urine protein/creatinine ratio.
*Overall treatment included Acthar Gel, torsemide, and lisinopril.

Consider Acthar Gel to help meet important treatment needs for patients with tough-to-treat proteinuria in FSGS

Clinical outcomes may not be solely attributable to Acthar Gel.

Commonly reported postmarketing adverse reactions for Acthar include injection site reaction, asthenic conditions (including fatigue, malaise, asthenia, and lethargy), fluid retention (including peripheral swelling), insomnia, headache, and blood glucose increased.

Dosage should be individualized according to the medical condition of each patient. Frequency and dose of the drug should be determined by considering the severity of the disease and the initial response of the patient.

Sudden withdrawal of Acthar Gel after prolonged use may lead to adrenal insufficiency or recurrent symptoms. It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

Reference: 1. Data on File – Ref-04990. Mallinckrodt Pharmaceuticals.

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Learn about a real patient experience using Acthar® Gel for the treatment of proteinuria in FSGS

and scan the code to see Acthar Gel's clinical data across nephrotic conditions

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- Acthar can cause gastrointestinal (GI) bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain GI disorders. Monitor for signs of perforation and bleeding
- Acthar may be associated with central nervous system effects ranging from euphoria, insomnia, irritability, mood swings, personality changes, and severe depression to psychosis. Existing conditions may be aggravated
- Patients with comorbid disease may have that disease worsened. Caution should be used when prescribing Acthar in patients with diabetes and myasthenia gravis
- Prolonged use of Acthar may produce cataracts, glaucoma, and secondary ocular infections. Monitor for signs and symptoms
- Acthar is immunogenic and prolonged administration of Acthar may increase the risk of hypersensitivity reactions. Cases of anaphylaxis have been reported in the postmarketing setting. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH and Acthar activity
- There may be an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver
- Long-term use may have negative effects on growth and physical development in children. Monitor pediatric patients
- Decrease in bone density may occur. Bone density should be monitored in patients on long-term therapy

Adverse Reactions

- Commonly reported postmarketing adverse reactions for Acthar include injection site reaction, asthenic conditions (including fatigue, malaise, asthenia, and lethargy), fluid retention (including peripheral swelling), insomnia, headache, and blood glucose increased
- The most common adverse reactions for the treatment of infantile spasms (IS) are increased risk of infections, convulsions, hypertension, irritability, and pyrexia. Some patients with IS progress to other forms of seizures; IS sometimes masks these seizures, which may become visible once the clinical spasms from IS resolve

Pregnancy

- Acthar may cause fetal harm when administered to a pregnant woman

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Mallinckrodt Pharmaceuticals

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