

Diagnosis: IgA nephropathy

Patient profile: Asian man, age 49, with a medical history of hepatitis B found to have elevated UPCR and creatinine levels on a routine wellness exam.

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 Acthar HCP.com.



Patient had ongoing proteinuria after prior treatment, resulting in a need for alternative therapy

August 2018 Patient referred to nephrology clinic • Routine wellness exam showed UPCR levels of November 2018 1.15 mg/dL and creatinine levels of 1.32 mg/dL Treatment #1 • Biopsy findings showed IgA deposits and 40% global sclerosis Initiated ACE inhibitor, omega-3 fatty acids, and atorvastatin for hyperlipidemia December 2019 Patient experienced relapse with an increase in proteinuria Following a viral upper respiratory tract infection, patient developed hematuria and frothy urine; October 2020 laboratory results revealed nephrotic syndrome with elevated creatinine and UPCR levels Steroid treatment paused • Initiated pulse steroids and MMF 1 q twice daily Creatinine and UPCR levels had stabilized • Stopped treatment with prednisone January 2021 Steroid treatment resumed **March 2021** Labs revealed increased creatinine and Patient experienced side effects **UPCR** levels • Reinitiated prednisone Titrated MMF down to 0.5 g twice daily due to gastrointestinal side effects

August 2021: Decision to treat with Acthar Gel

- Stopped treatment with prednisone
- Stopped MMF during the first 6 months of Acthar Gel treatment
- Remained on Acthar Gel for 16 months with no additional medicine except for ACE inhibitors



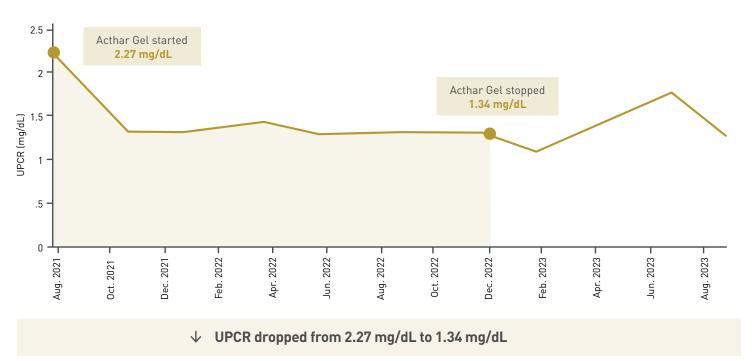
ACE=angiotensin-converting enzyme; MMF=mycophenolate mofetil; UPCR=urine protein/creatinine ratio.

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After treatment with Acthar Gel, UPCR was reduced by more than 40%

UPCR levels during treatment course and the following 9 months:



Patient continued experiencing improvements 9 months after stopping treatment with Acthar Gel

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.

SELECT IMPORTANT SAFETY INFORMATION 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





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

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

IMPORTANT SAFETY INFORMATION

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Warnings and Precautions

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- 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
- 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

Please see accompanying full <u>Prescribing Information</u> or visit ActharHCP.com for additional Important Safety Information.



