CLINICAL CASE STUDY

UV

For a patient with tough-to-treat disease

Discover how Acthar® Gel provided relief for the treatment of unilateral panuveitis

Diagnosis: Unilateral panuveitis

Patient profile: A 33-year-old man with painless blurring of vision and floaters in the left eye for 2 years.

Case study provided by:

Quan Dong Nguyen, MD, MSc

Stanford University School of Medicine,
Palo Alto, California

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 for severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation.

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 needed an alternative treatment after multiple local and systemic therapies

Patient was diagnosed with unilateral idiopathic panuveitis with retinal vasculitis

- Signs of moderate inflammation (anterior chamber: 0.5+ cells, 1+ flare; vitreous chamber: 2+ cells, 2+ haze), snow balls, and mild blurriness of the disc margins in left eye
- Blunted foveal reflex and focal perivascular sheathing in veins of the left eye. No visible hemorrhages
- Late-phase FA of the left eye showed hyperfluorescence of the optic disc, leakage temporal to the fovea in the macular region, and diffuse peripheral leakage mainly involving venules
- SD-OCT of the left eye showed macular edema
- Findings for the right eye were normal

Patient treatment history:

June 2014
Initial treatment with oral prednisone

- Oral prednisone given at 40 mg/day
- Topical prednisone 1% 3 times/day in left eye
- Plan to initiate immunosuppressive therapy to wean patient off oral prednisone

July 2014
Secondary treatment resulted in short-term improvement

- Patient joined a clinical trial for intravenous tocilizumab therapy
- Significant improvement in retinal vascular leakage and hyperfluorescence of the optic nerve head
- BCVA on the ETDRS chart improved to 20/20 in left eye with resolution of macular edema
- Resolved vitritis and anterior segment inflammation

July 2015
Patient needed alternative treatment due to pause in therapy

- Patient could not continue treatment with tocilizumab due to insurance denial

January 2016: Physician prescribed Acthar Gel

- Six months after completing the tocilizumab trial, the patient presented with mild blurring of vision
- Snellen BCVA was recorded as 20/20 in the left eye
- Patient needed an alternative treatment for unilateral idiopathic panuveitis with retinal vasculitis

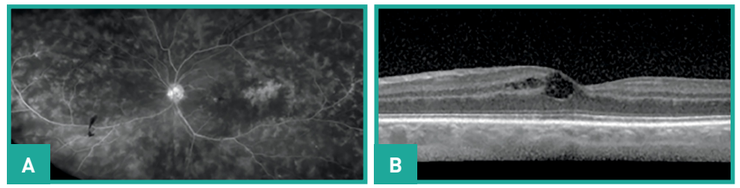
80 units
2X A WEEK
subcutaneous injection

BCVA=best-corrected visual acuity; ETDRS=Early Treatment Diabetic Retinopathy Study; FA=fluorescein angiography; SD-OCT=spectral-domain optical coherence tomography.

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

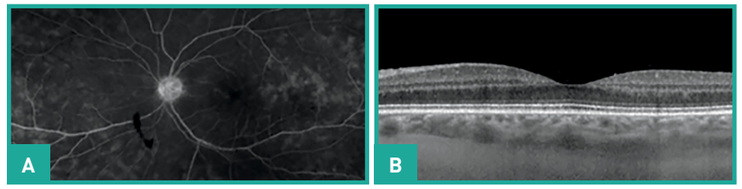
Acthar® Gel provided a substantial reduction in retinal vascular leakage after only 6 weeks

Imaging before treatment with Acthar Gel



FA in the late phase (A) and SD-OCT (B) of the left eye before Acthar Gel.

Imaging after treatment with Acthar Gel



FA in the late phase (A) and SD-OCT (B) of the left eye after Acthar Gel.

6 WEEKS
after initiation of Acthar Gel

- Vitritis resolved
- Retinal vascular leakage reduced substantially
- Intervals of optic nerve head hyperfluorescence decreased
- No systemic or local adverse events were recorded

Since the patient responded well, Acthar Gel treatment was continued after the initial 6 weeks.

Clinical outcomes may not be solely attributable to Acthar Gel.

Commonly reported postmarketing adverse reactions for Acthar Gel 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
- Cushing's syndrome may occur during therapy but generally resolves after therapy is stopped. Monitor patients for signs and symptoms

Reference: 1. Agarwal A, Hassan M, Sepah YJ, Do DV, Nguyen QD. Subcutaneous repository corticotropin gel for non-infectious panuveitis: Reappraisal of an old pharmacologic agent. *Am J Ophthalmol Case Rep.* 2016;4:78-82.

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

UV

Learn about real patient experience using Acthar® Gel for the treatment of unilateral panuveitis

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

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

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
- 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 Prescribing Information or visit ActharHCP.com for additional Important Safety Information.

Mallinckrodt Pharmaceuticals

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