CLINICAL CASE STUDY

KS

For a patient with tough-to-treat disease

Discover how Acthar® Gel provided relief for the treatment of peripheral ulcerative keratitis (PUK)[1]

Diagnosis: PUK

Patient profile: A 56-year-old woman with a history of increasing pain, redness, and declining vision in right eye.

Case study provided by:

John C. Affeldt, MD

Loma Linda University Eye Institute
Loma Linda, CA

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.

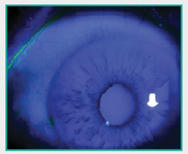
Acthar® GEL
(repository corticotropin injection) 80 U/mL

Patient had tough-to-treat eye disease and needed an alternative treatment[1,2]

July 2019: Initial patient assessment, diagnosis, and slit lamp examination (SLE)

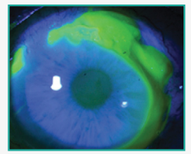
Left eye

- Best corrected visual acuity (BCVA) was hand motion
- SLE revealed 4 clock hours of limbal ischemia associated with mild peripheral stromal thinning and stain defect, and a stage 4+ mature white cataract



Right eye

- BCVA was 20/60
- Patient presented with a 4-month history of increasing pain, redness, and decline in vision
- SLE revealed 9 clock hours of peripheral stromal infiltrate with stain defect
- SLE revealed 1 clock hour of guttered 90% stromal melt centered at the 1:30 limbus



Patient was diagnosed with severe peripheral ulcerative keratitis (PUK)

Disease progressed despite prednisone treatment

Initial treatment: Oral prednisone 60 mg once daily

- After 2 weeks, disease progressed and patient was hospitalized for emergent rheumatology intervention
- Patient was diagnosed with severe relapsing polychondritis

Secondary treatment: Methylprednisolone 1 g once daily for 3 days

- Patient continued oral prednisone 60 mg daily
- Patient initiated the first of 6 intended monthly cyclophosphamide infusions

Decision to treat with Acthar Gel

- **August 2019:** Initiated Acthar Gel 80 units subcutaneously **every 3 days** for 3 months
- **October 2019:** Increased dosing to 80 units subcutaneously **every other day** for 3 months

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

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

Acthar® Gel provided relief in conjunction with existing therapies[1,2]

September 2019
Patient saw symptom improvement with Acthar Gel after 2 weeks

- Regression of active keratitis in both eyes after 3 weeks

December 2019
Complete control of disease

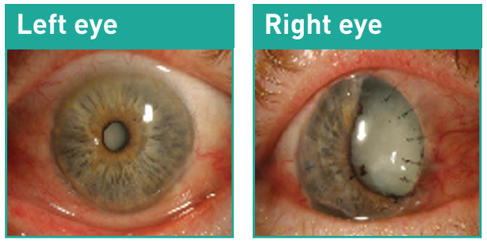
- Penetrating keratoplasty performed in right eye
- Patient experienced complete PUK control in both eyes

October 2019
Continued symptom improvement

- Continued active keratitis regression in right eye
- Complete control of active keratitis in left eye
- **Rheumatologist increased Acthar Gel dosing to 80 units every other day**

February 2020
PUK remained completely controlled in both eyes

- Clear stable transplant in right eye
- Stage 4+ mature white cataracts in both eyes
- Complete PUK control in both eyes while tapering oral prednisone and continuing to take Acthar Gel 80 units every other day



Slit lamp examination findings

Consider Acthar Gel for patients who need an alternative treatment for PUK

Clinical outcomes may not be solely attributable to Acthar Gel.

Commonly reported postmarketing adverse events 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 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 and gradually discontinue the medication.

References: 1. Affeldt JC. Novel use of HP Acther Gel in the treatment of peripheral ulcerative keratitis [Sonoma Eye abstract]. Abstract presented at Sonoma Eye, January 30, 2021 Virtual Meeting. 2021.
2. Data on File – Ref-03617. Mallinckrodt Pharmaceuticals.

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

Learn about a real experience using Acthar® Gel for the treatment of peripheral ulcerative keratitis

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