CLINICAL CASE STUDY

OCP

For a patient in need of an alternative treatment

See how Acthar® Gel provided continued relief for the treatment of ocular cicatricial pemphigoid (OCP)[1]

Diagnosis: OCP

Patient Profile: Female aged 75 years old, treated for eye disease in the past, with history of vision loss.

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 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 with history of vision loss and eye disease required an alternative therapy for OCP[1]

Initial patient assessment and diagnosis

Assessed with eye exam

- Slit lamp examination revealed conjunctival injection, trichiasis, fornix shortening, subconjunctival fibrosis, and corneal scarring in each eye
- Biopsy confirmed OCP in both eyes
- History of cataract surgery in right eye and multiple amniotic membrane transplants

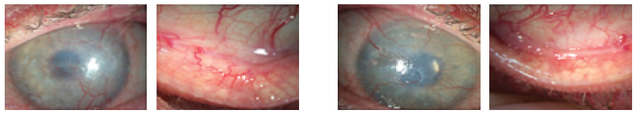
Began treatment with multiple therapies for OCP

- 60 mg of oral prednisone daily
- Systemic immunosuppressive treatment
- Additional therapies considered but not authorized by insurance

Experienced side effects after initial treatment with systemic steroids

- Side effects included nervousness, moon facies, fatigue, ecchymoses, joint pain, swelling, and muscle weakness

Imaging before treatment with Acthar Gel:



Left eye

Right eye

Physician prescribed Acthar Gel

Patient began treatment in conjunction with local and systemic therapies in an effort to find relief from OCP.

80 units
2X A WEEK
subcutaneous injection
for **16 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

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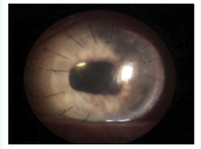
Patient experienced sustained relief from OCP with Acthar® Gel through Month 20 and beyond[1,2]

Months 1 to 9
Patient received Acthar Gel

- Acthar Gel subcutaneous injections 80 units twice a week
- Continued treatment with prednisone and immunosuppressive treatment
- Prednisone tapered and stopped
- Immunosuppressive treatment tapered
- During month 6, patient had cataract surgery and penetrating keratoplasty

Relief while on Acthar Gel:

- Left eye displayed clear corneal graft while being treated with Acthar Gel
- OCP was controlled
- Conjunctiva was scarred, but no longer inflamed

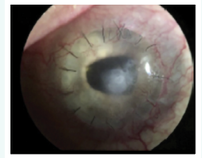


Months 10 to 12
Acthar Gel stopped due to insurance coverage issues

- Acthar Gel paused while patient was on other treatment
- Experienced sudden loss of visual acuity in left eye, corneal graft rejection in left eye, and OCP flare-up in both eyes

Acthar Gel paused and patient experienced flare-up:

During 3-month hiatus, the left eye immediately flared up, with corneal graft rejection and ulceration.



Months 13 to 19
Acthar Gel reinitiated

- Acthar Gel subcutaneous injections 80 units twice a week
- No significant side effects related to Acthar Gel
- Pemphigoid was inactive and no signs of inflammation were observed

Months 20 and beyond
Continued results with Acthar Gel

Acthar Gel continued to effectively control the disease and provided relief to the patient.

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.

References: 1. Sharon Y, Chu DS. Adrenocorticotropic hormone analogue as novel treatment regimen in ocular cicatricial pemphigoid. *Am J Ophthalmol Case Rep.* 2018;10:264-267. **2.** Data on File – Ref-07086. Mallinckrodt Pharmaceuticals.

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Learn about a real patient experience using Acthar® Gel for the treatment of OCP

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

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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

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Mallinckrodt Pharmaceuticals

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