CLINICAL CASE STUDY

RV

For a patient with tough-to-treat disease

Discover how Acthar® Gel provided relief for retinal vasculitis in both eyes

Diagnosis: Retinal vasculitis in both eyes

Patient profile: A 50-year-old woman, treated for eye disease in the past, with blurred vision.

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 history of inadequate response to multiple therapies demonstrated the need for alternative treatment

Initial patient assessment and diagnosis

- Patient presented with mild blurring and no other symptoms
- Doctor ordered FTA-ABS, RPR, lysozyme, ACE, QuantiFERON, chest X-ray, and brain MRI—all of which came back negative

Patient needed relief following treatment with multiple therapies

Failed therapies/combination therapies:

- Methotrexate
- Mycophenolate mofetil
- Infliximab
- Interferon
- Cyclosporine A
- Adalimumab
- Transseptal triamcinolone
- Intravitreal bevacizumab/ triamcinolone

Therapies at baseline:

- Adalimumab 40 mg once every 2 weeks
- Mycophenolate mofetil 1.5 g twice daily
- Cyclosporine A 100 mg once a day
- Acetazolamide 500 mg once a day
- Bromfenac ophthalmic solution twice daily in the right eye
- No IOP-lowering medications

Patient was prescribed Acthar® Gel

- Doctor referred patient to enroll in a retinal vasculitis trial using Acthar Gel
- Patient began treatment with Acthar Gel 80 units twice weekly for 24 weeks
- No corticosteroids were used prior to or during treatment

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

ACE=angiotensin-converting enzyme; FTA-ABS=fluorescent treponemal antibody-absorption; IOP=intraocular pressure; MRI=magnetic resonance imaging; RPR=rapid plasma reagin; VA=visual acuity.

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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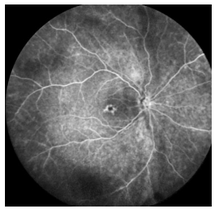
Patient experienced sustained relief from retinal vasculitis with Acthar Gel at 24 weeks

Baseline: Prescribed Acthar Gel as part of 24-week clinical trial

- Retinal swelling in right eye
- IOP was 16 mmHg in the right eye and 17 mmHg in the left eye
- VA was 20/30-2 in the right eye and 20/15 in the left eye
- Initiated Acthar Gel 80 units twice weekly



Prior to Acthar Gel treatment: Right eye at baseline visit

Week 9: Retinal swelling and IOP decreased, VA improved

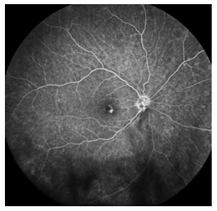
- Reduced retinal swelling in right eye
- IOP decreased to 11 mmHg in the right eye and 14 mmHg in the left eye
- VA in the right eye improved from 20/30-2 to 20/25-1

31% decrease in right eye IOP

18% decrease in left eye IOP

Week 27: Eye health improved

- Patient met with doctor 3 weeks after trial ended
- Nearly resolved retinal swelling in right eye
- Sustained benefits of VA in right eye
- Due to insurance denial, patient did not continue with Acthar Gel after 24-week trial
- During the trial, patient experienced trouble sleeping, which was mild and tolerable



After Acthar Gel treatment: Right eye at Week 24

Patient noted the greatest improvement in blurry vision during the 24 weeks of treatment with Acthar Gel

Clinical outcomes may not be solely attributable to Acthar Gel.

Prolonged use of Acthar may produce cataracts, glaucoma, and secondary ocular infections. Monitor for signs and symptoms.

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-06897. Mallinckrodt Pharmaceuticals.

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

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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