

When you take a multi-targeted approach* across patient types
**Consider Acthar Gel in the treatment
 of symptomatic sarcoidosis**

Patient type: Tough-to-treat disease



Not an actual patient.

Clinical case study

Diagnosis: Symptomatic sarcoidosis
 Woman, aged 65 years, with a 26-year history of sarcoidosis, experiencing shortness of breath, and skin and sinus issues despite treatment

Case study provided by:
Robert Baughman, MD, pulmonologist
 University of Cincinnati Medical Center
 Cincinnati, Ohio

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.

*Acthar Gel is indicated for certain immune-mediated and idiopathic conditions across a range of therapeutic areas and may be appropriate for multiple patient types.

INDICATION

Acthar[®] Gel is indicated for symptomatic sarcoidosis.

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 and full [Prescribing Information](#).

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

History and examination were consistent with tough-to-treat disease

Clinical examination¹

- Sinus biopsy found noncaseating granulomas
 - Lesion was eating away through roof of mouth
- Involvement in the skin, sinus, trachea, and lungs
- Symptoms included shortness of breath, chronic sinusitis, and skin lesions on legs and face

Treatment history¹

- Previously treated with multiple medications: prednisone, MTX, AZA, LEF, HCQ, and anti-TNFs (ADM and GOL)*
 - Treated with ADM for 1 year
 - Skin improved
 - Discontinued ADM and symptoms worsened
 - Treated with high-dose prednisone for severe subglottic stenosis
 - Treated with GOL for 3 months before left hip pain was reported
 - Mass present in right hip area was consistent with liposarcoma
 - Discontinued GOL

ADM=adalimumab; AZA=azathioprine; GOL=golimumab; HCQ=hydroxychloroquine; LEF=leflunomide; MTX=methotrexate; TNF=tumor necrosis factor.

*MTX, AZA, LEF, HCQ, ADM, and GOL are not FDA-approved to treat sarcoidosis.

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
- Acthar can cause elevation of blood pressure, salt and water retention, and hypokalemia. Monitor blood pressure and sodium and potassium levels

Patient required an alternative treatment

Decision to treat with Acthar Gel¹

- Patient was still symptomatic after glucocorticoids and cytotoxic treatments alone
- Further anti-TNF therapy was not given due to the history of malignancy
- Initiated Acthar Gel 40 units twice weekly



Results after Acthar Gel therapy¹

After 6 months of initial treatment with Acthar Gel in 2015:

- Pulmonary function tests improved (see chart below)
- Discontinued prednisone
- Adverse events included bloating and edema[†]

After 2 years of treatment reinitiation with Acthar Gel in 2018:

- Shortness of breath improved
- Sinus and skin issues resolved
- Stable disease after >2.5 years of continuous therapy
- Remains solely on Acthar Gel 40 units twice weekly
- No new AEs were observed

[†]Bloating and edema occurred during the 10-day loading schedule and resolved with Acthar Gel 40 units twice weekly.

Pulmonary function test values before and after 6 months of Acthar Gel therapy¹

| | Before Acthar Gel | After Acthar Gel |
|------------------|-------------------|------------------|
| FVC | 1.94 | 2.18 |
| FVC % predicted | 62% | 69% |
| FEV-1 | 1.75 | 1.91 |
| DLCO | 9.9 | 11.07 |
| DLCO % predicted | 38% | 48% |

Clinical outcomes may not be solely attributable to Acthar Gel.

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.

AEs=adverse events; DLCO=diffusing capacity for carbon monoxide; FEV-1=forced expiratory volume in 1 second; FVC=forced vital capacity.

Reference: 1. Data on file: REF-MNK04622. Mallinckrodt ARD LLC.

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

When you take a multi-targeted approach* across patient types
**Consider Acthar Gel in the treatment
 of symptomatic sarcoidosis**

Patient type: Tough-to-treat disease

*Acthar Gel is indicated for certain immune-mediated and idiopathic conditions across a range of therapeutic areas and may be appropriate for multiple patient types.

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 full [Prescribing Information](#).

