

For a patient with tough-to-treat,
recurring, or high disease activity

Discover how Acthar® Gel may be appropriate for rheumatoid arthritis (RA)

Not an actual patient.

Diagnosis: Rheumatoid arthritis

Patient profile: A 71-year-old woman at assessment in 2012 with pain, swelling, and joint stiffness for 4 years

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 as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy).

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 high disease activity despite multiple therapies

Patient was diagnosed with seropositive rheumatoid arthritis¹

- Symptoms and exhaustion affected daily functioning; patient was unable to kneel, clasp hands, or grasp small objects
- Patient experienced acute joint pain, swelling, and stiffness, and was unable to perform daily tasks

Treatment history prior to Acthar Gel¹

2008–2012: Patient developed acute symptoms of RA¹

- Treated by PCP with NSAIDs, prednisone (20–40 mg daily) and hydrocodone
- Treated irregularly by rheumatologists with methotrexate, sulfasalazine, and hydroxychloroquine; various medication combinations contained glucocorticoids
- Patient experienced daily pain, swelling, and stiffness of various joints (especially in her shoulders, knees, ankles, feet, hands, and wrists) despite treatment

2012–2018: Disease remained moderately active with occasional periods of low disease activity, despite multiple therapies^{1*}

- Patient continued experiencing moderate disease activity after initiating multiple treatments, including:
 - Adalimumab
 - Rituximab
 - Certolizumab pegol
 - Sarilumab
 - Tocilizumab
 - Baricitinib
 - Abatacept
 - Infliximab
 - Tofacitinib
- Patient continued to need prednisone to manage symptoms
- CDAI score remained elevated, reaching 30 in 2016–2017

Decision to treat with Acthar Gel¹

Patient's chronic refractory RA required constant steroid use, usually prednisone 5 mg. In 2018, patient needed frequent prednisone bursts of up to 10 mg, leading to tolerability issues

Began Acthar Gel
80 units **2X A WEEK**

CDAI=Clinical Disease Activity Index; NSAIDs=nonsteroidal anti-inflammatory drugs; PCP=primary care provider; RA=rheumatoid arthritis.

¹Level of disease activity is based on CDAI scores: remission (≤ 2.8), low (>2.8 to ≤ 10.0), moderate (>10.0 to ≤ 22.0), high (>22.0).²

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

Patient's RA symptoms improved with Acthar[®] Gel and concurrent medications

Treatment history with Acthar Gel¹

2018 (Week 1 to Week 12): Patient started on Acthar Gel 80 units twice a week¹

- CDAI score improved, decreasing from 24 to 16

2018 (Week 13 to Week 21): Patient discontinued Acthar Gel and her condition worsened¹

- CDAI score rose from 16 to 25

2018 (Week 22): Patient restarted Acthar Gel and saw improvements¹

- CDAI score lowered to 11
- Acthar Gel was tapered to 40 units twice a week

2019–2021: Patient's condition worsened with interruptions in Acthar Gel treatment¹

- Patient experienced multiple breaks in Acthar Gel therapy due to insurance and logistical issues
- Interruptions, each lasting 4 to 12 weeks, were associated with worsening of her condition
- Additional therapies during this time included upadacitinib and etanercept
- Patient was hospitalized with COVID-19 and went off Acthar Gel for 8 weeks; RA worsened
- Anakinra was added to treatment regimen, resulting in lower CDAI score

Patient continued low-dose Acthar Gel (20–40 units subcutaneously twice a week), with improved joint symptoms, and was off prednisone 50% of the time, with less frequent need for doses >5 mg¹

Continued Acthar Gel
20 to 40 units **2X A WEEK**

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.³

Dosage should be individualized according to the disease under treatment and the general 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.³

Sudden withdrawal of Acthar Gel after prolonged use may lead to adrenal insufficiency or recurrent symptoms.³

It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medication.³

References: 1. Data on File – Ref-05118. Mallinckrodt Pharmaceuticals. 2. Kremer JM, Pappas DA, Kane K, et al. The Clinical Disease Activity Index and the routine assessment of patient index data 3 for achievement of treatment strategies. *J Rheumatol.* 2021;48(12):1776–1783. doi:10.3899/jrheum.200692 3. Acthar Gel [repository corticotropin injection] [prescribing information]. Bridgewater, NJ: Mallinckrodt ARD LLC.

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



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

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