

When you take a multi-targeted approach* across patient types

Consider Acthar® Gel in the treatment of polymyositis (PM)

Patient type:

Recurring disease activity;
tough-to-treat disease;
high disease activity.



Not an actual patient.

Clinical case study

Diagnosis: Polymyositis

Woman, aged 55 years, experiencing muscle weakness and multiple flares for 6 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.

*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 during an exacerbation or as maintenance therapy in selected cases of dermatomyositis (polymyositis).

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 recurring disease activity, tough-to-treat disease, and high disease activity

Clinical examination¹

- 6-year history of polymyositis confirmed with biopsy that revealed cellular infiltrate predominantly within muscle fascicles, with inflammatory cells invading individual muscle fibers
- Patient experienced multiple flares
- No skin rash was present
- Patient presented with severe proximal extremity muscle weakness, weakness of neck flexors as measured by MMT, and mild dysphagia
- Initial CK level: 1526 IU/L
- Initial MMT score: 118/150

Treatment history¹

Treatment	Outcome
Prednisone <ul style="list-style-type: none"> • Initiated at 20–40 mg daily in March 2015 • Tapered off after 4 months 	<ul style="list-style-type: none"> • Reinitiated 2 years later when patient had a flare • Discontinued in July 2019
Azathioprine <ul style="list-style-type: none"> • Initiated at 50 mg daily in April 2015 • Dose increased to 150 mg daily • Discontinued in January 2020 	<ul style="list-style-type: none"> • Patient was doing well for 2 years until she had a flare with more muscle weakness and rising CK • After 4.5 years of treatment, patient experienced elevated transaminases that were 2–2.5 times upper limit of normal
Rituximab <ul style="list-style-type: none"> • Initiated at 1000 mg twice weekly every 2 weeks in December 2016 	<ul style="list-style-type: none"> • No appreciable response
IVIg <ul style="list-style-type: none"> • Initiated at 2 g/kg monthly in April 2018 • Discontinued in September 2018 	<ul style="list-style-type: none"> • Modest response • IVIg was discontinued after 6 months due to severe post-infusion headaches within 24 hours of each dose
Methotrexate <ul style="list-style-type: none"> • Initiated at 25 mg weekly in January 2020 • Treatment is still ongoing 	

CK=creatinine kinase; IVIg=intravenous immunoglobulin; MMT=Manual Muscle Testing.

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

Patient required an alternative treatment

Decision to treat with Acthar® Gel¹

- Based on lack of adequate response to multiple prior therapies or adverse events
- Initiated 80 units of Acthar Gel 3 times a week



Results after Acthar Gel therapy¹

- Improvements in muscle strength
- Patient's CK level began to decrease to 800 IU/L
 - Acthar Gel was reduced to 80 units twice weekly when the patient's CK level decreased to 350 IU/L
 - Acthar Gel was subsequently reduced to 80 units once weekly when the patient's CK level reached 202 IU/L
 - Patient is continuing to receive 80 units of Acthar Gel once weekly
- Latest CK level: 73 IU/L
- Latest MMT score: 142/150
- No adverse events were observed other than intermittent lower extremity edema

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. 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.

Reference: 1. Data on file: REF-MNK05292. Mallinckrodt ARD LLC.

SELECT IMPORTANT SAFETY INFORMATION (CONT'D)

Warnings and Precautions (cont'd)

- 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

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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

Please see full [Prescribing Information](#).

