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

Consider Acthar Gel in the treatment of systemic lupus erythematosus (SLE)

Patient type: Recurring disease activity; tough-to-treat disease; high disease activity

Clinical case study

Diagnosis: Systemic lupus erythematosus

Woman, aged 32 years, with a 5-year history of SLE, experiencing recurring disease activity and intolerance to current treatment

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.

INDICATIONS

Acthar® Gel is indicated for:

- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus
- Treatment during an exacerbation or as maintenance therapy in selected cases of dermatomyositis (polymyositis)
- Adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis
- 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 recurring disease activity, tough-to-treat disease, and high disease activity

Clinical examination[1]

- Initially referred to nephrology due to labile hypertension, proteinuria, and anemia
  - Advised to complete kidney biopsy but declined
- Patient reported fatigue, weakness, rash, ulcers, hair loss, joint stiffness and swelling, and frothy urine
  - Symptoms waxed and waned for at least 6 months
- SLE diagnosis based on positive antinuclear antibody, low complement levels, photosensitive rash, oral ulcers, alopecia, and proteinuria

Treatment history[1]

- Initially prescribed hydroxychloroquine and mycophenolate mofetil (MMF)*
  - Intolerant to gastrointestinal effects after 3 g daily MMF; remained on 2 g daily
  - After 3 months, proteinuria continued to rise
- Started on 60 mg daily of prednisone; later reduced to 20 mg daily over 8 weeks
- Adverse effects associated with corticosteroids included weight gain and Cushing's syndrome

BMI=body mass index; C3=component 3; C4=component 4; dsDNA=double-stranded DNA; ESR=erythrocyte sedimentation rate; HCT=hematocrit; Hgb=hemoglobin; WBC=white blood cells.

*MMF is not FDA-approved to treat SLE.

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 Gel[1]

- Patient needed another option due to continued high disease activity and adverse effects experienced after prednisone
- Six months after referral, initiated Acthar Gel 80 units every 3 days for 12 weeks

Results after Acthar Gel therapy[1]

- Inflammatory markers had normalized
- Discontinued prednisone
- No flares were reported
- No new adverse events were observed
- Fatigue and rash improved, hair loss stopped, ulcers resolved, and urine was less frothy
- During maintenance therapy with Acthar Gel treatment:
  - Joint stiffness and swelling are minimal
  - Patient has a very faint rash and her fatigue dramatically improved

Laboratory values before and after treatment[1]

Laboratory test	Reference range	At diagnosis	After initial treatment	After 12 weeks of Acthar Gel therapy
Complement C3	83–193 mg/dL	89	66	132
Complement C4	15–57 mg/dL	16	9	19
Anti-dsDNA	<10	118	82	41
Hgb	11.7–15.5 g/dL	8.7	9.3	11.2
HCT	35%–45%	27	29.6	35.3
WBC	3.8–10.8 × 10^9/L	3.2	4.1	4.2
ESR	<30 mm/hr	58	28	19
Protein to creatinine ratio	<161 mg/mg	1058	2038	242

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.

Reference: 1. Data on file: REF-MNK04568. Mallinckrodt ARD LLC.

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- 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.

Mallinckrodt Pharmaceuticals

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