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

Consider Acthar Gel in the treatment of multiple sclerosis (MS) relapse

Patient type: Tough-to-treat disease

Not an actual patient.

Clinical case study

Diagnosis: Multiple sclerosis relapse

Woman, aged 43 years, reported sensory changes, stiffness, and urinary-related symptoms

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 for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.

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

Treatment history[1]

- Previously diagnosed with MS 3 years after an initial episode of diplopia
  - MRI evaluation revealed several brain, brainstem, and thoracic cord lesions
- 1 g intravenous methylprednisolone (IVMP) for 3 days
  - Effective but was associated with a significant psychotic reaction and strong suicidal ideation
- Disease-modifying therapy initiated after IVMP
  - Well-tolerated with initial good compliance but patient admitted to "skipping injections here and there" over the past 7 months because of injection-site reactions and "running out of sites"

Clinical examination[1]

MS relapse signs and symptoms

- Patient reported new sensory changes and stiffness of the lower extremities associated with frequent urination and new urinary retention
- Symptoms began 2 days prior to presentation and were not getting better
- No fever reported
- Complete blood count and urinalysis were not significant for signs of infection
- Most recent MRIs were 9 months ago and did not reveal any new or active lesions; this was the first possible exacerbation since time of diagnosis

Clinical assessment: MS relapse was diagnosed

- Infection ruled out through laboratory evaluations
- In-office examination revealed:
  - Significantly diminished strength in legs: 4/5 hip flexor strength bilaterally; 3.5/5 strength of left foot dorsiflexion
  - Increased tone and bilateral deep sensation impairment in the lower extremities
  - Bilateral patellar hyperreflexia and left Babinski sign
  - Difficulty with tandem walk and had a Romberg sign

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]

- First-line therapy with IVMP was considered and declined, given her past experience
- Acthar Gel was initiated at 80 units intramuscularly once a day for 10 days

ONCE A DAY
10 DAYS

Results with Acthar Gel[1]

- At **2-week follow-up**, patient reported significant improvement in symptoms, although not quite back to baseline
  - Normal muscle strength
  - Sensory examination was unchanged
  - Reflexes were unchanged
  - Urinary symptoms had dissipated
  - No adverse events were reported in publication
- At **next follow-up 1 month later**, patient reported being back to baseline

Clinical outcomes may not be solely attributable to Acthar Gel.

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.

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. Berkovich RR. Acute multiple sclerosis relapse. *Continuum (Minneap Minn)*. 2016;22(3):799-814.

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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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