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

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

Patient type: Recurring disease activity, tough-to-treat disease

Clinical case study

Diagnosis: Multiple sclerosis relapse

Woman, aged 43 years, diagnosed with MS 4 years prior, developed exacerbation with multiple 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 recurring disease activity and tough-to-treat disease

Treatment history[1]

- Initially diagnosed with MS 4 years prior to exacerbation
- Previously received glatiramer acetate injection
- Treated with IV methylprednisolone in the past; experienced severe irritability and 10 lb weight gain
- 3 months prior to current exacerbation, patient received 80 units of Acthar Gel once a day for 5 days. Patient experienced resolution of left leg weakness, "brain fog," and urinary incontinence
- Patient was being treated with natalizumab when she received Acthar Gel for current exacerbation

IV=intravenous.

Clinical examination[1]

MS relapse signs and symptoms

- Patient developed a 5-day history of bilateral leg weakness, increased fatigue, urinary incontinence, vertigo, discoordination, ataxia, and cognitive/memory issues

Clinical assessment: MS relapse was diagnosed

Brain MRI

- Bihemispheric white matter T2/fluid-attenuated inversion recovery (FLAIR) hyperintensities compatible with demyelinating disease

Cervical spine MRI

- Several cord lesions in the upper thoracic region
- New small focus of signal abnormality in the cervical cord at C5-C6 to the left of midline

Thoracic spine MRI

- New focus of signal abnormality at the T4-T5 disc space level centrally and posteriorly

MRI=magnetic resonance imaging.

Patient required an alternative treatment

Decision to treat with Acthar Gel[1]

- The decision to use Acthar Gel was based on clinical symptoms and MRI lesions at C5-C6 and T4-T5
- Patient experienced adverse reactions to alternative relapse treatment in the past
- Past history of improvement after treatment with Acthar Gel
- Acthar Gel was initiated for 9 days in total; 80 units once a day on Day 1, followed by an increase to 120 units once a day for the remaining 8 days

DAY 1
80 UNITS ONCE A DAY

REMAINING 8 DAYS
120 UNITS ONCE A DAY

Results after Acthar Gel[1]

- Bilateral leg weakness, urinary incontinence, dizziness, discoordination, ataxia, fatigue, and cognitive/memory issues resolved
- At 3-month follow-up, brain MRI found no new areas of abnormal FLAIR signal, and no evidence of active demyelination
- No acute intracranial abnormality
- Adverse events: patient experienced mild pedal edema and insomnia

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.

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

Reference: 1. Data on file: REF-MNK04674. 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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