

**1. PATIENT INFORMATION** Patient has been notified of referral  YES  NO

PATIENT FIRST NAME	PATIENT MIDDLE INITIAL	PATIENT LAST NAME	DATE OF BIRTH	GENDER
HOME ADDRESS		CITY	STATE	ZIP
SHIPPING ADDRESS (IF NOT HOME ADDRESS)	CARE OF (IF NOT ADDRESSED TO PATIENT)	CITY	STATE	ZIP
HOME PHONE	MOBILE	OK TO TEXT	BEST TIME TO CALL	PREFERRED LANGUAGE IF NOT ENGLISH
EMAIL ADDRESS	PATIENT REPRESENTATIVE	RELATIONSHIP	TELEPHONE	

**2. INSURANCE INFORMATION (PLEASE INCLUDE COPIES OF CARDS)**

PHARMACY BENEFITS	SUBSCRIBER ID #		GROUP #	TEL #
PRIMARY MEDICAL INSURANCE	POLICY HOLDER	RELATIONSHIP	SUBSCRIBER ID #	GROUP #
			SUBSCRIBER ID #	GROUP #
			SUBSCRIBER ID #	GROUP #

**3. HEALTHCARE PROVIDER (HCP) INFORMATION**

HCP FIRST NAME	HCP LAST NAME	HCP MIDDLE INITIAL	NPI #	GROUP NPI # (IF APPLICABLE)	STATE LICENSE #
SPECIALTY: <input type="checkbox"/> NEPHROLOGY <input type="checkbox"/> NEUROLOGY <input type="checkbox"/> PULMONOLOGY <input type="checkbox"/> RHEUMATOLOGY <input type="checkbox"/> OPHTHALMOLOGY <input type="checkbox"/> OTHER _____					
IF OTHER PLEASE INDICATE					
FACILITY NAME	TELEPHONE	FAX			
ADDRESS	CITY		STATE	ZIP	
OFFICE CONTACT NAME	CONTACT TELEPHONE	EMAIL ADDRESS	PREFERRED METHOD OF COMMUNICATION		

**4. PRESCRIPTION: H.P. ACTHAR<sup>®</sup> GEL** NDC# 63004-8710-1 5 mL multidose vial containing 80 USP units per mL

**PRIMARY DIAGNOSIS:** \_\_\_\_\_ **ICD-10:** \_\_\_\_\_

**INITIATE PATIENT WITH:**  
 UNITS  
 DOSE: \_\_\_\_\_  ML SCHEDULE/FREQUENCY: \_\_\_\_\_ QUANTITY OF 5 ML MULTIDOSE VIALS: \_\_\_\_\_ REFILLS: \_\_\_\_\_ ROUTE OF ADMINISTRATION:  INTRAMUSCULAR  SUBCUTANEOUS  
 ADDITIONAL SPECIAL INSTRUCTIONS, OR TAPER DOSE, IF APPLICABLE: \_\_\_\_\_ ALLERGIES: \_\_\_\_\_

**SUPPLIES:**  
 SYRINGE SIZE:  1 mL  3 mL  Other size \_\_\_\_\_ QUANTITY: \_\_\_\_\_ NEEDLE SIZE:  20 g needle, 1 inch  23 g needle, 1 inch  25 g needle, 1 inch  25 g needle, 5/8 inch  (other): \_\_\_\_\_ QUANTITY: \_\_\_\_\_  
 PATIENT WEIGHT (FOR WEIGHT-BASED DOSING ONLY): \_\_\_\_\_ SUPPLY REFILLS: \_\_\_\_\_ SHARPS CONTAINER: \_\_\_\_\_ OTHER SUPPLIES: \_\_\_\_\_

**HOME INJECTION TRAINING SERVICES (HITS)**  
 By initialing here (original required) I request that company-funded HITS services be arranged for my patient. I understand that HITS is for one instruction visit only and NOT a home health nursing service. I also understand that all reasonable efforts will be made to schedule the HITS training visit within 24 hours of the patient's receipt of drug shipment.

\_\_\_\_\_  
 INITIALS DATE

**5. PRESCRIPTION, CONSENT AND STATEMENT OF MEDICAL NECESSITY: HCP SIGNATURE REQUIRED**

I certify that H.P. Acthar<sup>®</sup> Gel is medically necessary for this patient and that I have reviewed this therapy with the patient and will be monitoring the patient's treatment. I verify that the patient and healthcare provider information on this enrollment form is complete and accurate to the best of my knowledge. I understand that I must comply with my practicing state's specific prescription requirements such as, e-prescribing, state specific prescription form, fax language, etc. Non-compliance of state specific requirements could result in outreach to me by the dispensing pharmacy.

I authorize United BioSource Corporation ("UBC"), the current operator of the Acthar Support and Access Program ("Program"), and other designated operators of the Program, to perform a preliminary assessment of benefit verification for this patient and furnish information requested by the patient's insurer that is available on this form. I understand that insurance verification is ultimately the responsibility of the provider and third-party reimbursement is affected by a variety of factors. While UBC tries to provide accurate information, they and Mallinckrodt make no representations or warranties as to the accuracy of the information provided.

I understand that representatives from the Program or UBC may contact me or my patient for additional information relating to this prescription. I acknowledge and agree that the designated specialty pharmacy receive this prescription via a designated third party, the Program and that no additional confirmation of receipt of prescription is required by the designated specialty pharmacy.

**HCP Prescriber Signature - Please sign ONE LINE below**

\_\_\_\_\_  
 DISPENSE AS WRITTEN DATE SUBSTITUTIONS ALLOWED DATE

Prescriber signature required to consent and validate prescriptions. Prescriber attests that this is her/his signature. NO STAMPS. By signing, I certify that the above is medically necessary.



**6. DIAGNOSIS AND MEDICAL INFORMATION**

**Diagnosis**

Please select diagnosis and responses to associated questions

**Ankylosing spondylitis**

**Dermatomyositis**

**Infantile spasms**

Has diagnosis been confirmed by EEG?

YES  NO

Patient's weight: \_\_\_\_\_

Requested drug delivery date: \_\_\_\_\_

**Multiple sclerosis**

Is Acthar to be used to treat an acute exacerbation?

Exacerbation  Other \_\_\_\_\_ *Must check one*

Onset of acute exacerbation Date: \_\_\_\_\_

**Optic neuritis**

**Polymyositis**

**Proteinuria in nephrotic syndrome**

Please indicate etiology:

Focal segmental glomerular sclerosis (FSGS)

IgA nephropathy (IgAN)

Lupus nephritis

Membranous nephropathy (MN)

Other: \_\_\_\_\_

**Psoriatic arthritis**

**Rheumatoid arthritis**

**Sarcoidosis**

**Systemic lupus erythematosus**

Is Acthar to be used to treat an acute exacerbation?

YES  NO *Must check one*

**Lupus nephritis?**

YES  NO

**Uveitis**

**Other diagnosis** \_\_\_\_\_

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**7. HISTORY OF CORTICOSTEROID USE (IF APPLICABLE) PLEASE ADD DETAILS IN SECTION 8 BELOW**

Please check all that apply

**A corticosteroid was tried with the following response(s):**

Corticosteroid use failed, but same response not expected with Acthar

Patient hypersensitive or allergic to corticosteroids

Patient intolerant to corticosteroids

Other: \_\_\_\_\_

OR

**A corticosteroid was not tried due to the following response(s):**

Corticosteroid use is contraindicated for this patient

Intravenous access is not possible for this patient

Patient has known intolerance to corticosteroids

Other: \_\_\_\_\_

**8. CONCURRENT MEDICATIONS**

\_\_\_\_\_  
 \_\_\_\_\_

**9. RELEVANT TREATMENT HISTORY (INCLUDING RECENT STEROID HISTORY)**

Therapy Name	Dose	Start Date	Stop Date (if applicable)	Explain Outcome With Detail (ex. type of outcome)

(Attach additional pages as necessary)

**OTHER RELEVANT CLINICAL INFORMATION**

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**HCP SIGNATURE: REQUIRED FOR DOCUMENTATION**

NAME \_\_\_\_\_ SIGNATURE \_\_\_\_\_ DATE \_\_\_\_\_





## **INDICATIONS AND USAGE**

- **Infantile spasms:** H.P. Acthar Gel (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- **Multiple Sclerosis:** H.P. Acthar Gel (repository corticotropin injection) is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel 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
- **Rheumatic Disorders:** As 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
- **Collagen Diseases:** During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
- **Dermatologic Diseases:** Severe erythema multiforme, Stevens-Johnson syndrome
- **Allergic States:** Serum sickness
- **Ophthalmic Diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
- **Respiratory Diseases:** Symptomatic sarcoidosis
- **Edematous State:** To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

## **IMPORTANT SAFETY INFORMATION**

### **CONTRAINDICATIONS**

- Acthar should never be administered intravenously
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of Acthar
- Acthar is contraindicated where congenital infections are suspected in infants
- Acthar is contraindicated 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 origins

### **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-axis (HPA) 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 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. Blood pressure, sodium and potassium levels may need to be monitored
- 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 GI bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain gastrointestinal disorders. Monitor for signs of bleeding
- Acthar may be associated with central nervous system effects ranging from euphoria, insomnia, irritability, mood swings, personality changes, and severe depression, and 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. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH activity
- There is 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 for patients on long-term therapy
- Pregnancy Class C: Acthar has been shown to have an embryocidal effect and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

### **ADVERSE REACTIONS**

- Common adverse reactions for Acthar are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain
- Specific adverse reactions reported in IS clinical trials in infants and children under 2 years of age included: infection, hypertension, irritability, Cushingoid symptoms, constipation, diarrhea, vomiting, pyrexia, weight gain, increased appetite, decreased appetite, nasal congestion, acne, rash, and cardiac hypertrophy. Convulsions were also reported, but these may actually be occurring because some IS patients progress to other forms of seizures and IS sometimes mask other seizures, which become visible once the clinical spasms from IS resolve

**Other adverse events reported are included in the full Prescribing Information.**

**Please see accompanying full Prescribing Information.**