H.P. **Acthar**® GEL
(repository corticotropin injection) 80 U/mL

**FAX: 1-877-937-2284**

# Acthar Start Form

**Please complete Start Form and fax toll-free**
**TEL: 1-888-435-2284**
**Monday through Friday (8:00 am to 9:00 pm EST)**
**Saturday (9:00 am to 2:00 pm)**

## 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 # | TEL #

## 3. HEALTHCARE PROVIDER (HCP) INFORMATION

HCP FIRST NAME | HCP LAST NAME | HCP MIDDLE INITIAL | NPI # | GROUP NPI # (IF APPLICABLE) | STATE LICENSE #

SPECIALTY: NEPHROLOGY ☐ NEUROLOGY ☐ PULMONOLOGY ☐ RHEUMATOLOGY ☐ OPHTHALMOLOGY ☐ 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® GEL

NDC# 63004-8710-1 5 mL multidose vial containing 80 USP units per mL

**PRIMARY DIAGNOSIS:** _____ **ICD-10:** _____

**INITIATE PATIENT WITH:**

**DOSE:** _____ ☐ UNITS ☐ 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 ☐ Subcutaneous only 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® 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.**

For Patient: _____ DOB: _____

## 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

**For completion by patient or their representative**

**Patient Name:**_____ **DOB:**_____

## 10. PATIENT AUTHORIZATION(S)

**For Patient Review and Completion. If patient is not available, authorization will be obtained from patient by Acthar Support and Access Team upon receipt of referral.**

By signing this authorization, I authorize my physician(s), my health insurance company, my pharmacy providers and Mallinckrodt ARD Inc., the distributor of Acthar ("Mallinckrodt"), and its agents, authorized designees and contractors, including Mallinckrodt reimbursement support personnel and United BioSource Corporation ("UBC") or any other operator of the Acthar Support and Access Program on behalf of Mallinckrodt (collectively, "Designated Parties"), to use and disclose to other Designated Parties health information relating to my medical condition, treatment, and insurance coverage (my "Health Information") in order for them to (1) provide certain services to me, including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injection training, (2) provide me with support services and information associated with my Acthar therapy, (3) for internal business purposes, such as for marketing research, internal financial reporting and operational purposes, and (4) to carry out the Designated Parties' respective legal responsibilities.

Once my Health Information has been disclosed to the Designated Parties, I understand that it may be re-disclosed by them and no longer protected by federal and state privacy laws. However, the Designated Parties agree to protect my Health Information by using and disclosing it only for the purposes detailed in this authorization or as permitted or required by law.

I understand that I may refuse to sign this authorization and that my physician and pharmacy will not condition my treatment on my agreement to sign this authorization form, and my health plan or health insurance company will not condition payment for my treatment, insurance enrollment or eligibility for insurance benefits on my agreement to sign this authorization form. I understand that my pharmacies and other Designated Parties may receive payment in connection with the disclosure of my Health Information as provided in this authorization. I understand that I am entitled to receive a copy of this authorization after I sign it.

I may revoke (withdraw) this authorization at any time by mailing a letter to Acthar Support and Access, 255 Technology Park, Lake Mary, FL 32746. Revoking this authorization will end further disclosure of my Health Information to Designated Parties by my pharmacy, physicians and health insurance company when they receive a copy of the revocation, but it will not apply to information they have already disclosed to the Designated Parties based on this authorization. I also know I may cancel my enrollment in a patient support program at any time in writing by contacting Mallinckrodt via fax at 877-937-2284.

This authorization is in effect for 1 year or until the conclusion of any ongoing coverage support, whichever is longer, once I have signed it unless I cancel it before then.

| PATIENT NAME OR LEGAL REPRESENTATIVE | PATIENT SIGNATURE | IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT | DATE |
|---|---|---|---|
| | | | |

I authorize Mallinckrodt and its agents to receive, use, and disclose my health information relating to my medical condition, treatment, insurance coverage, and contact information from me, my healthcare providers, my pharmacies, and my health insurance company in order to (1) contact me about participation in Acthar patient programs, (2) provide me with educational or other informational materials, (3) administer its education and other patient-related programs, (4) conduct surveys that request my feedback, and (5) for Mallinckrodt to carry out its legal responsibilities in connection with these education and support programs. I agree to let Mallinckrodt or its agents contact me in the future about these offerings. Once my health information has been disclosed to the education, informational and/or support program I choose to participate in, I understand that it may be redisclosed by Mallinckrodt or its agents, and they are authorized to use or disclose this information in the manner described here and as permitted by this authorization or as otherwise permitted or required by law, and that federal and state privacy laws may no longer protect the information. However, Mallinckrodt and its agents agree to protect my health information by using and disclosing it only for the purposes described in this authorization or as permitted or required by law. This authorization will remain in effect until I cancel it which I may do so at any time by contacting Mallinckrodt via fax at 877-937-2284. Cancelling this authorization will end further use or disclosure of my health information by Mallinckrodt or its agents (except to the extent that such parties took actions based on this authorization prior to my revocation). If I withdraw my permission, I know that this means I may no longer receive information on supplemental education or support programs. Once I withdraw my permission, no new information will be disclosed to Mallinckrodt or its agents, but Mallinckrodt and its agents may continue to use the information that was collected before I withdrew my permission as permitted by this authorization or as otherwise permitted or required by law. I may request a copy of this signed authorization.

| PATIENT NAME OR LEGAL REPRESENTATIVE | PATIENT SIGNATURE | IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT | 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.**



Mallinckrodt Pharmaceuticals