

Images are not actual patients.



## CHOICE MATTERS

### Acthar® Gel Single-Dose Pre-filled SELFJECT™ INJECTOR

The only medication in its class approved in a self-injection device<sup>1\*</sup>

<sup>1</sup>Among adrenocorticotrophic hormone products.

The 80-unit (1.0 mL) injector is shown here. Device is not shown at actual size. The exterior configuration of the drug delivery device is owned by West Pharmaceutical Services, Inc. and is used with permission.

#### INDICATIONS

Acthar Gel is indicated for:

- Rheumatoid arthritis
- Dermatomyositis and polymyositis
- Symptomatic sarcoidosis
- Systemic lupus erythematosus
- Proteinuria in nephrotic syndrome
- Ocular inflammatory diseases
- Multiple sclerosis relapse
- Infantile spasms

**Please see complete Acthar Gel indications on page 8 of this brochure. Please see additional Important Safety Information throughout. Please see accompanying full Prescribing Information or visit [ActharHCP.com](http://ActharHCP.com).**

#### 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; and 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.

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

Single-Dose Pre-filled  
SelfJect™ Injector

## THERE'S ANOTHER WAY TO ADMINISTER ACTHAR® GEL

### Single-Dose Pre-filled SELFJECT™ INJECTOR<sup>1-4</sup>



**Colored Body**

Indicates the dosage and when the dose is complete. The dose is fully administered when the colored body disappears. Users may also hear a "click" when the dose is complete

**Handle**

Designed for easy grip when holding the device

**Bottom Cap**

Prevents accidental locking of the needle guard and protects from needlestick injuries or needle contamination

**Window**

Viewing window to inspect the medicine

**Needle Guard**

Locks the needle after use to prevent injury

**Latex-free design**

SelfJect is not made with latex.

### 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

## KEY FEATURES OF SELFJECT

### ✓ Ease-of-use-design<sup>1-4</sup>

- Pre-filled with the prescribed dose of Acthar Gel<sup>1</sup>
- Helps deliver the prescribed dose by pressing down on the handle<sup>3,4</sup>
- Easy-to-hold design may help people with dexterity and vision issues<sup>2</sup>

### ✓ Available in 2 doses<sup>1,3,4</sup>

- Used to administer single doses of 40 units or 80 units<sup>1,3,4</sup>
- SelfJect is not approved for infantile spasms, but is approved for all other indications for Acthar Gel in patients whose dose is 40 units (0.5 mL) or 80 units (1.0 mL) subcutaneous injection<sup>1</sup>

### ✓ Requires fewer steps<sup>3,4</sup>

- Compared with administration with vial and syringe<sup>3,4</sup>



For subcutaneous administration by people 18 years of age or older.<sup>1</sup>



SCAN TO WATCH THE **SELFJECT DEMONSTRATION VIDEO.**

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(repository corticotropin injection) 80 U/mL

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## HOW TO PRESCRIBE the Acthar® Gel Single-Dose Pre-filled SelfJect™ Injector

### Recommended dosing from the label<sup>1</sup>

<b>MULTIPLE SCLEROSIS (RELAPSE)</b>	<b>80 to 120 units</b> (1.0 to 1.5 mL) IM or SC Daily for 2 to 3 weeks**
<b>RA, SLE, PSA, DM/PM, SYMPTOMATIC SARCOIDOSIS, PROTEINURIA DUE TO NEPHROTIC SYNDROME, AND OPHTHALMIC DISEASES</b>	<b>40 to 80 units</b> (0.5 to 1.0 mL) IM or SC Every 24 to 72 hours**

\*Acthar Gel is provided as either a 5-mL multi-dose vial containing 80 USP units/mL or as a pre-filled self-injection device containing 40 units (0.5 mL) or 80 units (1.0 mL).<sup>1</sup>

\*\*It may be necessary to taper the dose or increase the injection interval to gradually discontinue treatment.<sup>1</sup>

- SelfJect is available for subcutaneous use only, in single doses of 40 units and 80 units<sup>1</sup>
- Depending on dose frequency, patients may need approximately 10 to 15 devices per month<sup>1</sup>
- SelfJect injectors come in a box of 4 injectors. Patients may receive more than 1 box
- The Specialty Pharmacy will set up arrangements for shipment and delivery to your patient's home

Dosage and frequency should be individualized according to the medical condition, severity of disease, and initial response of the patient.

**Acthar Referral Form**

**PRESCRIPTION: ACTHAR® GEL**

**Acthar Single-dose pre-filled SelfJect injector**  
Subcutaneous Injection  
 80 Units  40 Units  
Frequency:  Every 72 hours  Every 48 hours  
Dispense quantity sufficient for up to 35 days  
Other: \_\_\_\_\_  
Number of Refills: \_\_\_\_\_

**Acthar 5 mL multi-dose vial**  
Subcutaneous Injection  
 80 Units  40 Units  Other \_\_\_\_\_  
Frequency:  Every 72 hours  Every 48 hours  
Dispense quantity sufficient for up to 35 days  
Other: \_\_\_\_\_  
Number of Refills: \_\_\_\_\_

**Acthar Gel Enrollment/  
Prescription Form**  
FILL IN IMPORTANT SELFJECT  
PRESCRIPTION DETAILS

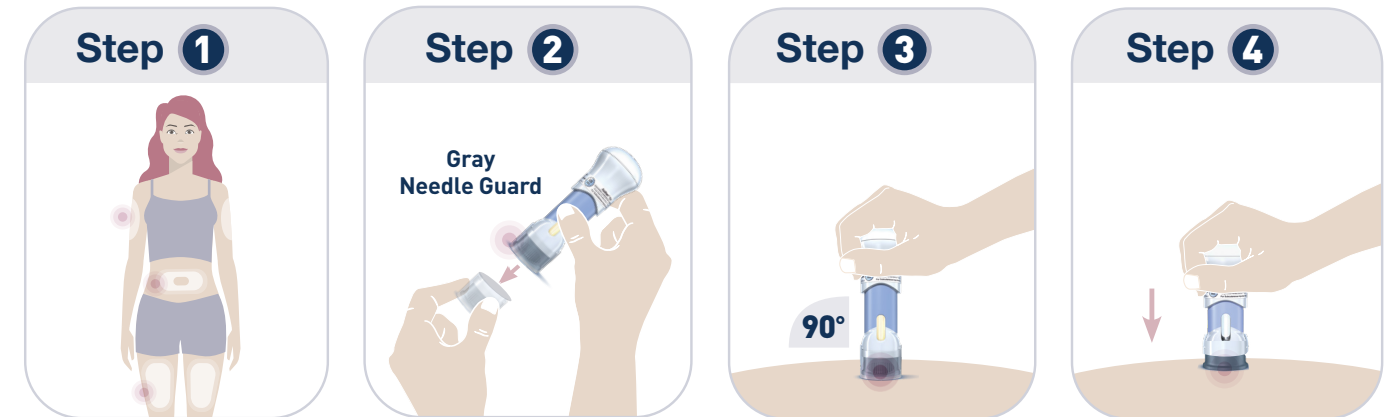
### SELECT IMPORTANT SAFETY INFORMATION

#### Warnings and Precautions (continued)

- 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

## HOW TO USE Acthar Gel Single-Dose Pre-filled SelfJect Injector<sup>3,4</sup>

The following steps do not include the full administration instructions for SelfJect. Please read full Instructions for Use for more information.



Choose one of these injection sites:

- Upper thigh
- Abdomen (not within 1 inch of belly button)
- Back of arm (only if someone else is giving the injection)

**Choose a different site for each injection.**

Pull off the Bottom Cap to remove.

- Avoid touching the Gray Needle Guard
- Use the injector right away

**Do not recap** the injector as this may damage the needle.

Place the injector straight on cleaned skin at a 90° angle.

**Do not pinch skin.**

**Slowly push** the Handle down to inject the medicine.

**Do not lift** the injector during the injection. The injector will lock out and the patient will not get the full dose of medicine.

**The injection is complete when the colored body of the device disappears (the patient may hear a “click”).**



40-UNIT

Please see additional Important Safety Information throughout. Please see accompanying full Prescribing Information or visit [ActharHCP.com](http://ActharHCP.com) for additional Important Safety Information.



80-UNIT

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

Single-Dose Pre-filled  
SelfJect™ Injector

## HOW TO PREPARE AND DISPOSE OF the Acthar® Gel Single-Dose Pre-filled SelfJect™ Injector<sup>3,4</sup>

Store SelfJect in the refrigerator between 36 and 46 °F (2 and 8 °C). Do not heat, freeze, or put SelfJect in direct sunlight.



Before injection, SelfJect needs to sit on a clean, dry, flat surface at room temperature, **between 68 and 77 °F (20 and 25 °C), for a minimum of 45 minutes, and the device can be left out for up to 24 hours.**



Mallinckrodt is committed to the safe disposal of SelfJect. Mallinckrodt will supply an FDA-cleared sharps disposal container at no cost to the patient for their used SelfJect devices.



### SELECT IMPORTANT SAFETY INFORMATION

#### Warnings and Precautions (continued)

- 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

## MALLINCKRODT IS COMMITTED TO HELPING PATIENTS start and stay on therapy



### The Commercial Starter Program is available for SelfJect

- Help your eligible patients with commercial or private insurance get Acthar Gel while you and the Acthar Patient Support team work through the reimbursement process
- The program is available to patients until the decision of insurance coverage
- The program is not available to patients on government-funded health care programs
- Other Terms and Conditions apply. Scan QR code below for full Terms and Conditions or visit [ActharHCP.com/csp-terms](http://ActharHCP.com/csp-terms)



### Mallinckrodt offers robust support and services for your practice and patients

- **Support for your practice:** Connects you and your office staff to an Access and Reimbursement Manager (ARM) to help navigate the approval process
- **Support for your patients:** Connects patients to a Nurse Navigator to help answer questions they may have. They will never provide medical advice to your patients
- **Support with insurance:** Provides information on financial assistance and help with prior authorization and appeal



SCAN THE CODE OR CALL 1-888-435-2284 FOR MORE INFORMATION ABOUT THE COMMERCIAL STARTER PROGRAM, INCLUDING THE TERMS AND CONDITIONS.

Please see additional Important Safety Information throughout. Please see accompanying full [Prescribing Information](#) or visit [ActharHCP.com](http://ActharHCP.com) for additional Important Safety Information.

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## INDICATIONS

Acthar Gel is indicated for:

- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic dermatomyositis (polymyositis)
- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus
- 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
- 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
- Inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
- 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
- Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age

## 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

### 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
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- 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

**References:** **1.** Acthar Gel [repository corticotropin injection] [prescribing information]. Bridgewater, NJ: Mallinckrodt ARD LLC. **2.** Data on File - Ref-07341. Mallinckrodt Pharmaceuticals. **3.** Acthar Gel [repository corticotropin injection] Single-Dose Pre-filled SelfJect Injector, 40 USP Units/0.5 mL [Instructions for Use]. Bridgewater, NJ: Mallinckrodt ARD LLC. **4.** Acthar Gel [repository corticotropin injection] Single-Dose Pre-filled SelfJect Injector, 80 USP Units/1.0 mL [Instructions for Use]. Bridgewater, NJ: Mallinckrodt ARD LLC.

Please see accompanying full **Prescribing Information** or visit **ActharHCP.com** for additional **Important Safety Information**.

**Acthar**<sup>®</sup>GEL  
(repository corticotropin injection) 80 U/mL

Single-Dose Pre-filled  
SelfJect<sup>™</sup> Injector



## CHOICE MATTERS

Acthar® Gel: The only medication in its class that comes in 2 forms of administration<sup>1\*</sup>

## Single-Dose Pre-filled SELFJECT™ INJECTOR & MULTI-DOSE VIAL

<sup>1</sup>Among adrenocorticotrophic hormone products.



**Do you have appropriate patients who could benefit from Acthar Gel?**

Talk to your Immunology Sales Specialist today to learn more.

## SELECT IMPORTANT SAFETY INFORMATION

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