

# FDA-APPROVED TO TREAT RELAPSES OR FLARES OF MULTIPLE SCLEROSIS (MS)

## Relief is possible with Acthar<sup>®</sup> Gel

Ask your doctor if Acthar Gel  
may be right for you



Brandi, treated with Acthar Gel for an autoimmune  
disease. Individual results may vary.

### What is Acthar Gel?

Acthar Gel is a prescription medicine for adults with acute relapses or flares of multiple sclerosis (MS). Studies have shown Acthar to be effective in speeding recovery from an MS relapse. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.

Acthar is injected beneath the skin or into the muscle.

### SELECT IMPORTANT SAFETY INFORMATION

**DO NOT** take Acthar until you have talked to your doctor if you have any of the following conditions:

- Have been given or are about to receive a live or live attenuated vaccine
- A skin condition called scleroderma
- Bone density loss or osteoporosis
- Any infections, including fungal, bacterial, or viral

Please see additional Important Safety Information throughout and the accompanying full [Prescribing Information](#).

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

## Could Acthar® Gel be right for you?

Acthar Gel is an **FDA-approved medication to treat acute relapses or flares of MS** in adults that may help if you are still looking for symptom relief.

**Acthar Gel is not a steroid.** Acthar Gel is **thought to work differently from steroids** but it can have similar side effects in some people. Talk to your doctor about what to expect.

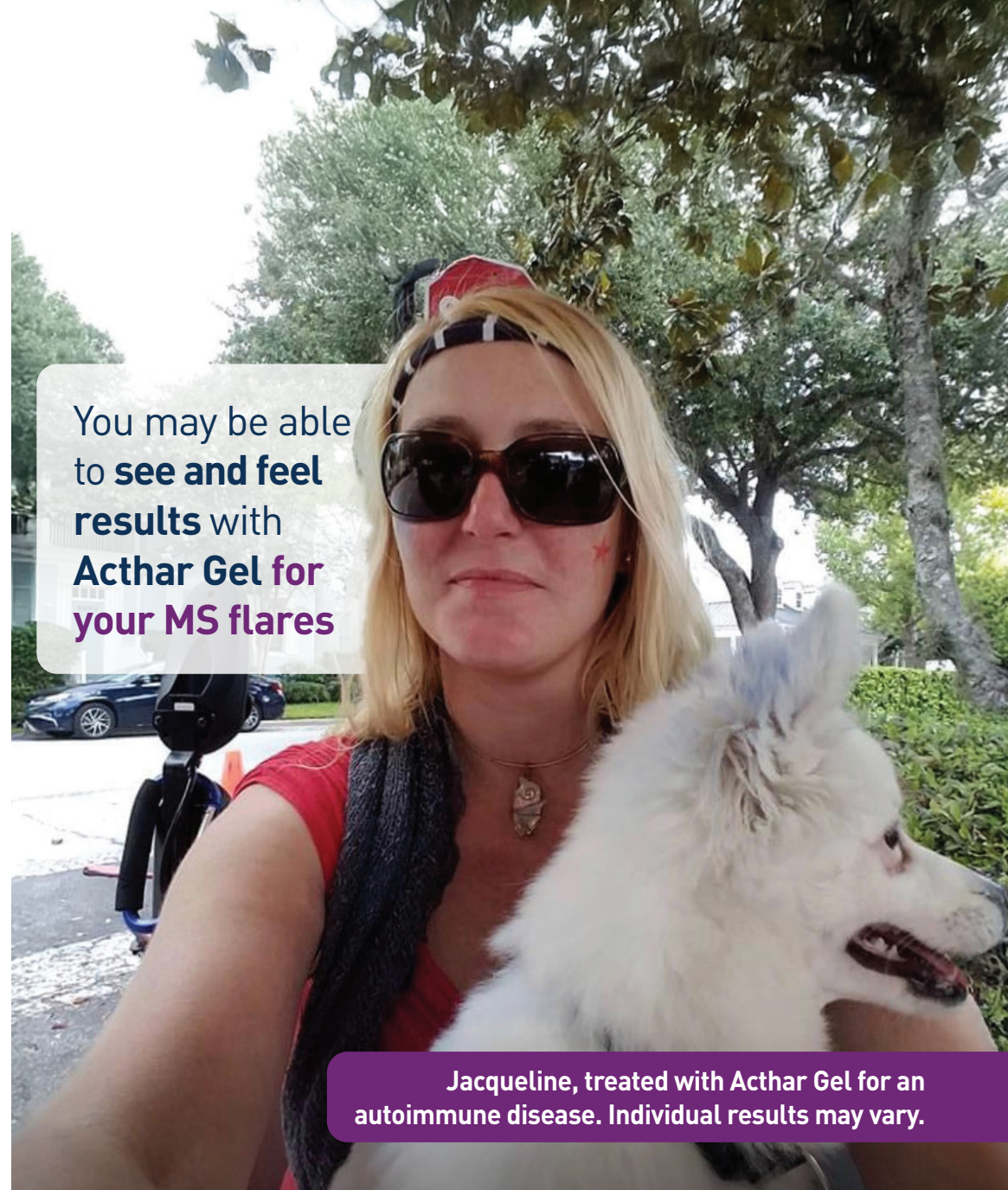
### SELECT IMPORTANT SAFETY INFORMATION

**DO NOT** take Acthar until you have talked to your doctor if you have any of the following conditions (continued):

- Eye infections, such as ocular herpes simplex
- Had recent surgery
- Stomach ulcers or a history of stomach ulcers
- Heart failure
- Uncontrolled high blood pressure
- Addison's disease or Cushing's syndrome
- Allergies to pig-derived proteins
- Suspected infections at birth (in infants under 2 years of age)

2

Please see additional Important Safety Information throughout and the accompanying full Prescribing Information.



Jacqueline, treated with Acthar Gel for an autoimmune disease. Individual results may vary.

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3

## In this brochure, you will learn:

Symptoms of MS relapse .....	6
What is Acthar® Gel? .....	8
How Acthar Gel worked in adults with MS .....	10
Ways to take Acthar Gel .....	14
Your support team .....	16
Starting a conversation with your doctor .....	18

### SELECT IMPORTANT SAFETY INFORMATION

Tell your doctor about any other health problems that you have. Give your doctor a complete list of medicines you are taking, including all prescription and nonprescription medicines, vitamins, and herbal supplements.

#### What is the most important information I should know about Acthar?

- Never inject Acthar directly into a vein
- Acthar is injected beneath the skin or into the muscle. Always inject Acthar with SelfJect beneath the skin
- Follow your doctor's instructions for injecting Acthar



Not an actual patient.

- Never stop treatment suddenly unless your doctor tells you to do so
- Try not to miss any scheduled doctor's appointments. It is important for the doctor to monitor you while taking Acthar
- You may be more likely to get new infections. Also, old infections may become active. Tell your doctor if you see any signs of an infection. Contact your doctor at the first sign of an infection or fever. Signs of infection are fever, cough, vomiting, or diarrhea. Other signs may be flu or any open cuts or sores

4

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5

## Are you struggling with a sudden worsening of MS symptoms?

MS is a type of neuroinflammatory condition that may affect your brain, optic nerve, and spinal cord. It can affect walking, vision, and even thought processes.

In multiple sclerosis, the immune system mistakenly attacks myelin (a substance that covers nerve fibers) in the brain, optic nerve, and spinal cord.

### MS symptoms can temporarily worsen, even if you're taking medicine for your condition

If you've been diagnosed with MS, you may be taking medication to modify the course of disease. Nevertheless, you may still experience unpredictable attacks, also known as relapses, exacerbations, or flares.

When symptoms that have been stable (partial or complete recovery) for at least 30 days worsen or new symptoms lasting over 24 hours appear, this may be a relapse. These symptoms occur in the absence of fever or infection. Relapses may last from a few days to several weeks or months.

### Relapses may have long-term effects

Most people with MS have relapses, which may cause lasting neurological problems and make day-to-day life harder. MS relapses have been linked to increasing disability over time—particularly when there is incomplete recovery from early relapses. Given the short- and long-term effects of MS relapses, specialists generally agree on the importance of recognizing, treating, and shortening these inflammatory events.

## Recognizing an MS flare

Different people may experience MS flares in different ways. Here are a few common signs and symptoms:



Pain



Muscle tightness or stiffness



Poor balance



Mental or physical fatigue



Rapid Vision loss



Numbness or tingling

## SELECT IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about Acthar? (continued)

- When taking Acthar long-term, your adrenal gland may produce too much of a hormone called cortisol. This can result in symptoms of Cushing's syndrome. This may cause increased upper body fat, a rounded "moon" face, bruising easily, or muscle weakness

# What is Acthar® Gel?

Acthar Gel is a prescription medication used to treat acute MS relapses or flares in adults.

Hear about  
**Julia's** experience  
with **Acthar Gel**



Visit [Acthar.com/patient-stories](https://www.acthar.com/patient-stories).

Julia, treated with Acthar Gel for an autoimmune disease. Individual results may vary.

## SELECT IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about Acthar? (continued)

- Sometimes when you stop taking Acthar long-term, your body may not produce enough natural cortisol. This is called "adrenal insufficiency." Your doctor may prescribe a steroid medicine to protect you until the adrenal gland recovers

8

Please see additional Important Safety Information throughout and the accompanying full Prescribing Information.

## How is Acthar Gel believed to work?

Acthar Gel is a blend of proteins and natural hormones, like those already found in your body. It is believed to work differently from steroids. Acthar is thought to work with the immune system to help reduce inflammation.

Ask your doctor what you should expect while taking Acthar Gel. Even though Acthar is not a steroid, it can have similar side effects because it may boost your own body's production of natural steroids.

The way Acthar Gel works is not fully understood. Further studies are being done. The information above is based on studies done in labs and with healthy volunteers. How the information relates to patient benefits is still uncertain.

- You might develop high blood pressure, retain too much salt and water, or have low blood potassium levels. As a result of this, your doctor may recommend some changes to your diet, such as eating less salt or taking certain supplements
- Vaccines may not work well when you are on Acthar. Talk to your doctor about which vaccines are safe to use when you are taking Acthar

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9

# How well did Acthar<sup>®</sup> Gel work in people experiencing a relapse?

## Overall, patients reported a lower physical impact of MS after treatment

**125 patients** experiencing a relapse who enrolled in an observational registry were evaluated 2 months and 6 months after beginning treatment with Acthar Gel. The effectiveness analyses were completed in the intention-to-treat (ITT) population. The ITT population comprised 125 patients; 80 patients completed the study and received at least 1 dose of Acthar Gel.

- 60% had experienced inadequate response, intolerance of side effects, or IV access issues with high-dose corticosteroids for an MS relapse.

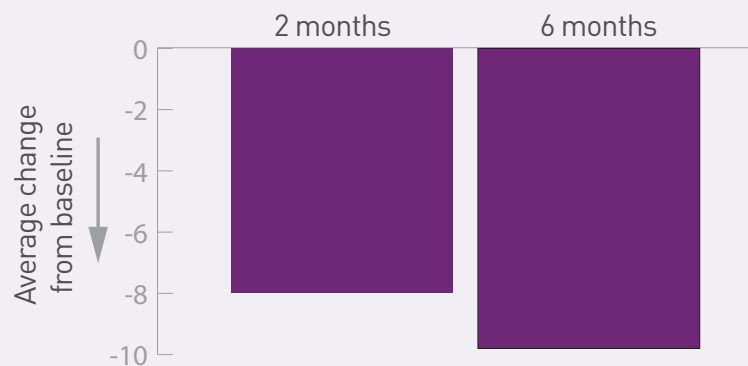
Thirty-five people reported a total of 83 side effects. The most common side effects included MS relapse, urinary tract infection, common cold, and swelling in the arms or legs. Eleven people reported serious side effects (MS relapse, urinary tract infection, and weakness).

**There were limits to this study. Many people were taking disease-modifying and other therapies along with Acthar Gel. The exact role Acthar Gel had in the improvements seen is not known.**

### Ask your doctor about Acthar<sup>®</sup> Gel

Acthar Gel may be able to **ease the symptoms of your acute relapses or flares of MS.**

The average physical impact score\* reported by patients had decreased at the 2-month and 6-month evaluations<sup>‡</sup>



\* A lower physical impact (MSIS-29) score indicates that patients reported less physical impact of MS on their lives.

<sup>‡</sup>69 patients were evaluated at 2 months and 48 at 6 months.

## SELECT IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about Acthar? (continued)

- Acthar may hide symptoms of other diseases. This can make it more difficult for your doctor to make a diagnosis if something else is going on
- Stomach or intestinal problems. Acthar may increase the risk of bleeding and stomach ulcers. Tell your doctor if you have stomach pains, bloody vomit, bloody or black stools, excessive tiredness, increased thirst, difficulty breathing, or increased heart rate

**10** Please see additional Important Safety Information throughout and the accompanying full Prescribing Information.

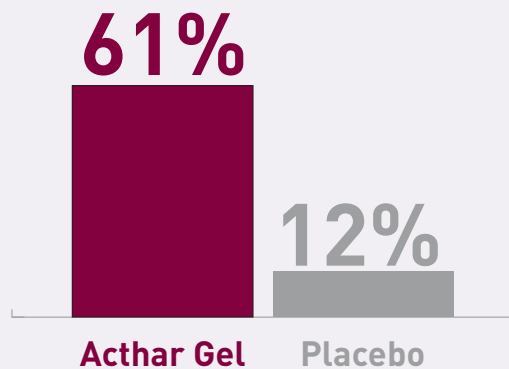
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# How well did Acthar<sup>®</sup> Gel work in patients who needed another treatment option after steroids?

## Disability scores decreased significantly after treatment

In a double-blind clinical study, 35 patients experiencing an MS relapse were randomized to receive either Acthar Gel (18) or placebo (17) for 14 days after an inadequate response to high-dose corticosteroid treatment.

More patients taking Acthar Gel than placebo had improved disability scores [EDSS]\* at Day 42



\*The Expanded Disability Status Score (EDSS) is a standard measure of disability in MS.

**There were limits to this study. Some people were taking disease-modifying therapy along with Acthar Gel. The exact role Acthar Gel had in the improvements seen is not known.**

**12** Please see additional Important Safety Information throughout and the accompanying full [Prescribing Information](#).

61% of patients in the Acthar Gel group experienced treatment-emergent adverse events (TEAEs), compared to 47% in the placebo group. The most reported side effect in both treatment groups was injection site bruising, reported in 17% of the patients taking Acthar Gel and 24% of those taking placebo. Other side effects included generalized swelling, pain, common cold, oral thrush, urinary tract infection, liver enzyme elevations, fluid retention and insomnia in the Acthar Gel group and injection site inflammation and headache in the placebo group.

## SELECT IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about Acthar? (continued)

- Taking Acthar can make you feel irritable or depressed. You may also have mood swings or trouble sleeping. These effects are reversible once Acthar therapy is stopped
- If you have other conditions, such as diabetes or muscle weakness, you may find they get worse
- You might develop certain eye conditions, such as cataracts, glaucoma, or optic nerve damage
- Your body may develop allergies to Acthar; these allergies may be severe. Signs of allergic reaction include:
  - Skin rash and itching
  - Swelling of the face, tongue, lips, or throat
  - Trouble breathing

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**13**

## How can you take Acthar® Gel?

Acthar Gel is available to take in **2 ways**. Talk to your doctor to see which way could work for you.

### The Acthar® Gel Single-Dose Pre-filled SelfJect™ Injector

It is designed to help people take a **single 40- or 80-unit dose of Acthar Gel under the skin** (subcutaneously). For doses other than 40 or 80 units, only use the Acthar Gel vial.

SelfJect is a device that may be helpful to people who have vision impairment or issues with grip. SelfJect is only to be administered by adults (18 years of age and older).



The exterior configuration of the drug delivery device is owned by West Pharmaceutical Services, Inc. and is used with permission.

### New to injections?

Don't worry, a nurse educator will provide the injection **training you need**, whether it's in your home, online, or by phone.

### Vial and Syringe

An option for people who take **any dose of Acthar Gel**. The vial and syringe can be used to inject **under the skin or into a muscle** (intramuscularly).



**Acthar Gel is injected in the upper thigh, abdomen, or back of arm. Avoid injecting within 1 inch of the belly button, knee, or groin area.**

### SELECT IMPORTANT SAFETY INFORMATION

#### What is the most important information I should know about Acthar? (continued)

- The effects of Acthar may be intensified if you have an underactive thyroid or cirrhosis of the liver

Please see the accompanying full Prescribing Information and the 40-unit and 80-unit SelfJect Instructions for Use. If you've been prescribed SelfJect, please see the Quick Reference Guide in the SelfJect carton.

- Long-term Acthar use can affect growth and physical development in children. This can be reversed when Acthar is no longer needed
- Acthar may cause osteoporosis (weak bones)
- Acthar might harm an unborn baby. Therefore, tell your doctor if you are pregnant or plan to become pregnant

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## Support from the start

If Acthar® Gel is right for you, **Acthar Patient Support is here to help you** on your treatment plan.

You are automatically enrolled in **Acthar Patient Support** when your doctor submits your prescription. The support program helps with **navigating insurance coverage** and **learning** to give injections.

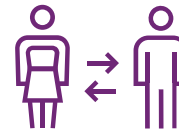


Support team member

## Acthar Patient Support will provide:



A **Nurse Navigator** to partner with you throughout your time taking Acthar Gel who can answer questions and provide support.\*



**Free injection training**, based on your needs.



Support for insurance coverage questions. Your **Case Manager** is ready to help review your options and create a plan.

### You won't be starting this care journey alone

You have a dedicated care team available to support you every step of the way.

\*Nurse Navigators do not give medical advice and will direct you to your healthcare provider for any treatment-related questions, including further referrals.

# Start the conversation about Acthar® Gel with your doctor today



You and your doctor can **work together** to decide if Acthar Gel is the right treatment for you. Here are a few **questions** to help you get the conversation started:

- Is Acthar Gel an appropriate treatment option for my condition?
- What side effects have your patients experienced while on Acthar Gel?
- What benefits have your patients experienced using Acthar Gel?

## SELECT IMPORTANT SAFETY INFORMATION

### What are the most common side effects of Acthar?

Commonly reported side effects of Acthar include:

- Injection site reaction
- Fatigue, physical weakness, and lack of energy
- Fluid retention
- Insomnia (difficulty sleeping)
- Headache
- High blood sugar

18

Please see additional Important Safety Information throughout and the accompanying full [Prescribing Information](#).



Be an **active** member of your **care team**.

Not an actual patient.

The most common side effects for the treatment of infantile spasms (IS) are:

- Increased risk of infections
- Convulsions
- High blood pressure
- Irritability
- Fever

The above side effects may also be seen in adults and children over 2 years of age. Some children with IS progress to other forms of seizures; IS sometimes masks these seizures, which may become visible after treatment for IS has been completed.

**These are not all of the possible side effects of Acthar.**

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19

# See if Acthar<sup>®</sup> Gel may be able to ease your symptoms

Hear about real patient experiences and **ask your doctor if Acthar Gel** could be right for you.



Visit [Acthar.com/patient-stories](https://www.acthar.com/patient-stories).

## SELECT IMPORTANT SAFETY INFORMATION

Tell your doctor about any side effect that bothers you, or that does not go away. Call your doctor or pharmacist for medical advice about side effects. You may report side effects to the FDA. Call 1-800-FDA-1088 or visit [www.fda.gov/medwatch](https://www.fda.gov/medwatch). You may also report side effects by calling 1-800-844-2830.

**Please see additional Important Safety Information throughout and the accompanying full Prescribing Information.**

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