

# FDA-APPROVED TO TREAT DERMATOMYOSITIS (DM) AND POLYMYOSITIS (PM)



**Relief is possible  
with Acthar® Gel**

Ask your doctor if Acthar Gel  
may be right for you

Rebecca, treated with Acthar Gel.  
Individual results may vary.

## What is Acthar Gel?

Acthar Gel is a prescription medicine used for treatment for flares or on a regular basis (maintenance) in people with dermatomyositis or polymyositis (DM-PM).

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

## Could Acthar® Gel be right for you?

Acthar Gel is an **FDA-approved medication to treat dermatomyositis (DM) and polymyositis (PM)** 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)

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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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## In this brochure, you will learn about:

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### 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

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



- 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

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# Are you struggling with symptoms of dermatomyositis (DM) or polymyositis (PM)?

## Both are forms of the autoimmune condition, myositis

Myositis is a general term for muscle inflammation. In the case of DM and PM, the inflammation is caused by the immune system attacking body tissues and cells.

**In DM**, the small blood vessels that supply the skin and muscles are attacked by the immune system.

**In PM**, the immune system attacks the muscle fibers directly.

In both diseases, pain, swelling, and muscle weakness occur as a result.

### Ask your doctor about Acthar® Gel

Acthar Gel may be able to **ease the symptoms of your DM or PM**

## 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

Symptoms may vary from person to person—and over time



#### Skin rash (DM only)

Itchy and painful rash, typically developing on the face, eyelids, elbows, knees and/or chest.



#### Muscle weakness

Progressive weakness that can limit mobility



#### Joint pain

Affects multiple joints



#### Shortness of breath (More common in PM)

Due to inflammation, scarring or stiffness of lung tissue



#### Trouble swallowing

Due to weakness of muscles in tongue, throat or neck

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# What is Acthar® Gel?

Acthar Gel is a prescription medicine used to treat flares—or on a regular basis (maintenance)—for people with dermatomyositis or polymyositis



## 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

## How is Acthar Gel believed to work?

- It's **not a steroid**—Acthar Gel is believed to work differently from steroids
- It's thought to work with the immune system to help **reduce inflammation**
- It's a blend of **proteins and natural hormones**, like those already found in your body

Acthar Gel can have similar side effects to steroids. Ask your doctor what you should expect from treatment with Acthar. 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

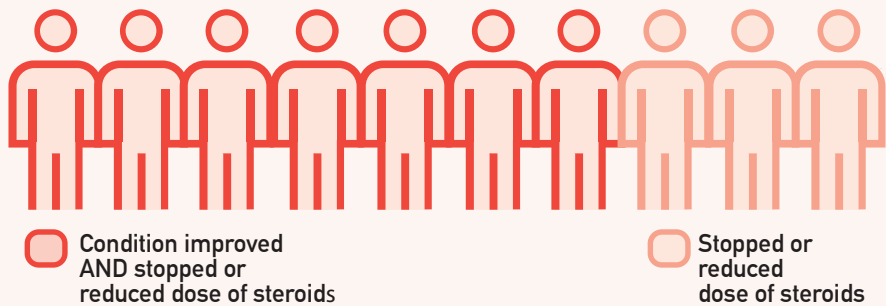
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## How well did Acthar<sup>®</sup> Gel work in people with persistent symptoms?

In a 6-month, unblinded study, 10 people\* with dermatomyositis or polymyositis who needed an alternative to steroids or conventional immunosuppressants were treated with Acthar Gel

**70%** saw improvements in their condition and **100%** stopped or reduced their dose of steroids<sup>†</sup> by 6 months after taking Acthar Gel



\*The study started with 11 people. One person stopped participating in the study because of a symptom not related to treatment with Acthar Gel.

<sup>†</sup>All 10 patients reduced their steroid dose, while half stopped taking steroids completely.

**There were limits to this relatively small study. People were taking other treatments along with Acthar Gel. The exact role Acthar Gel had in the improvements seen is not known.**

8 patients were observed for 6 additional months

**50%** of patients remained stable, with no flares

Eight patients reported side effects. Common side effects among these patients that were related to Acthar included injection site bruising and rash, high blood sugar, calcinosis, and trouble sleeping. Three patients reported serious side effects that were related to Acthar (viral infections, bone loss, and chest pain).

### SELECT IMPORTANT SAFETY INFORMATION

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

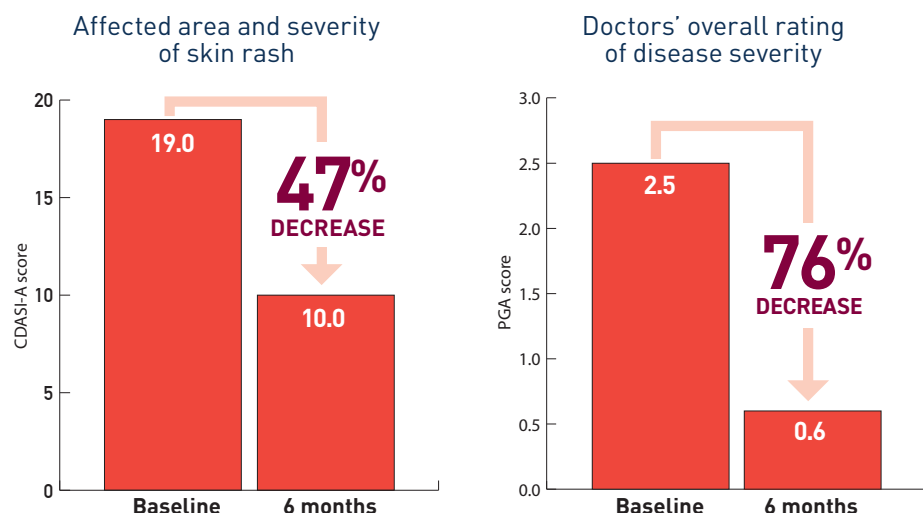
- Acthar may hide symptoms of other diseases. This can make it more difficult for your doctor to make a diagnosis if something else is going on
- Stomach or intestinal problems. Acthar may increase the risk of bleeding and stomach ulcers. Tell your doctor if you have stomach pains, bloody vomit, bloody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

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## How well did Acthar® Gel work when people needed another treatment option?

In an unblinded study conducted at the Cleveland Clinic, 15 patients with dermatomyositis and persistent skin symptoms received Acthar Gel for 6 months

### Rash and disease severity scores decreased significantly with Acthar Gel



**73%** of patients **decreased the dose of steroids or immunosuppressants** they had been taking

There were limits to this relatively small study. People could have been taking other treatments along with Acthar Gel. The exact role Acthar Gel had in the improvements seen is not known.

### An example of rash improvement seen during the study



Relatively common patient-reported side effects were all noted specifically on or following the day of Acthar injection, including: increased energy (8 patients), difficulty sleeping (6 patients), irritability (3 patients), and weight gain (4 patients).

### SELECT IMPORTANT SAFETY INFORMATION

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

- 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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## 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

A device designed to help people take a **40- or 80-unit dose of Acthar Gel under the skin** (subcutaneously). It may be helpful to people who have vision impairment or issues with grip.

SelfJect is only to be administered by people 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.

### 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.

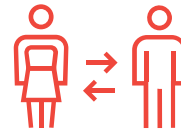


Support team member

## 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

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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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# See if Acthar® 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://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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