

# RELIEF IS POSSIBLE

*let's go*



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

## What is H.P. Acthar® Gel?

- A prescription medicine for flares or on a regular basis (maintenance) in people with dermatomyositis or polymyositis (DM-PM), or systemic lupus erythematosus (lupus)
- A prescription add-on medicine for the short-term administration (to tide patients over an acute episode or exacerbation) in: psoriatic arthritis (PsA); rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis

## SELECT IMPORTANT SAFETY INFORMATION

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

- A skin condition called scleroderma
- Bone density loss or osteoporosis
- Any infections, including fungal, bacterial, or viral

**Please see additional Important Safety Information on pages 12-13 and throughout this guide, and accompanying full Prescribing Information.**



# COMMITTED TO HELPING YOU FROM PRESCRIPTION TO TREATMENT

Mallinckrodt, the maker of Acthar, offers many different types of support. In this guide you will learn about these services, and how each can assist you.

**Inside, you will find information about the following no-cost services:**

- Injection training in the privacy of your own home
- Personalized support with a Nurse Coach
- Help with financial assistance options

# YOU'VE BEEN APPROVED FOR ACTHAR, HERE ARE THE NEXT STEPS

- Your Specialty Pharmacy calls to schedule delivery of Acthar, since it is not available at your local pharmacy
  - You must confirm delivery timing with the Specialty Pharmacy to receive Acthar
- Acthar is shipped to your home in a refrigerated container
  - A signature is required for delivery because someone must be available to place the Acthar vials in the refrigerator when they are received



To help you throughout your Acthar treatment, there are support resources available to you, including injection training and access to a registered Nurse Coach. Read on to learn more about these resources and how to start getting support.



**For more information about support resources,  
call 1-888-435-2284 Monday through Friday  
from 8 AM to 9 PM ET, and Saturday from 9 AM to 2 PM ET,  
to speak to an Acthar Case Manager.**

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## Acthar Injection Training in the privacy of your home

You can have a registered nurse visit you at home, work with you online, or speak to you by phone to teach you how to inject Acthar. During your welcome call, your Acthar Case Manager will tell you about injection training and ask if you would like to have this service.

Once you or your doctor requests training, the injection training nurse will:



- Contact you to schedule your training. This typically occurs within 48 hours after you receive Acthar from the Specialty Pharmacy
  - You must receive Acthar before the nurse can train you
- Review injection materials and supplies with you. This includes needles, syringes, alcohol wipes, etc
- Prepare the medication and supplies for your Acthar injection
- Show you or your care partner how and where to administer Acthar. (You or your care partner will actually perform the injection)
- Review how to store Acthar and dispose of used needles and syringes
- Answer any questions about your injection and treatment with Acthar

If you are interested in **Acthar Injection Training**, please call your Case Manager at the Acthar Hub at **1-888-435-2284** Monday through Friday from 8 AM to 9 PM ET, and Saturday from 9 AM to 2 PM ET.

For more information about injecting Acthar,  
visit [Acthar.com/injections](https://acthar.com/injections)  
where you will find instructional videos.

## Personalized support with a Nurse Coach

ActharPACT (Patient & Acthar Coaching Team) offers you support now and throughout your treatment, for as long as you need it.

With ActharPACT on your side, you can:



- Talk to a registered nurse about Acthar treatment and your condition, as well as any challenges that you face
- Get a personal registered Nurse Coach who can answer your questions and connect you to the right type of help and information
- Get suggestions to help you stay motivated and address problems as they arise
- Receive personalized follow-up materials and mailings with useful information about your Acthar treatment as well as helpful tips

Get one-on-one support from a registered nurse.  
Nurses are available by phone to help with questions or concerns.  
Call ActharPACT at 1-877-546-PACT (1-877-546-7228).  
You'll receive around-the-clock assistance. Right when you need it.



## Financial assistance options

If you haven't done so already, talk with your Acthar Case Manager about which of the three options may be right for you. These options are based on the type of insurance coverage you have.

### If you have commercial or private insurance:



You may be eligible for the Acthar Commercial Co-pay Program to help with the cost of Acthar

- \$0 co-pay for eligible patients (see Terms and Conditions to the right)
- Enrollment over the phone during the Acthar welcome call or anytime you are speaking with your Case Manager
- Automatic processing by the Acthar Specialty Pharmacy with no attempt to collect a co-pay

### If you have government insurance:



You may be eligible to receive financial support through Independent Charitable Foundations

- Your Case Manager will provide information on Independent Charitable Foundations, fund availability, and contact information, and will let you know about documentation you may have to provide
- Please note that you will be responsible for working with the Independent Charitable Foundations and applying for funding
- Mallinckrodt does not determine Independent Charitable Foundations' fund eligibility criteria, or have any influence over the patients chosen or types of assistance provided

### If you do not have insurance coverage:



You may be able to receive financial support through the Acthar Patient Assistance Program

- Mallinckrodt provides Acthar at no cost to eligible patients with a valid, on-label prescription for Acthar who have no insurance, are underinsured, or are rendered uninsured
- Your Case Manager will transfer you to the Acthar Patient Assistance Program to determine eligibility\*
- This program is administered via a third-party organization

#### Terms and Conditions:

- The Acthar Commercial Co-pay Program provides drug co-pay assistance of up to \$25,000 per calendar year for each eligible patient
- This program is valid for eligible privately and commercially insured patients. Uninsured patients are not eligible for this program
- This program is not valid for prescriptions for which payment may be made in whole or in part under federal or state health programs, including, but not limited to, Medicare or Medicaid, or where prohibited by law
- Patient must have a valid Acthar prescription for an FDA-approved, on-label indication
- Patient must be a permanent US resident. This program is not valid outside of the United States
- Patient (or patient's legal representative) must be 18 years of age or older to opt in to program
- This program offer is limited to 1 membership per person and is not transferable
- Patients should consult their insurance provider concerning any limitations that may apply to this program under their insurance policy
- This program does not constitute prescription drug coverage or insurance and is not intended to substitute for such coverage
- Patients are responsible for any co-payment or coinsurance costs above and beyond the program's annual maximum benefit
- Absent a change in Massachusetts law, effective July 1, 2019, the Acthar Commercial Co-pay Program will no longer be valid for residents of Massachusetts
- Mallinckrodt ARD, Inc. reserves the right to terminate or modify this program at any time without notice

#### \*Acthar Patient Assistance Program eligibility criteria:

- Valid Acthar prescription for an FDA-approved indication
- Permanent US resident
- Household income at or below 700% of the Federal Poverty Level
- Patients may be subject to random income verification to determine eligibility

## How Acthar may help you

Acthar is an FDA-approved injectable medication. It is used to treat a number of rheumatic conditions. In some patients, Acthar may help fight inflammation.

**Acthar may be added to your current treatment plan when additional symptom relief is needed**



**Acthar has been shown to help some patients manage their symptoms.** This includes patients who were taking other treatments for their condition. If you have DM-PM or lupus, your doctor may be able to lower your steroid dose with Acthar.

## SELECT IMPORTANT SAFETY INFORMATION

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

- Eye infections, such as ocular herpes simplex
- Had recent surgery
- Stomach ulcers or a history of stomach ulcers
- Heart failure
- Uncontrolled high blood pressure

**8 Please see additional Important Safety Information on pages 12-13 and throughout this guide, and accompanying full Prescribing Information.**

### Suggested questions to ask your doctor during your next appointment:

How often will I take Acthar?

### What is my Acthar dose?

### What should I do if I experience side effects?

How can I tell if my treatment is working?

### How do I get a refill of Acthar?

### When should I schedule a follow-up doctor visit?

**List additional questions you may want to ask your doctor:**

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## How Acthar may work\*



**Acthar is not a steroid.** It's believed to work differently than steroids. Its active ingredient is ACTH, a natural hormone. Acthar is designed to work by helping your body produce its own natural hormones.

**\*The exact way Acthar works in the body is not fully understood. Further studies are being carried out. The above information is based on lab and scientific data, and how it relates to patient benefits is not completely known.**

## SELECT IMPORTANT SAFETY INFORMATION

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

The most common side effects of Acthar are similar to those of steroids. They include:

- Fluid retention
- High blood sugar
- High blood pressure
- Behavior and mood changes
- Changes in appetite and weight

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



## IMPORTANT SAFETY INFORMATION

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

- A skin condition called scleroderma
- Bone density loss or osteoporosis
- Any infections, including fungal, bacterial, or viral
- Eye infections, such as ocular herpes simplex
- Had recent surgery
- Stomach ulcers or a history of stomach ulcers
- Heart failure
- Uncontrolled high blood pressure
- Allergies to pig-derived proteins
- Have been given or are about to receive a live or live attenuated vaccine
- Suspected congenital infections (in children under 2 years of age)
- If you have been told that you have Cushing's syndrome or Addison's disease

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

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

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

### Acthar and corticosteroids have similar side effects.

- 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
- 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
- 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
- You might develop high blood pressure, or retain too much fluid. As a result of this, your doctor may recommend some changes to your diet, such as eating less salt and 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

- 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 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
- 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. Signs of allergic reaction are:
  - Skin rash and itching
  - Swelling of the face, tongue, lips, or throat
  - Trouble breathing
- 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 on becoming pregnant

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

The most common side effects of Acthar are similar to those of steroids. They include:

- Fluid retention
- High blood sugar
- High blood pressure
- Behavior and mood changes
- Changes in appetite and weight

Specific side effects in children under 2 years of age include:

- Increased risk of infections
- High blood pressure
- Irritability
- Symptoms of Cushing's syndrome
- Thickening of the heart muscle (cardiac hypertrophy)
- Weight gain

The above side effects may also be seen in adults and children over 2 years of age.

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

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](http://www.fda.gov/medwatch)**. You may also report side effects by calling **1-800-778-7898**.



## Notes

## Helpful websites and organizations

These sites can help you find more information about your condition, along with support groups and other services.

## Dermatomyositis-Polymyositis (DM-PM)

The Myositis Association  
**www.myositis.org**

## Systemic Lupus Erythematosus (lupus)

Lupus Foundation of America (LFA)  
**www.lupus.org**  
Lupus Research Alliance (LRA)  
**www.lupusresearch.org**

## Psoriatic Arthritis (PsA)

National Psoriasis Foundation  
**[www.psoriasis.org/about-psoriatic-arthritis](http://www.psoriasis.org/about-psoriatic-arthritis)**

## Rheumatoid Arthritis (RA)

The Arthritis Foundation  
**www.arthritis.org**  
 American College of Rheumatology  
**www.rheumatology.org/I-Am-A/Patient-Caregiver**

## Ankylosing Spondylitis (AS)

Spondylitis Association of America  
**[www.spondylitis.org/Ankylosing-Spondylitis](http://www.spondylitis.org/Ankylosing-Spondylitis)**

**For even more resources, visit [ActharRheumatology.com](http://ActharRheumatology.com).**





Get more information about Acthar and helpful support resources. Visit [ActharRheumatology.com](http://ActharRheumatology.com).

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