What is Acthar?

H.P. Acthar® Gel (repository corticotropin injection) is a prescription add-on medicine for 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. Acthar is also used for flares or on a regular basis (maintenance) in people with dermatomyositis or polymyositis (DM-PM) and systemic lupus erythematosus (lupus). Acthar is also used for symptomatic sarcoidosis. Acthar is also for people with severe acute and chronic allergic and inflammatory conditions affecting different parts of the eye. This can include the front part of the eye such as the cornea and iris, or the back part of the eye such as the optic nerve and retina.

Selected Important Safety Information

• 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

Please see additional Important Safety Information on pages 14-15 and the accompanying full Prescribing Information.
Acthar can be used to help many conditions

Acthar is a prescription medicine that is FDA-approved to help manage the following conditions. Acthar can be added to other medicines temporarily to help manage symptoms when they suddenly get worse (or flare) in people with:

- Psoriatic arthritis
- Rheumatoid arthritis, including juvenile rheumatoid arthritis (some patients may require low-dose ongoing therapy)
- Ankylosing spondylitis

Acthar can also be used when symptoms suddenly get worse (or flare), or on a regular basis (as maintenance), in people with:

- Dermatomyositis or polymyositis (DM-PM)
- Systemic lupus erythematosus (lupus)

Acthar can also be used to treat people with symptomatic sarcoidosis. Acthar can also be used for people with severe acute and chronic allergic and inflammatory conditions affecting different parts of the eye. This can include the front part of the eye such as the cornea and iris, or the back part of the eye such as the optic nerve and retina.

Selected 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.

Please see additional Important Safety Information on pages 14-15 and the accompanying full Prescribing Information.
What kind of medicine is Acthar?

Acthar is not a steroid. Acthar contains the hormone ACTH, which stands for adrenocorticotropic (a-DRE-no-cor-ti-co-tro-pic) hormone. ACTH occurs naturally in your body and is known as a melanocortin protein.

Acthar is given as an injection under the skin (subcutaneously) or in the muscle (intramuscularly) as directed by your doctor. The dose and frequency of injections depend on the rheumatic condition being treated and will be determined by your doctor.

Only your doctor can determine if Acthar is right for you.

How is Acthar believed to work?*

Acthar is believed to assist your immune system to treat your condition. It works by helping your body produce its own natural steroid hormones.

Acthar may work directly with your body to impact inflammatory and immune processes.

*While the exact way Acthar works in the body is unknown, further studies are being conducted. This information is based on laboratory data and how it relates to patient benefits is unknown.

What can I expect with Acthar?

- Everyone is different, so responses to treatment will vary
- Continue to take Acthar as your healthcare provider prescribed, even if you feel better
- Contact your healthcare provider regarding any questions you have about your treatment

What are the most common side effects?

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. You may also report side effects by calling 1-800-778-7898.
Taking Acthar

How is Acthar taken?

- Acthar is an injection that is given under the skin (subcutaneously) or in the muscle (intramuscularly) as directed by your doctor.
- Acthar should never be given intravenously (into a vein) or by mouth.
- Acthar can be used when and where it is best for you. You can give it to yourself or it can be given by a friend, family member, caregiver, or your healthcare provider.
- Your doctor will advise you on how and where to inject Acthar and what the appropriate dose is for you.

How do I learn how to take Acthar?

- Your doctor will show you how to inject Acthar.
- You can have a licensed nurse visit you at home, work with you online, or speak to you by phone to teach you how to inject Acthar. The maker of Acthar offers this service at no cost to you.
- 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 (see Getting Started on Acthar on page 12).
  - 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 inject. (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 taking Acthar.

Selected Important Safety Information

- 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.

If you are interested in Acthar Injection Training, ask your doctor or contact the Acthar Support & Access Program (A.S.A.P.) at 1-888-435-2284, Monday-Friday 8 AM–8 PM ET and Saturday 9 AM–2 PM ET.

Please see additional Important Safety Information on pages 14-15 and the accompanying full Prescribing Information.
Taking Acthar

How is Acthar stored?

• Acthar should be kept refrigerated (36°F-46°F or 2°C-8°C) between uses.
• Acthar is a gel when refrigerated and changes to liquid form at room temperature. Acthar must be brought to room temperature by rolling the vial between your hands before the injection is given.

What if I miss a dose of Acthar?

• Talk with your doctor as soon as you realize that you missed a dose.
• Your doctor will let you know when to take the next dose.
• If you have questions about your Acthar dose, talk to your doctor.

Store Acthar in the refrigerator

Can I take other medications while taking Acthar?

• Continue taking your other treatments as prescribed by your doctor.
• Tell your doctor about any other health conditions you may have or medicines you are taking, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Selected Important Safety Information

• 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.

For answers to questions about how to take or store Acthar, contact Mallinckrodt Product Monitoring and Medical Information at 1-800-778-7898.
Is there financial assistance for Acthar?

The Acthar Support & Access Program (A.S.A.P.) is a no-cost program that helps you get all the information you need about cost, insurance coverage, and home delivery.

A.S.A.P. works directly with your insurance company to help you get the best coverage at the lowest possible co-pay.

A.S.A.P. helps identify sources of financial assistance, including:

- $0 co-pay per dispense of Acthar for eligible patients with commercial and private insurance
- Offering Acthar at no cost for eligible uninsured and underinsured patients*

To learn more about A.S.A.P., visit www.Acthar.com or call 1-888-435-2284. Representatives are available Monday through Friday, 8 AM–8 PM and Saturday, 9 AM–2 PM ET.

*Program administered via a third-party organization.

ACTHAR SUPPORT & ACCESS PROGRAM
A.S.A.P.

For financial assistance or patient support, contact A.S.A.P. at 1-888-435-2284 or visit www.Acthar.com

Acthar Commercial Co-pay Assistance Program Terms and Conditions

- The Acthar Commercial Co-pay Program provides drug co-pay assistance of up to $25,000 per calendar year for eligible patients
- This program is valid for eligible, privately and commercially insured patients. For more details about the eligibility criteria, see below
- 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
- This program is not valid for uninsured patients
- Program offer is limited to one membership per person and is not transferrable
- Patients should consult their insurance provider concerning any limitations that may apply to this program under their insurance policy
- The program does not represent 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
- Void where prohibited by law
- Not valid outside the United States
- Mallinckrodt ARD, Inc. reserves the right to terminate or modify this program at any time without notice

Eligibility Criteria for Acthar Commercial Co-pay Assistance Program

- FDA-approved or on-label indication
- US permanent resident
- Patient (or patient’s legal representative) must be 18 years of age or older to opt in to program
- Commercially or privately insured
- Not insured by a federal or state healthcare plan or where prohibited by law
How do I get started on Acthar?

You can only get Acthar through a Specialty Pharmacy that will arrange delivery directly to you.

Here’s what happens when you are prescribed Acthar (if your doctor chooses not to work through A.S.A.P., please contact his or her office):

- You receive a welcome call from A.S.A.P.
  - If you miss the call, please call back toll-free at 1-888-435-2284
- A.S.A.P. discusses cost, coverage, and injection training with you
- An Acthar Starter Kit arrives at your home
- Your Specialty Pharmacy calls to schedule delivery
  - Required: 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

Ask your doctor about enrolling in **Acthar Injection Training**

5 steps to getting your medication in hand:

1. **Your doctor sends your Acthar prescription to A.S.A.P.**
2. A.S.A.P. works with your insurance company and an independent, in-network Specialty Pharmacy to ensure delivery of Acthar directly to you
3. You may receive a call from A.S.A.P. for information
4. The Specialty Pharmacy calls you to schedule delivery of your medication and track its shipment
5. Acthar is delivered to your door
**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 problems, such as ocular herpes simplex
- Had recent surgery
- Stomach ulcers or a history of stomach ulcers
- Heart failure
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- 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
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- Irritability
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- 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.**

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Getting Started With Acthar

For help managing symptoms in multiple rheumatic conditions

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