Acthar is a prescription medicine for the reduction of proteinuria in people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or that due to lupus erythematosus (lupus).

SELECT IMPORTANT SAFETY INFORMATION

Acthar is injected beneath the skin or into a muscle. It should never be injected into a vein.

You should NOT take Acthar before talking to your doctor if you have any of these conditions:
A skin condition called scleroderma, bone density loss, any infections, herpes simplex of the eye, had recent surgery, stomach ulcers or history of stomach ulcers, heart failure, uncontrolled high blood pressure, have been given, or are about to receive, a live or live attenuated vaccine, or have allergies to pig-derived protein. Tell your doctor if you are pregnant or plan on becoming pregnant.

Please see additional Important Safety Information throughout this brochure.
Please see accompanying full Prescribing Information.
Welcome to treatment with Acthar.

Acthar is an FDA-approved medication your healthcare provider prescribed to help treat your proteinuria due to nephrotic syndrome for a chance at remission.

Starting a new medicine can often mean lots of calls and paperwork. An Acthar Care Counselor will contact you to help navigate the process with you as quickly as possible. This support, offered at no cost to you, will help:

- Check your insurance coverage for Acthar
- Work with your healthcare provider to get insurance approvals that are often required
- Make you aware of special programs you can use, such as co-pay assistance
- Work with the Specialty Pharmacy to arrange delivery of Acthar to you

You also have access to a 24-hour nurse help line through ActharPACT (1.877.546.PACT).

See page 15 of this brochure for more details.
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
- Eye infections, such as ocular herpes simplex
- Had recent surgery
- Stomach ulcers or a history of 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.
About Proteinuria

What is nephrotic syndrome?

Nephrotic syndrome ("nef-rah-tik sin-drohm") is a condition that describes a group of signs and symptoms that often occur together in the kidneys. The kidneys are an important organ in your body because they help filter materials from your blood. When they are not working properly, different symptoms can occur.

The most common signs and symptoms of nephrotic syndrome are:

- **Proteinuria**: high amounts of protein in the urine
- **Hypoalbuminemia**: low amounts of albumin, a type of protein, in the blood
- **Edema**: a buildup of fluids in body tissues or skin that can cause swelling
- **Hyperlipidemia**: a high blood level of lipids, or cholesterol

Acthar is a prescription medicine for the reduction of proteinuria in people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or that due to lupus erythematosus (lupus).

What is proteinuria of nephrotic syndrome?

Proteinuria ("proh-teen-yoo-ree-uh") is a condition that occurs when the filters in your kidneys do not work properly, causing protein to “leak” into your urine. These filters are found in the glomeruli ("gloh-mair-yoo-lie") and are made of interlocking fingerlike structures known as podocytes ("poh-doh-sights").

Podocytes: fingerlike structures that make up the filters in your kidney. In proteinuria, gaps between podocytes become larger, allowing blood proteins to escape into the urine

Podocytes keep in important materials your body needs, and allow waste to pass through the small pores. In people with proteinuria, the structure of the podocytes is changed so blood proteins—normally too big to pass through—escape and “spill out” into the urine. While having some protein in the urine is normal, too much for too long can be a warning sign of a more serious problem.
What are some of the signs and symptoms of proteinuria?

- Foamy-looking urine
- Swelling of the face or ankles
- Weight gain
- Fatigue

It is important to remember that Acthar is indicated to treat excess protein in the urine; it is not indicated to treat other symptoms of nephrotic syndrome.

**Proteinuria of nephrotic syndrome can be associated with a variety of conditions including:**

- Membranous nephropathy (MN)
- Focal segmental glomerulosclerosis (FSGS)
- Minimal change disease (MCD)
- IgA nephropathy (IgAN)
- Lupus nephritis (LN)

Acthar can be used to treat proteinuria that occurs when you have one of these kidney conditions. If you have proteinuria, you and your doctor should work together to create a plan that may help lower the level of protein in your urine.

**SELECT IMPORTANT SAFETY INFORMATION**

**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
About Acthar

What is Acthar?

H.P. Acthar® Gel (repository corticotropin injection), commonly known as Acthar, is a prescription medication. Acthar was FDA approved in 1952 for multiple conditions, including proteinuria due to nephrotic syndrome.

Acthar is indicated to reduce proteinuria in people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or due to lupus, giving them a chance at remission.

Acthar is:
- FDA approved to reduce proteinuria in nephrotic syndrome
- Medicine that contains adrenocorticotropic hormone (ACTH), a naturally occurring hormone produced in your body
- Not a steroid

Why has my healthcare provider prescribed Acthar for me?

After your discussions together, your healthcare provider reviewed your individual medical assessment and determined that Acthar is an option for the treatment of your proteinuria. The goal of treatment is to lower levels of protein in your urine.

Only your healthcare provider can determine if Acthar is right for you. It is important to follow Acthar treatment as prescribed by your healthcare provider.
How does Acthar work?*

Acthar is not a steroid, and is thought to work differently than steroids. Acthar is believed to work by helping your body produce its own natural steroid hormones. Natural steroid production helps your body regulate inflammation.

Acthar is also believed to work with your immune system throughout various parts of your body, including in your kidneys.

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

Acthar may also work by helping your body make its own natural steroid hormones

*While the exact way that 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 benefit is unknown.

SELECT IMPORTANT SAFETY INFORMATION

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

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
How do I administer Acthar?

- Acthar is an injection that can be given either:
  - Under the skin (subcutaneously)
  - Or into the muscle (intramuscularly)
- Acthar can be taken when and where is best for you; it can be self-injected or given to you by a friend, family member, or caregiver, as well as your healthcare provider
- Acthar is designed to provide a prolonged release of medication once it has been injected

Your healthcare provider will describe how to correctly inject Acthar and tell you what dose is appropriate for you.

See page 14 to learn about how Home Injection Training Services are available to help you with injecting Acthar.

**Do not stop taking Acthar without speaking with your healthcare professional.**

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**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
- 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
What can I expect with Acthar?

- Acthar may lower the amount of protein in your urine to a more normal level; it will not cure your condition.
- Everyone is different, so response to treatment will vary.
- Remember to continue to take Acthar exactly as prescribed, even if you feel better. Only your healthcare provider can determine when or if it is appropriate to change your treatment.

Contact your healthcare provider with any questions you have about treatment.

It is important to work with your doctor to set and understand treatment goals. You can write down and track goals in your Treatment Journal.

What is important to know about Acthar?

- Acthar is a medicine that affects the immune system, and therefore patients may be more likely to get new infections, or inactive infections may become active.
- Common side effects of Acthar can be similar to those seen with steroid medicines and may include:
  - Fluid retention
  - Changes in blood sugar
  - Increased blood pressure
  - Behavior or mood changes
  - Increased appetite
  - Weight gain

Remember that sometimes you need to be patient. Everyone responds to treatment differently. It is very important to communicate with your doctor and the rest of your healthcare team.

—Shari, Acthar patient with minimal change disease
What if I miss a dose of Acthar?

If you have missed a dose or taken more than prescribed, contact your healthcare provider for instructions about how to take your next dose of Acthar.

Can I take other medications while taking Acthar?

- Tell your healthcare provider about any other medications including over-the-counter medications and herbal supplements you are taking, and he or she will instruct you on any changes you will need to make with them
- Continue taking your other treatments as prescribed by your healthcare provider

How should I store Acthar?

Acthar should be kept refrigerated (36°F–46°F or 2°C–8°C) between uses. Acthar is a gel when refrigerated, but changes to liquid form at room temperature. Remember to only inject Acthar once it has reached room temperature; this will help make the injection more comfortable for you.

Can I travel with Acthar?

If you will be traveling, it is important that your Acthar medication is kept refrigerated at all times. You should also remember to:

- Stay on your regular injection schedule
- Plan how many doses you will need during travel. Bring an extra dose in case your itinerary changes
- Carry a list of your updated medications, doctors, and emergency contacts
- Pack all of your supplies together in your carry-on to ensure you always have your medications with you

Check with TSA before you fly to make sure that you are carrying Acthar on the plane according to TSA regulations. Visit the TSA website at tsa.gov or call TSA Cares at 1.855.787.2227.

You can find out more about your condition and Acthar treatment at Acthar.com/NephPatients
Can I get financial assistance for Acthar?

The Acthar Support & Access Program (A.S.A.P.) was created because getting help working with your insurance company and paying for medication is sometimes needed. A.S.A.P. works directly with your healthcare provider and insurance company to help try to secure the best coverage with the lowest possible co-pay.

A.S.A.P. was created to help ensure that all eligible patients who need Acthar can get it.

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.
- 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.

Please see additional Important Safety Information throughout this brochure.
Please see accompanying full Prescribing Information.
Acthar Support & Access Program (A.S.A.P.)

A.S.A.P. is a no-cost resource provided to patients that:

- Contacts your insurance company to help try to secure the best insurance at the lowest possible co-pay
- Helps ensure that Acthar is sent directly to your home as fast as possible

A.S.A.P. helps make Acthar affordable for patients by identifying sources of financial assistance including:

- $0 co-pay for eligible patients with commercial or private insurance*
- Acthar offered at no cost for eligible uninsured and underinsured patients†
- Other sources of financial assistance for qualified patients in need‡

To learn more about A.S.A.P., or to see if you are eligible for financial assistance, visit Acthar.com/ASAP or call A.S.A.P. at 1.888.435.2284.

$0 CO-PAY for qualified patients with commercial or private insurance*

*A.S.A.P. Terms and Conditions:
- The Acthar Commercial Co-pay Assistance 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 transferable
  - 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:
- Approved 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

†Programs are administered via a third-party organization.
‡Programs are administered via an independent charitable organization.
Please see additional Important Safety Information throughout this brochure.
Please see accompanying full Prescribing Information.

Quick Reference: Getting your medication

Your healthcare provider sends your Acthar prescription to A.S.A.P.

A.S.A.P. works with your insurance company and a Specialty Pharmacy

You receive a call
- A.S.A.P. may call for information
- The Specialty Pharmacy will call to schedule delivery

Acthar is delivered to your door

If you do not receive a call from the Specialty Pharmacy within 3 days, please contact A.S.A.P. at 1.888.435.2284.

A.S.A.P. helped coordinate financial assistance to get Acthar. It was a huge relief. It definitely takes a load off your mind.
—Don, Acthar patient with focal segmental glomerulosclerosis

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
Home Injection Training Services

You can have a licensed nurse visit you at your home to provide Home Injection Training Services and answer any questions about administration.

This service is provided at no cost to patients and caregivers, and can be repeated if needed. To find out more about free Home Injection Training Services, you or your caregiver can call A.S.A.P. at 1.888.435.2284.

I was a little nervous about injecting myself. A home injection training nurse walked me through the process; she was very professional and knowledgeable.

—Kerean, Acthar patient with idiopathic membranous nephropathy

SELECT IMPORTANT SAFETY INFORMATION

What are the most common side effects of Acthar? (continued)

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

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

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

These are not all 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.

Please see accompanying full Prescribing Information.
Personalized Nurse Support with ActharPACT

ActharPACT (Patient and Acthar Coaching Team) offers you access to a 24-hour nurse help line, plus helpful treatment reminders—all at no cost.

- By signing up, you can:
  - Talk to a trained nurse about Acthar treatment and any challenges that may come up
  - Get a personal nurse coach who can answer your questions and connect you to the right resources
  - Get suggestions to problem-solve and stay motivated throughout your treatment
  - Receive individualized mailings with helpful tips

To sign up for ActharPACT, visit ActharPACT.com or call 1.877.546.PACT (7228).

ActharPACT provides you with encouragement and support throughout your time on Acthar, even before you begin treatment.

—Don, Acthar patient with focal segmental glomerulosclerosis
Find out more at Acthar.com/NephPatients