

# FDA-APPROVED FOR REDUCTION OF EXCESS URINARY PROTEIN DUE TO NEPHROTIC SYNDROME

Relief is  
possible with  
Acthar® Gel

Ask your doctor if  
Acthar Gel may be  
right for you



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

## What is Acthar Gel?

Acthar Gel 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).

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 **injectable medication that is FDA-approved for reduction of excess urinary protein (proteinuria) in people with nephrotic syndrome.**

**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.

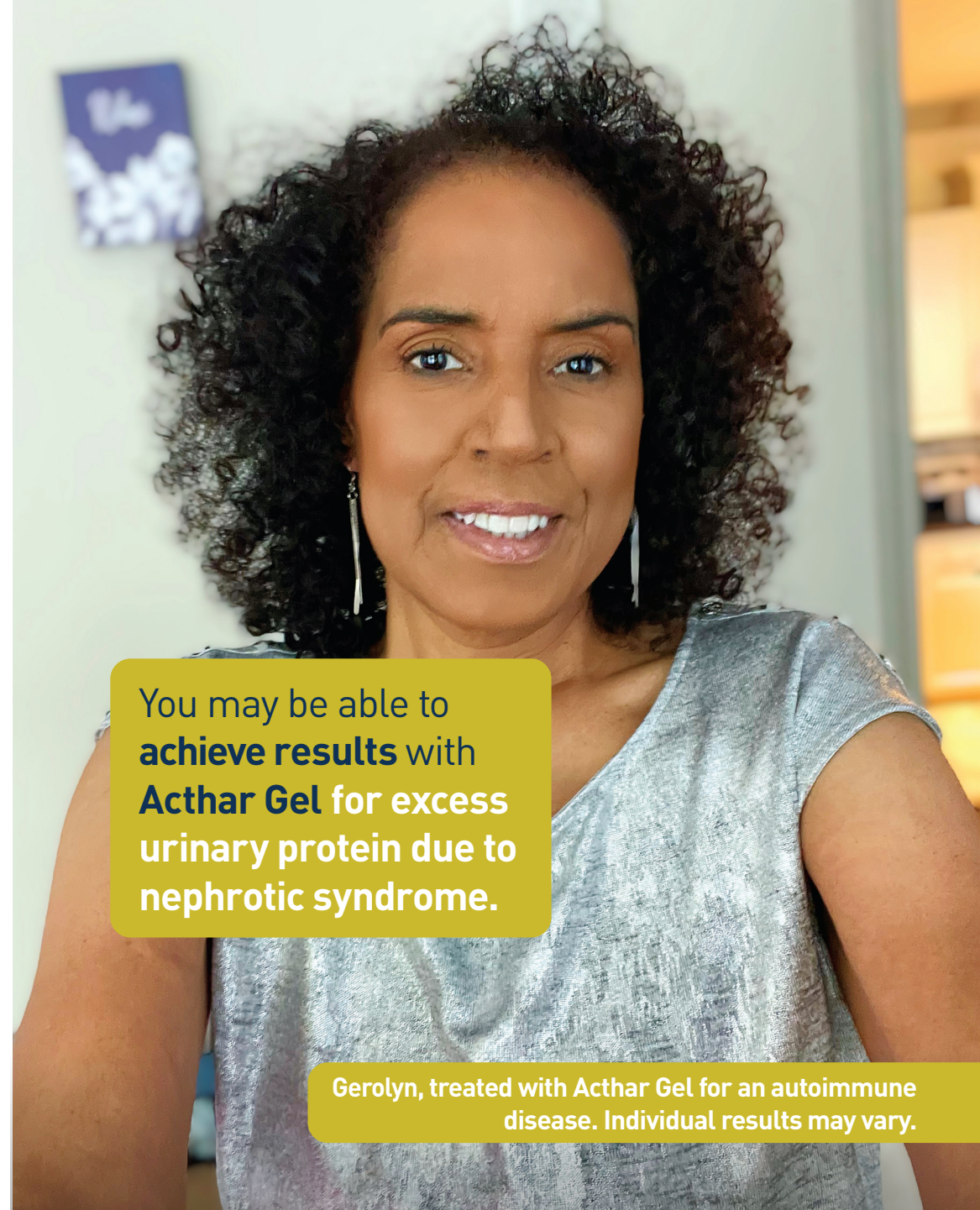
### **SELECT IMPORTANT SAFETY INFORMATION**

**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](#).



You may be able to **achieve results** with **Acthar Gel for excess urinary protein due to nephrotic syndrome.**

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

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## In this brochure, you will learn:

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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.



Talk to your doctor to find out if Acthar Gel is right for you.

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

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## Excess protein in the urine may be a sign of kidney damage

The kidneys normally filter waste and extra water from the blood, which become urine. When the kidneys' filtering units are inflamed, they can't clean the blood properly and essential proteins leak into the urine along with the waste.

When this happens, it may be accompanied by a group of symptoms called nephrotic syndrome.

**Signs and symptoms of nephrotic syndrome can vary from person to person, but commonly include:**



Fatigue



Weight gain



Loss of appetite



Swelling in legs, feet or ankles



Foamy urine

### 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

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

## Many diseases and conditions can trigger kidney damage and excess protein in the urine

Nephrotic syndrome may be associated with diseases that directly affect the kidneys, as well as some generalized conditions.

**FSGS (focal segmental glomerulosclerosis)** is one condition associated with nephrotic syndrome. FSGS is a condition in which there is injury to cells in the kidney filters (glomeruli) for unknown or poorly understood reasons. Severe cases of FSGS can eventually cause permanent damage or kidney failure.

**IgA nephropathy** is a condition in which an antibody produced by the immune system (IgA) to fight infection collects in the kidney tissue. This can cause inflammation and damage to the kidney tissues, leading to blood and excess protein in the urine. The exact cause of IgA nephropathy is unknown, but it can run in families. The immune system's response to respiratory or intestinal infections may also play a role. People with more severe cases of IgA nephropathy may develop end-stage renal disease or kidney failure.

Nephrotic syndrome can also occur in membranous nephropathy, minimal change disease, membranoproliferative glomerulonephritis (MPGN), fibrillary glomerulonephritis (FGN) and other glomerular disorders.

**If you've been living with one of these conditions and are still experiencing excess protein in your urine, there may be a treatment that can help.**

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## What is Acthar® Gel?

Acthar Gel is an injectable medication that is FDA-approved for reduction of excess urinary protein (proteinuria) in people with nephrotic syndrome.\*



John, treated with Acthar Gel.  
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

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

### Acthar Gel is not a steroid

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. It is not based on clinical studies done with people who took Acthar Gel. How the information relates to patient benefits is unknown.

\*Of unknown origin without accumulation of urea in the blood (uremia) due to malfunctioning kidneys or that due to lupus.

- 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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## Excess protein in the urine may be a sign of kidney damage

Urinary protein levels were reduced in most people who developed FSGS after transplant

20 patients with new or recurring FSGS after kidney transplant were treated with Acthar Gel (typically 80 units twice a week) for at least 6 months

**62%** reduction in average urinary protein levels

**50%** of patients (10/20) achieved complete or partial remission\*

Eight people in the study ultimately experienced failure of the kidney transplant. Five of those were due to new or recurring FSGS. One person died during treatment, and 2 people died after treatment with Acthar Gel.

\*Complete remission was defined as a decrease in the ratio of urine protein to creatinine levels (a standard measure of proteinuria) to 1 g/g or less with stable kidney function. Partial remission was defined as a decrease to between 1 and 3.5 g/g with stable kidney function.

There were limits to these relatively small and shorter studies. People may have been taking other treatments before and along with Acthar Gel. The exact role Acthar Gel had in the improvements seen is not known.

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

## In another study, urinary protein decreased for most patients with nephrotic syndrome due to a range of causes

In an unblinded study of 37 patients with a range of causes of nephrotic syndrome<sup>‡</sup> who completed 6 months of treatment with Acthar Gel

**57%** of patients (21/37) achieved complete or partial remission<sup>§</sup>

Approximately 30% (13/44) patients who started (but did not necessarily complete) the study experienced side effects during treatment with Acthar Gel. Side effects included weight gain, increased swelling, hypokalemia, hyperglycemia, seizures, decreased bone mineralization, high blood pressure, fatigue, dizziness, and upper respiratory infection. Seven patients stopped taking Acthar Gel early due to treatment-related side effects; they were not included in the study results reported here

<sup>§</sup>Complete remission (4 patients) was defined as a urine protein to creatinine ratio less than 500 mg/g. Partial remission (17 patients) was defined as  $\geq 50\%$  reduction in proteinuria from baseline and final proteinuria 500 – 3500 mg/d.

<sup>‡</sup>Causes of nephrotic syndrome included: FSGS, idiopathic membranous nephropathy, IgA nephropathy, diabetic nephropathy, membranous nonproliferative glomerulonephritis, systemic lupus erythematosus class V membranous lupus nephritis, minimal change disease, and fibrillary glomerulonephritis.

### 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

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# How well did Acthar® Gel work in patients at high risk of disease progression?

Overall, urinary protein levels dropped substantially in people with IgA nephropathy

In an unblinded study, **19 patients** with excess urinary protein due to IgA nephropathy were **treated with Acthar Gel for 6 months and followed for 12 months**

**57%** reduction in excess urinary protein was seen among patients after 6 months of treatment with Acthar Gel

**42%** of patients (8/19) **achieved partial remission** at 12 months\*

Seven patients had an injection-related reaction, 6 had an infection, 4 muscle soreness and 3 each had acne, hot flashes, anxiety and insomnia. No patient discontinued Acthar Gel.

**There were limits to this relatively small and shorter study. People may have been taking other treatments before receiving Acthar Gel. The exact role Acthar Gel had in the improvements seen is not known.**

\*Partial remission was defined as greater than 50% reduction in proteinuria and less than or equal to 25% decrease in estimated glomerular filtration rate (eGFR) from baseline.

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

## SELECT IMPORTANT SAFETY INFORMATION

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

- 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
- 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 single 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 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.

### 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](#).

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### 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.

- 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<sup>®</sup> 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.

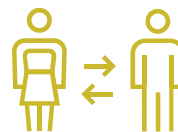


Support team member

## 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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# 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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