

Acthar[®] GEL
(repository corticotropin injection) 80 U/mL

Brandi,
treated with Acthar Gel for sarcoidosis.
Individual results may vary.

Living with a certain chronic inflammatory
or autoimmune condition?

RELIEF IS POSSIBLE



What is Acthar Gel?

Acthar Gel is a prescription medicine used for:

Dermatomyositis and Polymyositis (DM-PM)	Treatment for flares or on a regular basis (maintenance)
Systemic Lupus Erythematosus (SLE)	Treatment for flares or on a regular basis (maintenance)
Rheumatoid Arthritis (RA)	Add-on medicine for short-term administration to tide patients over an acute episode or exacerbation (selected cases may require low-dose maintenance therapy)
Symptoms of Sarcoidosis	Treatment for people with symptoms of sarcoidosis
Allergic & Inflammatory Eye Conditions • Keratitis, Uveitis	Treatment of severe acute and chronic allergic and inflammatory conditions affecting different parts of the eye
Excess Urinary Protein	Reduction of proteinuria in people with nephrotic syndrome of unknown origin or that due to lupus without accumulation of urea in the blood due to malfunctioning kidneys
Multiple Sclerosis (MS) Attacks	Treatment for adults with acute relapses or flares of MS. Studies have shown Acthar to speed relapse recovery. However, there is no evidence it affects the natural history of the disease

Please see page 8 for complete descriptions of Acthar Gel's prescribed uses.

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

Please see additional Important Safety Information on pages 8–10 and the full [Prescribing Information](#).

About Acthar® Gel

What is Acthar Gel?

Acthar Gel is a treatment for people living with certain chronic inflammatory or autoimmune conditions. It is administered as an injection. It can be given subcutaneously (under the skin) or intramuscularly (into the muscle). It's a mixture of proteins and natural hormones similar to ones that already exist in your body.



Abby,
treated with Acthar Gel
for sarcoidosis.
Individual results may vary.

Remember,

your doctor is always your best resource for information about your condition and treatment. Reach out to him or her if you have any questions.

How Is Acthar Gel Thought to Work?

Acthar Gel is not a steroid

Acthar Gel is thought to work differently from steroids. Acthar Gel interacts with melanocortin receptors and may affect cell activity relating to your condition.

Remember that Acthar Gel can have similar side effects to what you may experience with steroids.



Bianca,
treated with Acthar Gel for SLE.
Individual results may vary.

Acthar Gel is believed to work with your immune system

Acthar Gel is thought to work with the body's immune system to help reduce inflammation associated with certain chronic inflammatory or autoimmune conditions.

The way Acthar Gel works is not fully understood. Further studies are being done. The information above is based on lab and clinical data, and how it relates to patient benefits is unknown.

Visit [Acthar.com](https://www.acthar.com)

to learn if Acthar Gel could be right for you.

SELECT IMPORTANT SAFETY INFORMATION

DO NOT take Acthar until you have talked to your doctor if you have any of the following conditions (cont'd):

- Any infections, including fungal, bacterial, or viral
- Eye infections, such as ocular herpes simplex
- Had recent surgery

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With Acthar® Gel, Your Acthar Patient Every Step



1 Prescription

Once your Case Manager receives your referral (prescription) for Acthar Gel, you are automatically enrolled in the Acthar Patient Support Program. To receive the complete level of support available to you, **you may need to sign an Acthar Consent Form.** Your Case Manager will work with you to get the form signed and submitted.

2

Prior Authorizations and Appeals

Often, insurance companies require your doctor to complete an extra step before approving Acthar Gel. This is called a prior authorization. Your Case Manager will work with your doctor to submit the needed forms to your insurance company. Your Case Manager will also give you regular updates so you know what's going on during the insurance approval process.

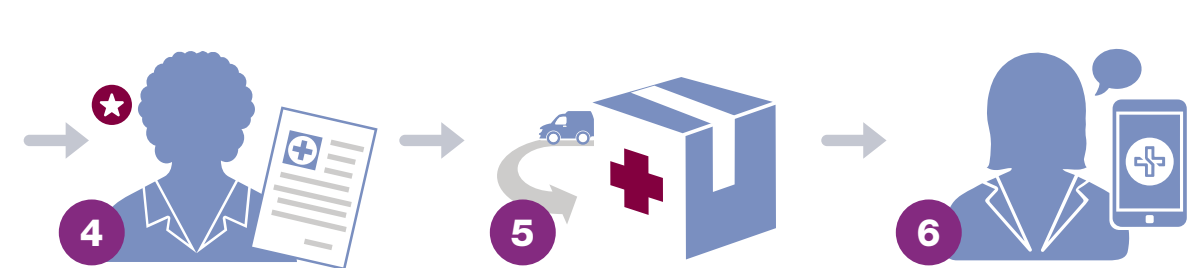
Acthar Gel may be denied for insurance coverage for any number of reasons. A denial is common. If this happens, **you have a right to appeal the decision.** Acthar Patient Support can help you and your doctor with the appeals process. Ask your Case Manager about ways that you can get involved!

3

Assistance Options

No matter what type of insurance you have, we can help you explore your coverage options. Your Case Manager will guide you through the options and programs that may be available to you and that you may qualify for. We want to help you gain access to the medicine your doctor prescribed for you.

Support Team Is by Your Side of the Way



4

Free Acthar Gel Injection Training

While your prescription is going through the approval process, your Nurse Navigator will contact you to discuss your injection training needs. They will **coordinate your training session** to take place in your home, online, or by phone. Remember, your Nurse Navigator is here to answer your questions and guide you along the way.*

*Nurse Navigators do not give medical advice and will direct you to your healthcare professional for any treatment-related questions, including further referrals.

5

Delivery

Because the way you get specialty medicines like Acthar Gel is different than going to your neighborhood drug store, we know you may have questions about how it works. Your Case Manager will let you know when your prescription has been approved. The Specialty Pharmacy will call you to set up a delivery time for when someone will be home to sign for, receive, and immediately refrigerate the medicine.

6

Ongoing Support

When it is time to refill your prescription, your Case Manager and Nurse Navigator will continue to help. As you move along your journey, your Acthar Patient Support Team will remain by your side.

For more information, visit us at [Acthar.com/acthar-patient-support](https://acthar.com/acthar-patient-support)

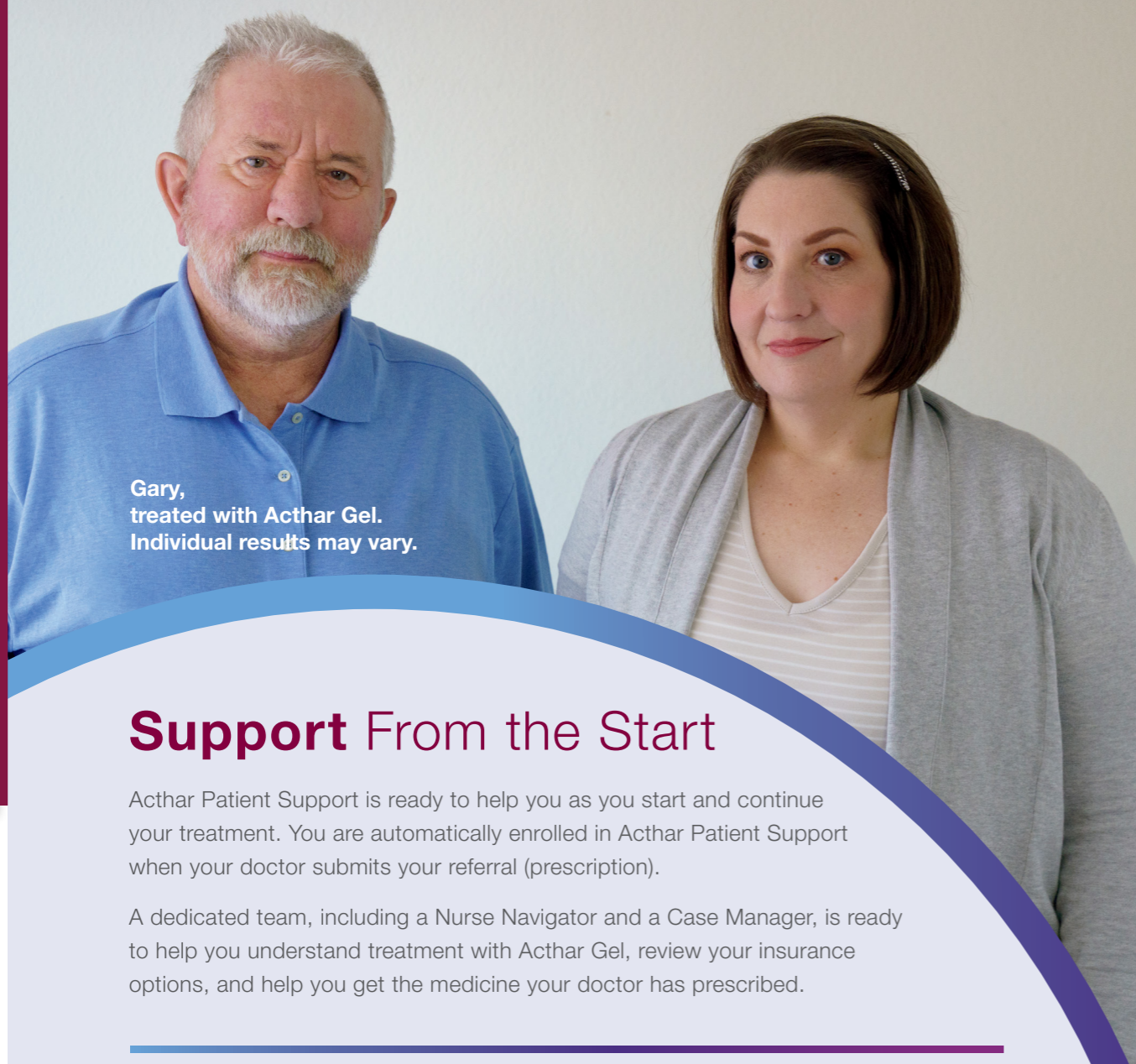
Call Acthar Patient Support at 1-888-435-2284

Monday through Friday, 8 AM to 9 PM ET

Saturday, 9 AM to 2 PM ET

Acthar® GEL
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Patient Support



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

Support From the Start

Acthar Patient Support is ready to help you as you start and continue your treatment. You are automatically enrolled in Acthar Patient Support when your doctor submits your referral (prescription).

A dedicated team, including a Nurse Navigator and a Case Manager, is ready to help you understand treatment with Acthar Gel, review your insurance options, and help you get the medicine your doctor has prescribed.

Visit [Acthar.com/financial-assistance](https://acthar.com/financial-assistance) to sign up for support and to see if you are eligible* for our \$0 co-pay offer

Co-Pay Program Terms & Conditions

*Terms and Conditions apply. This benefit covers Acthar® Gel (repository corticotropin injection). The program provides up to \$15,000 per calendar year toward the patient's Acthar Gel prescription costs. Eligibility: Available to patients with commercial prescription insurance coverage for Acthar Gel. Co-pay assistance program is not available to patients receiving any form of prescription coverage under any federal, state, or government-funded insurance program or where prohibited by law. Such programs include Medicare (including Medicare Part D and Medicare Advantage), Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs. If at any time a patient begins receiving prescription drug coverage under any such federal, state, or government-funded healthcare program, patient will no longer be able to use the Acthar Gel Copay Card and patient must call Acthar Patient Support at 1-888-435-2284 to stop participation. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Patients are responsible for any out-of-pocket costs above and beyond the program's annual maximum benefit. The offer does not constitute prescription drug coverage and is not intended to substitute health insurance. Patients who are members of insurance plans that adjust their patients' out of pocket co-pay or co-insurance responsibilities for certain prescription drugs based upon the patient's enrollment in manufacturer sponsored co-pay assistance for such drugs (often termed "accumulator" or "maximizer" programs) may be restricted from the Acthar Gel Copay Card program. Patients may not seek reimbursement for value received from the Acthar Gel Copay program from any third-party payers. Restrictions, including monthly maximums, may apply. Other Terms and Conditions apply. Offer subject to change or discontinuance without notice.

Your Partners Throughout Your Treatment Journey



Nurse Navigator

Your Nurse Navigator† will:

- Coordinate free Acthar® Gel injection training
- Help you understand your treatment journey and provide continued support
- Answer questions about your condition and guide you to support resources



Case Manager

Your Case Manager will call to explain how Acthar Patient Support may help, including with:

- Insurance coverage and financial assistance
- Co-pay or coinsurance
- Coordinating injection training
- Welcome Letter and Starter Kit Information

Have a question about injection training?

Speak to your Nurse Navigator†

†Nurse Navigators do not give medical advice and will direct you to your healthcare professional for any treatment-related questions, including further referrals.

Have a question about insurance coverage?

Speak to your Case Manager

Your Acthar Patient Support team is ready to help every step of the way.

Visit [Acthar.com/acthar-patient-support](https://acthar.com/acthar-patient-support) or call **1-888-435-2284**

to speak with your Nurse Navigator or Case Manager
Monday through Friday, 8 AM to 9 PM ET
Saturday, 9 AM to 2 PM ET†

†Please note that Nurse Navigators are not available on Saturdays.



You've got a team by your side.

Remember, **your doctor** is always your best resource for information about your condition and treatment. Reach out to him or her if you have any questions.

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Patient Support

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)
- Treatment for flares or on a regular basis (maintenance) in people with systemic lupus erythematosus (lupus)
- Add-on therapy for short-term administration (to tide patients over an acute episode or exacerbation) in: psoriatic arthritis (PsA); rheumatoid arthritis (RA), including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis
- Treatment for people with symptoms of sarcoidosis
- Treatment of 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
- 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)
- Treatment for adults with acute relapses or flares of multiple sclerosis (MS). Studies have shown Acthar to be effective in speeding recovery from an MS relapse. However, there is no evidence that it affects the ultimate outcome or natural history of the disease
- Treatment of infantile spasms in infants and children under 2 years of age

Acthar is injected beneath the skin or into the muscle.

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
- 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)

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
- 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
- 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, 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
- 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
- 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
- The effects of Acthar may be intensified if you have an underactive thyroid or cirrhosis of the liver
- 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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IMPORTANT SAFETY INFORMATION (cont'd)

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

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.

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 1-800-844-2830.


Ready to learn more?

Click here for more information about [excess urinary protein](#) and people's results after taking Acthar Gel.

SUPPORT FROM THE START

Your Acthar® Patient Support Team is ready to help as you start and continue your treatment plan.

For more information, visit [Acthar.com/acthar-patient-support](https://acthar.com/acthar-patient-support) or call 1-888-435-2284



Abby,
treated with Acthar Gel
for sarcoidosis.
Individual results may vary.

Visit [Acthar.com](https://acthar.com) to learn more about Acthar Gel

Visit [Acthar.com/financial-assistance](https://acthar.com/financial-assistance) to see if you are eligible* for our \$0 co-pay offer

*Please see Co-Pay Program Terms & Conditions on page 6.

SELECT IMPORTANT SAFETY INFORMATION

DO NOT take Acthar until you have talked to your doctor if you have any of the following conditions (cont'd):

- Stomach ulcers or a history of stomach ulcers
- Heart failure
- Uncontrolled high blood pressure

Please see additional Important Safety Information on pages 8–10 and the full [Prescribing Information](#).

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For People With Excess Urinary Protein



Don,
treated with
Acthar Gel for
proteinuria due to
nephrotic syndrome.
Individual results may vary.

What is Acthar® Gel?

Acthar Gel is a prescription medicine used 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

Please see additional Important Safety Information on pages 18–19 and the full [Prescribing Information](#).

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Acthar® Gel for People With Excess Urinary Protein

Some kidney conditions cause the protein in your blood to leak into your urine. When you have too much protein in your urine, this is known as proteinuria due to nephrotic syndrome.

About FSGS:

Some people get proteinuria due to nephrotic syndrome from a condition called focal segmental glomerulosclerosis (or FSGS). FSGS is a condition where you have scarring in the special areas of the kidney that filter the blood. It can be caused by an infection, certain medications, or other conditions. Sometimes, the cause is unknown.

If you have a more severe case of FSGS, you may have kidney damage or even kidney failure. If you've been living with FSGS and haven't found relief for your proteinuria, you're not alone. There may be a treatment that can help.

About IgA nephropathy:

Some people develop proteinuria due to nephrotic syndrome from immunoglobulin A (IgA) nephropathy. IgA is a protein that helps your body fight infections.

IgA can sometimes collect in the kidneys and cause inflammation that hurts the kidneys. This can result in blood and protein leaking into the urine.

The exact cause of IgA nephropathy is unknown, but you may be at a higher risk if you have family members with the same condition.

If you have a more severe case of IgA nephropathy, you may develop long-term kidney disease or even kidney failure. If you've been living with IgA nephropathy, you're not alone. There may be a treatment that can help.

Signs and Symptoms of Proteinuria Due to Nephrotic Syndrome

FSGS OR IgA NEPHROPATHY MAY LEAD TO:



Foamy-looking urine



Swelling in your face or ankles



Unexpected weight gain

Keep in mind that some people may not have any of these symptoms.

Visit [Acthar.com/protein](https://acthar.com/protein)
for more helpful facts about excess urinary protein,
including people's experiences with Acthar Gel.

SELECT IMPORTANT SAFETY INFORMATION

DO NOT take Acthar until you have talked to your doctor if you have any of the following conditions (cont'd):

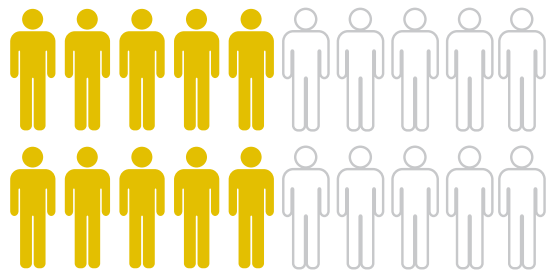
- Bone density loss or osteoporosis
- Any infections, including fungal, bacterial, or viral
- Eye infections, such as ocular herpes simplex
- Had recent surgery
- Stomach ulcers or a history of stomach ulcers

Some People With FSGS and IgA Nephropathy **Saw Improvements**

Proteinuria due to post-transplant FSGS was lowered for some people taking Acthar Gel.

A study based on a review of medical records looked at the effects of taking Acthar Gel in **20 people** with FSGS that developed after kidney transplant.

In this study,
50%



OF THE 20 PEOPLE HAD REDUCTION OF PROTEINURIA THAT MET REMISSION CRITERIA* AFTER TAKING ACTHAR GEL FOR AN AVERAGE OF 6 MONTHS

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

*Complete remission was defined as a decrease in proteinuria levels of <1 g/g with stable kidney function. Partial remission was defined as a decrease in proteinuria levels between 1 and 3.5 g/g with stable kidney function.

Some People With IgA Nephropathy Had Lowered Proteinuria After **Treatment With Acthar® Gel**

A separate study based on a review of medical records looked at whether Acthar Gel was effective in treating people with IgA nephropathy. In this study, **19 people** took Acthar Gel for 6 months and were followed for 6 months after completing the treatment.

In this study, **42%** OF THE **19 PEOPLE** HAD REDUCTION OF PROTEINURIA THAT MET REMISSION CRITERIA[†] 6 months after completing a round of treatment with Acthar Gel

No one in the study stopped participating because of side effects. There were 53 side effects reported. These included 6 infections and 7 injection-site reactions. The most common side effects from Acthar Gel were muscle soreness, acne, hot flashes, anxiety, and trouble sleeping. No one reported serious adverse events.

[†]Complete remission was defined as a decrease in proteinuria levels to <300 mg/24 h and a decrease in eGFR levels of ≤10%. Partial remission was defined as a decrease in proteinuria levels of >50% and a decrease in eGFR levels of ≤25%. No one in the study had complete remission. eGFR is short for estimated glomerular filtration rate. It is a way to measure the health of your kidneys.

There were certain limits in these studies. Acthar Gel is not a cure. Though Acthar Gel has been shown to help some people, not all people may experience the same results. Keep in mind that people in these clinical settings were on several treatments in addition to Acthar Gel. The results seen in these people may not be due to Acthar Gel.

SELECT IMPORTANT SAFETY INFORMATION

DO NOT take Acthar until you have talked to your doctor if you have any of the following conditions (cont'd):

- 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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- Eye infections, such as ocular herpes simplex
- Had recent surgery
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- 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
- 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, 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

- 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
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- 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
- The effects of Acthar may be intensified if you have an underactive thyroid or cirrhosis of the liver
- 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

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

The most common side effects for the treatment of infantile spasms (IS) are:

- Increased risk of infections
- Convulsions
- High blood pressure
- Irritability
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These are not all of the possible side effects of Acthar.

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You may also report side effects by calling 1-800-844-2830.

If you've been living with
excess urinary protein and are
still experiencing symptoms, you're not alone.
There may be a treatment that can help.

Visit [Acthar.com/protein](https://acthar.com/protein)

for more helpful facts about excess urinary protein, including people's experiences with Acthar® Gel.

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