

Learn about Acthar

What is Acthar Gel?

Acthar® Gel is a prescription medicine for the treatment of infantile spasms in infants and children under 2 years of age.

Acthar is injected into the muscle. Do not inject it into a vein, under your child's skin, or give it to your child by mouth.



SELECT IMPORTANT SAFETY INFORMATION

DO NOT give Acthar to your child until you have talked to your doctor if your child has any of the following conditions:

- Suspected infections at birth (in infants under 2 years of age)
- Has been given or is 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

Please see additional Important Safety Information on pages 12-14. Please see accompanying full Prescribing Information and Medication Guide or visit <https://www.acthar.com/Static/pdf/Acthar-PI.pdf> and https://www.acthar.com/Static/pdf/IS_Medication_Guide.pdf.

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

You have just learned your child has a condition called infantile spasms (IS) and has been prescribed Acthar. There is no doubt you have many questions about the disease and treatment for your child.

This brochure is intended to provide information about IS and how treatment with Acthar may help. It may not cover everything you want to know, so after reading this information, write down any questions you have as a reminder to ask your doctor or nurse.

Here is some Important Safety Information you should know about Acthar® Gel (repository corticotropin injection):

- Never inject Acthar directly into a vein, under your child's skin, or give it to your child by mouth
- Always inject Acthar into the muscle of your child
- 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 your child while taking Acthar
- Your child 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
- These are not all of the Warnings and Precautions for Acthar. Please see additional Important Safety Information on pages 12-14 and accompanying full Prescribing Information or visit <https://www.acthar.com/Static/pdf/Acthar-PI.pdf>. For parents and caregivers of patients with IS, please also see Medication Guide or visit https://www.acthar.com/Static/pdf/IS_Medication_Guide.pdf

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A photograph of a woman with dark hair tied back, wearing a grey t-shirt and a floral patterned top, hugging a young child from behind. The child is wearing a green long-sleeved shirt. They are outdoors in a sunlit forest with green foliage in the background. A faint rainbow is visible in the lower right quadrant of the image.

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4 INFANTILE SPASMS (IS)

What is IS?

IS is a rare and specific type of seizure disorder also known as West syndrome. IS usually begins within the first year of life. Children with IS typically have:

- A specific type of seizure (called spasms)
- A chaotic brain-wave pattern called hypsarrhythmia (hips-a-rith-me-ya)

The spasms are described as sudden, uncontrolled movements of the neck, body, arms, and legs that last only for a few seconds.

You may see the following:

- Repetitive forward head nodding or bobbing
- Bowing from the waist when sitting
- Drawing up of knees when lying down
- Extending or stiffening of the neck, trunk, arms, and legs
- Crossing arms across body as if self-hugging
- Thrusting arms to the side, elbows bent

Spasms are most common during the early morning or when your child wakes up from naps. Often, IS is mistaken for colic. Colic frequently begins at the same time each day. Children with colic will cry, tend to lift their legs repeatedly with their hands clenched, and may have a swollen stomach. It's important to speak with your doctor about your infant's spasms.

When making the diagnosis, your doctor may have taken a complete medical history and asked you to describe your child's spasms. Some parents and caregivers find it helpful to take a video of the child's spasms and record how often they happen in a journal as soon as they begin. Doctors and nurses may find this information helpful when making the diagnosis and during treatment.

Your doctor may have performed an electroencephalogram (EEG) to determine if your child has hypsarrhythmia. An EEG is a test of brain activity. Children with IS typically have EEGs that show hypsarrhythmia, a chaotic pattern of brain waves.

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What causes IS?

Once IS is diagnosed, your doctor may run several more tests to try to find out the cause of your child's IS.

In some children, no cause for IS can be found. This is called cryptogenic, or idiopathic, IS. In most cases, IS is caused by an underlying disease or injury to the brain. Causes could include central nervous system infection, abnormal brain development, or brain injury.

No matter what the cause is, it is important to find and treat IS as quickly and effectively as possible. Be sure to talk to your child's doctor about the potential effects of IS, as well as the available treatment options and when a follow-up EEG may be appropriate.

How is IS treated?

If children are thought to have IS, they may be sent to an epilepsy center to be diagnosed. Once IS is confirmed, treatment should be started as soon as possible.

The American Academy of Neurology and Child Neurology Society specify that successful treatment must stop both spasms and hypsarrhythmia.

Acthar is one clinically proven therapy that has been shown to help stop spasms and hypsarrhythmia in both children with idiopathic (cryptogenic) IS and those with symptomatic IS, including tuberous sclerosis.

The most common side effects for the treatment of IS are increased risk of infections, convulsions, high blood pressure, irritability, and fever.

**LEARN EVEN MORE ABOUT IS AND
EXPLORE HELPFUL RESOURCES AT:**

www.acthar.com/infantile-spasms/

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6 WHAT IS ACTHAR?

Acthar® Gel (repository corticotropin injection) is a Food and Drug Administration (FDA)-approved medication for IS that contains ACTH (adrenocorticotrophic hormone), a naturally occurring hormone, which has been proven to stop spasms and hypsarrhythmia in infants and children under 2 years of age with IS.

How can Acthar help?

Acthar is an FDA-approved treatment for IS that has been shown to help stop both spasms and hypsarrhythmia. Although each child will respond to Acthar differently, in a clinical study, 13 of 15 children (87%) had no spasms and no hypsarrhythmia at week 2.

Side effects such as high blood pressure and high blood sugar were monitored. Irritability and increased appetite were the most frequent side effects, but no infant had to stop or change treatment.



ACTHAR IS PROVEN TO:

- Stop spasms
- Stop hypsarrhythmia

How is Acthar given?

Acthar is injected into the muscle. It should never be injected into a vein, under your child's skin, or given to your child by mouth. Your doctor or nurse should provide detailed instructions about where to give the injection, how much to give, how often, and when to give Acthar to your child. Additionally, the Starter Kit contains a Step-by-Step Injection Guide for your reference. There's also a video you can watch at www.acthar.com/taking-acthar-gel/ to help guide you through the injection.

Contact your doctor or nurse if you have any questions about using Acthar.

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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 your child, 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.

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Supporting you from prescription through treatment

The Acthar Patient Support Team is a no-cost resource provided by Mallinckrodt Pharmaceuticals, the distributor of Acthar. The Acthar Patient Support Team provides several support services for Acthar patients. From the moment your child's doctor prescribes Acthar, you'll be supported every step of the way.

INSURANCE SUPPORT

- The Acthar Patient Support Team works directly with your child's doctor and insurance company to help determine insurance coverage and work through any plan requirements and/or approvals

ACTHAR INJECTION TRAINING

- Schedules injection training with a licensed nurse at home, online, or by phone
- Helps you get comfortable with the injection process

FINANCIAL ASSISTANCE

- The Acthar Commercial Copay Program provides patients with copay assistance up to \$15,000 per calendar year with as little as a \$0 copay. Eligible patients must have commercial or private insurance and no presence of government insurance. Please visit the Acthar Commercial Copay Assistance website at <https://www.activatecard.com/8019/> or speak to your Acthar Case Manager to see if you qualify.*
- For information on Independent Charitable Foundations that may be able to provide financial assistance for those with government insurance plans, please reach out to the Acthar Patient Support Team at 1-888-435-2284.
- The Acthar Patient Assistance Program provides Acthar Gel at no cost for eligible patients with a valid, on-label prescription who are uninsured or underinsured.^{†§}

(Please see page 11 for information about terms and conditions and eligibility criteria.)

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Around 90% of insured patients who are prescribed Acthar for IS are covered. If prior authorization paperwork is required, the Acthar Patient Support Team provides information and resources to help. You can find out more about access, reimbursement, and support at www.acthar.com/financial-assistance/

Availability and delivery

Because Acthar is available only through what is called a Specialty Pharmacy—not your local pharmacy—the Acthar Patient Support Team coordinates the shipment of Acthar to your home or to another location as chosen by you and your child’s doctor. This process can take a few days, and it is very important that you are able to be contacted for arrangements, whether by the Specialty Pharmacy team or your child’s doctor. Please be sure to provide your child’s doctor with the best phone number to reach you, and if you miss the call from the Specialty Pharmacy, call back as soon as you can.

TO LEARN MORE ABOUT THE ACTHAR PATIENT SUPPORT TEAM:

Call 1-888-435-2284

Monday through Friday, 8 AM to 9 PM ET

Saturday, 9 AM to 2 PM ET

*Co-Pay Program Terms and Conditions apply. This benefit covers Acthar Gel. 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 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.

†Mallinckrodt does not determine Independent Charitable Foundations’ fund eligibility criteria, or have any influence over the patients or types of assistance provided.

‡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

§Program administered via a third-party organization.

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12 IMPORTANT SAFETY INFORMATION

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- Has been given or is 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

Tell your doctor about any other health problems that your child has. Give your doctor a complete list of medicines your child is 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, under your child's skin, or give it to your child by mouth
- Always inject Acthar into the muscle of your child
- 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 your child while taking Acthar
- Your child 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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What is the most important information I should know about Acthar? (continued)

- When taking Acthar long-term, people's adrenal glands 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 people stop taking Acthar long-term, their bodies may not produce enough natural cortisol. This is called "adrenal insufficiency." Your doctor may prescribe a steroid medicine to protect your child until the adrenal gland recovers
- Your child 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 child's diet, such as eating less salt or taking certain supplements
- Vaccines may not work well when people are on Acthar. Talk to your doctor about which vaccines are safe to use when your child is 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 your child has stomach pains, bloody vomit, bloody or black stools, excessive tiredness, increased thirst, difficulty breathing, or increased heart rate
- Taking Acthar can make people feel irritable or depressed. They may also have mood swings or trouble sleeping. These effects are reversible once Acthar therapy is stopped
- If your child has other conditions, such as diabetes or muscle weakness, you may find they get worse
- Your child might develop certain eye conditions, such as cataracts, glaucoma, or optic nerve damage
- Your child's 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 your child has 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

14 IMPORTANT SAFETY INFORMATION (continued)

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

- Acthar may cause osteoporosis (weak bones)
- Acthar might harm an unborn baby. People should tell their doctor if they 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
- 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.

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For parents and caregivers of patients with IS, please also see accompanying Medication Guide or visit https://www.acthar.com/Static/pdf/IS_Medication_Guide.pdf.

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