

ACTHAR FOR INFANTILE SPASMS

Injection Treatment Tracker Calendar



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 page 3.
Please also see full Prescribing Information and Medication Guide at <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

Getting started

Preparing Acthar

- Remove the vial of Acthar from the refrigerator
 - Let it sit for 15 to 30 minutes to reach room temperature. You can roll it in the palms of your hands or hold it under your arm during the warming process

- Wash your hands
- For a video demonstration on how to properly inject your child, please view our injection training video at www.acthar.com/taking-acthar-gel.

Materials Needed for Injection

- Vial of Acthar Gel
- Drawing Needle (20 G)
- Injection Needle (23 G)*
- Syringe
- Alcohol Wipes
- Sterile Gauze Pad
- Sharps Container

* Please use the injection needle size as instructed by your healthcare provider.

Use the Treatment Tracker Calendar to keep track of your child's treatment schedule and progress†.

Follow the treatment schedule provided by your doctor

- The treatment calendar tracks when you gave Acthar, at what dose, and where the injection was given
- The dose may change over time, and injections are given in different parts of the thigh. It is helpful to record this information on the Treatment Tracker Calendar to share with your doctor

† The treatment calendar is an example of the most common injection schedule. Always follow your doctor's instructions.

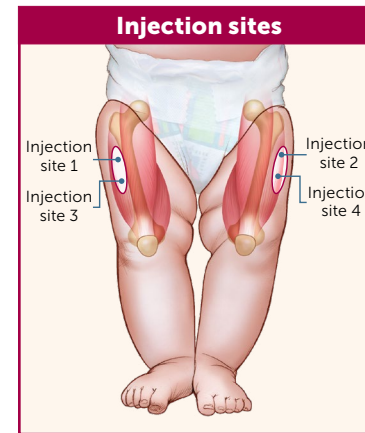
Please see Important Safety Information on page 3. Please also see full Prescribing Information and Medication Guide at <https://www.acthar.com/Static/pdf/Acthar-PI.pdf> and https://www.acthar.com/Static/pdf/IS_Medication_Guide.pdf.



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Doses	
■	Initial dose
■	Tapered dose

For step-by-step injection guide, visit: <https://www.acthar.com/taking-acthar-gel>

For help with injections or other questions, call the Nurse Navigator at 1-888-435-2284

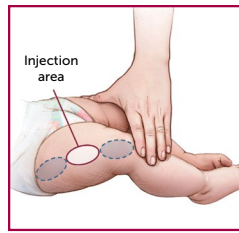
- Available Monday through Friday, 8 am to 9 pm ET

My Child's Treatment Calendar

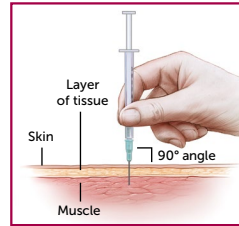
AM	1 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	2 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	3 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	4 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	5 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL
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AM	16 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	17 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	18 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	19 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	20 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL
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AM	21 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	22 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	23 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	24 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	25 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL
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AM	26 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	27 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	28 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	29 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL	30 Date: _____ Injection site (circle area) 1 2 3 4 Injection volume: _____mL
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Injection in 6 Steps

1. Lay child flat on back or hold in your lap with child's leg between yours
2. Find the thickest portion of the thigh muscle, which is the middle third (between the knee and uppermost point of the thighbone) on the outer side
3. Clean the area to be injected with an alcohol swab, let dry, then use the thumb and forefinger of the hand not holding the syringe to stretch or pinch together the skin
4. Use the 20-gauge needle to draw Acthar into syringe, replace the needle cap, detach the needle, and attach the 23-gauge needle for injection, or as instructed by your healthcare provider
5. Hold the syringe like a pencil or dart and, using a quick motion, insert the needle at a 90° angle through the skin
6. Slowly push the plunger in until the syringe is empty, then pull straight out



Do not inject into the front of the thigh; keep the injection site to the outer side of the muscle



This quick reference guide is not intended to replace the injection training that you received from your doctor or nurse. This injection summary is intended to complement, and be used in conjunction with, the Acthar Step-by-Step Injection Guide and instructional video. Remember, your doctor or nurse is always the best source of advice. You can also visit www.acthar.com/taking-acthar-gel for written injection instructions, an instructional injection video, and additional information. Prior to injecting Acthar, please refer to the full Prescribing Information and Medication Guide at <https://www.acthar.com/Static/pdf/Acthar-PI.pdf> and https://www.acthar.com/Static/pdf/IS_Medication_Guide.pdf, or the Important Safety Information in this document. Speak with your doctor about the potential side effects associated with Acthar.

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

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

- 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. Signs of allergic reaction are:
 - 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
- 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 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.

Please see full Prescribing Information for additional Important Safety Information at <https://www.acthar.com/Static/pdf/Acthar-PI.pdf>.

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

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