



Getting started with Acthar

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

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 17-19. 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

Acthar® Gel

(repository corticotropin injection) [AK-thar jel]

What is Acthar Gel?

Acthar 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

Your child should **NOT** take Acthar until you have talked to your doctor if your child has any of these 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; any infections; herpes simplex of the eye; had recent surgery; stomach ulcers or history of stomach ulcers; heart failure; uncontrolled high blood pressure; Addison's disease or Cushing's syndrome; or allergies to pig-derived proteins.

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.

While taking Acthar your child may have an increased risk of infections; increased blood pressure, salt and water retention, or low blood potassium levels; unpredictable response to vaccines; stomach or intestinal problems; changes in mood or behavior; worsening of other medical conditions; eye problems; or allergic reactions that may be severe. Acthar can cause adrenal gland changes that may result in symptoms of Cushing's syndrome including: an increase in upper body fat, rounded "moon" face, bruising easily, or muscle weakness. Acthar can affect growth and physical development in children and may cause bone density loss at any age.

Tell your doctor if your child experiences any of the above symptoms. Also tell your doctor about any other health problems your child has and about all medicines your child is taking, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Acthar may hide symptoms of other diseases. Sometimes when people stop taking Acthar, their body may not produce enough natural cortisol, called "adrenal insufficiency," and their doctor may prescribe a steroid medicine until the adrenal gland recovers. The effects of Acthar may be intensified if your child has an underactive thyroid or cirrhosis of the liver. Acthar might harm an unborn baby; people should tell their doctor if they are pregnant or plan to become pregnant.

Commonly reported side effects include injection site reaction, fatigue, physical weakness, lack of energy, fluid retention, insomnia (difficulty sleeping), headache, and 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, and 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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STEP-BY-STEP INJECTION GUIDE

Learn how to inject Acthar

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



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Getting started with Acthar

Once you receive Acthar:

1. Check the expiration date on the Acthar vial to make sure you are using it before the date listed
2. Prior to each use, check for any signs of contamination (cloudiness, small flecks, particles, etc)
3. Refrigerate Acthar as soon as you receive it and check that your refrigerator is set between 36°F and 46°F or 2°C and 8°C
4. Unopened vials that are refrigerated (36°F-46°F or 2°C-8°C) are good until the last day of the month listed for expiration on the vial. **For example, if your vial's expiration date is 10-2020, it should be discarded on October 31, 2020**
5. After a vial has been opened (the top seal has been punctured by a needle), it should be discarded after 28 days. **For example, if the date you punctured your vial was 10/1/2020, you would need to dispose of that vial on 10/29/2020**

Do not use if:

- The vial is expired
- Any signs of contamination are seen

Read this entire instruction guide before you begin your first injection and as needed prior to any injection.



To schedule one-on-one injection training, call Acthar Patient Support at **1-888-435-2284**

Monday through Friday, 8AM to 9PM ET
Saturday, 9AM to 2PM ET

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I. ORGANIZE THE INJECTION MATERIALS

You may find it useful to lay the following items on the Materials Organization Mat included in this kit as you prepare to inject Acthar:

- Vial of Acthar
- A 20-gauge needle to use for drawing the medication (or the size prescribed by your doctor)
- A 23-gauge needle for injecting the medication (or the size prescribed by your doctor)
- Syringe
- Alcohol swabs
- Sterile gauze pad
- Puncture-resistant container to safely dispose of syringe and needles after use

You will also find included in this kit the Treatment Tracker Calendar to track your child's treatment schedule and progress.

You may find it helpful to fill in the prescribed dose of medicine on your Treatment Tracker Calendar once you receive your prescription.



An injection training video is available in English online at www.acthar.com/taking-acthar-gel/.
If you have any additional questions, please contact your doctor or healthcare team.

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2. PREPARE THE INJECTION



LOT # XXXX-XX
EXP XX/XXXX



1. Take the vial of Acthar out of the refrigerator. Recheck the expiration date to make sure the vial has not expired
2. Wash your hands with soap and warm water for at least 20 seconds
3. Let the vial of Acthar get to room temperature by leaving it out for 15 to 30 minutes. You can roll it between the palms of your hands or hold it under your arm for a few minutes during the warming process
4. Remove the cap of the vial and use an alcohol swab to wipe the rubber stopper on top of the vial

Do not inject Acthar immediately after removing from the refrigerator. Let the vial warm to room temperature by leaving it out for 15 to 30 minutes.

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PREPARE THE INJECTION



5. Attach the 20-gauge needle to the syringe. Before removing the cap of the needle, draw air into the syringe by pulling the syringe plunger to the exact amount your doctor has prescribed
6. Remove the needle cap. (Save the cap—you will need to recap the needle later.) Make sure the vial is on a flat surface. Holding the vial between the



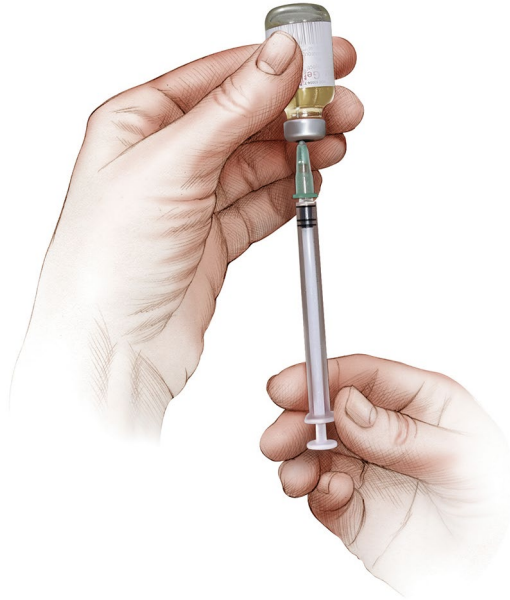
thumb and index figure, slowly insert the needle through the rubber stopper at a slight angle with the bevel facing up

Once the bevel has passed through the top of the stopper, straighten the needle and push through the stopper. Inject air into the upright vial by pushing down on the plunger until it cannot be pushed farther

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PREPARE THE INJECTION



7. While the syringe is still in the vial, turn vial and syringe upside down



8. While keeping the needle tip in the medication, slowly pull back the plunger to the exact amount your doctor prescribed

Keep needle tip in the Acthar at all times when drawing the amount your doctor prescribed.

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PREPARE THE INJECTION



9. With the tip of the syringe upright and the needle still in the vial, tap the syringe with your finger until any air bubbles rise to the top
10. If bubbles are present in the syringe, slowly press the plunger until only the bubbles are pressed out of the syringe. Check that you still have the amount your doctor prescribed in the syringe. If not, repeat Step 9 until you have your prescribed dose of medicine for injection
11. Return the vial to an upright position and place on a flat surface. Remove needle from the vial

If you used the thinner (23G) needle (or the size prescribed by your doctor) for drawing up Acthar into the syringe, continue to the section tab labeled, “Choose injection site” and learn how to inject Acthar.

Before injecting, ensure that the needle for injecting remains sterile (for example, do not place on an unclean surface).

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PREPARE THE INJECTION

If you used the wider (20G) needle to draw Acthar into the syringe

- a. Draw back the plunger to remove any medicine located in the 20G needle (or the size prescribed by your doctor for drawing up Acthar into the syringe)
- b. Using the scooping method to recap the needle, hold the syringe with the needle attached in one hand and bring the needle to the opening of the needle cap. Slip the needle into the cap without using the other hand and gently lift up
- c. When the cap is completely covering the needle, use the other hand to secure the cap to the needle
- d. Remove capped 20G needle (or the size prescribed by your doctor for drawing up Acthar into the syringe) from the syringe and place in the sharps container
- e. Keeping the syringe in your hand, open the 23G needle (or the size prescribed by your doctor for injecting Acthar) and attach to the syringe. Do not remove the needle cap

Remember, the 20-gauge needle (or the size prescribed by your doctor for drawing up Acthar into the syringe) is not for injecting. Remove and properly dispose of the 20-gauge needle before attaching the thinner 23-gauge needle to inject with.

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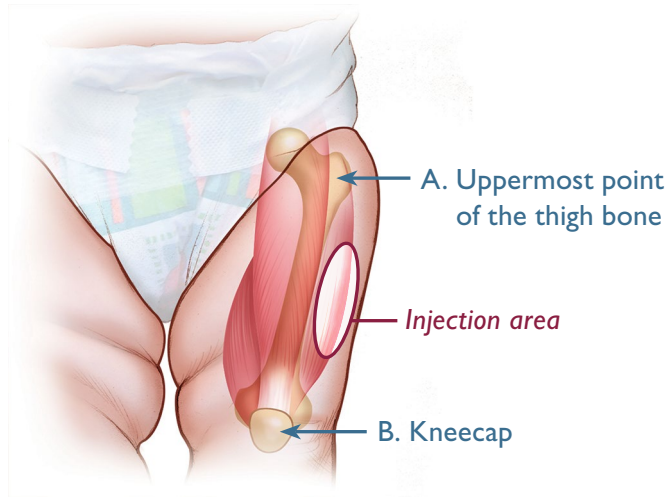
Preparation is now complete. Continue to the following sections to learn about injection sites and how to inject Acthar.

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3. CHOOSE THE INJECTION SITE



- The injection area is located on the upper outer thigh
- To locate the correct muscle, start by placing your fingertips on the middle of the thigh and gently press down to locate the thigh bone
- Run your fingers along the bone toward the hip until you feel a bony protrusion. This is the uppermost point of the thigh bone (see arrow A)
- Now locate the kneecap (see arrow B)

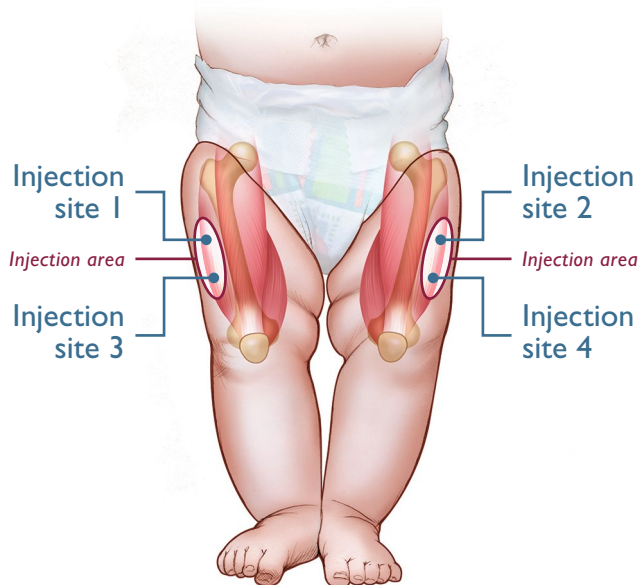
- Divide the distance between these 2 points into thirds
- The thickest portion of the muscle is in the middle third. Inject into the outer side of the middle third

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

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CHOOSE THE INJECTION SITE



Injecting the upper outer thigh muscle

- Common approach for children 0 to 12 months of age; also the preferred site for older children

Do not inject into:

- The same site (small area of the muscle) more than once a week
- An area that has skin irritation, including red or swollen areas
- An area that has hardened or is sensitive to touch

Choose
injection site

You may inject into the same muscle more than once in a day, but rotate the injection sites counterclockwise in that muscle each time, keeping 1 inch between sites.

Keep track of the injections on your Treatment Tracker Calendar.

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Contact your doctor if you notice any injection-site reactions, including redness, pain, and swelling.
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4. POSITION YOUR CHILD



- Your child can be lying back flat or held in your lap during the injection, whichever works best
- Remove any clothing around the chosen injection site
- Position the leg so the hip and knee are bent slightly; this will help relax the muscle that will be injected



You also may find it helpful to have another person who can help by:

- Holding your child in the proper position
- Distracting your child with a toy during and after the injection

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5. PERFORM THE INJECTION



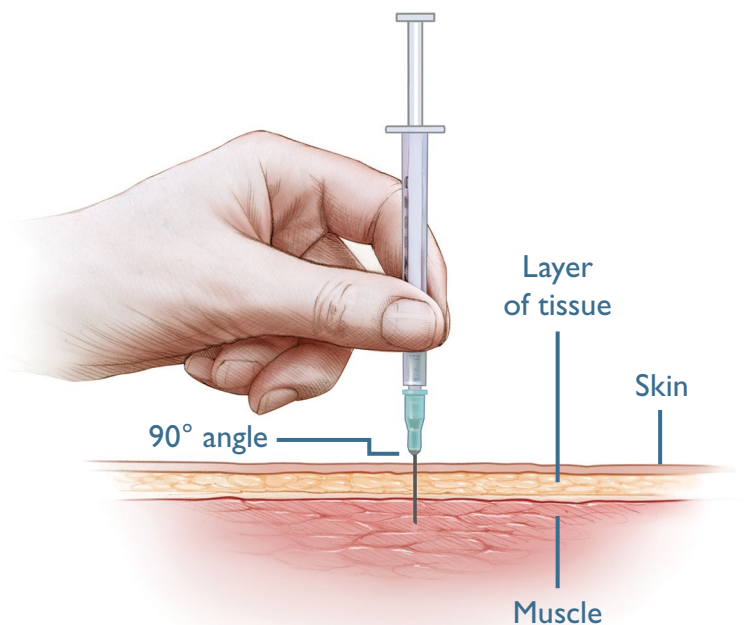
- Clean the area to be injected with an alcohol swab; let the alcohol dry before injecting
- Press the plunger until a droplet forms at the tip of the needle
- Stretch and hold the skin around the injection site between the thumb and fingers of the hand that is not holding the syringe. Steady the muscle by grasping it on each side

Always inject Acthar into the muscle of your child. Never inject Acthar directly into a vein, under your child's skin, or give it to your child by mouth

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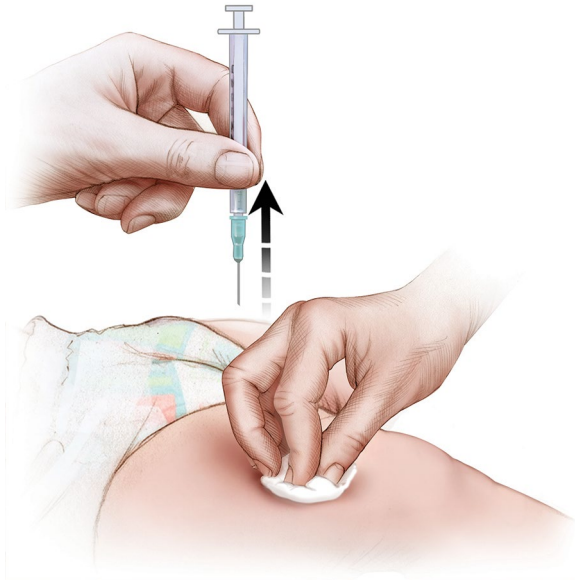
PERFORM THE INJECTION



- Hold the syringe like a pencil or dart with your right hand if you are right-handed and your left if you are left-handed. Using a quick motion, insert the needle at a 90° angle through the skin
- Once the needle is inserted, release the skin. Using your free hand, hold the barrel of the syringe in place and push the plunger down until the syringe is empty

It may be helpful to use a noisy toy to distract and calm your child during and after the injection.

6. COMPLETE THE INJECTION



- Once the syringe is empty, pull the needle straight out. It may be helpful to hold a gauze pad over the injection site and use it to apply pressure once the needle has been removed
- If there is any blood, wipe it off and, if necessary, apply an adhesive bandage
- **Dispose of the used syringe, needle, and**



needle cap in a puncture-resistant container. Do not replace the needle cap prior to disposal

- Wash your hands with soap and warm water
- Mark the Treatment Tracker Calendar with the injection site location
- Return the Acthar to the refrigerator (36°F-46°F; 2°C-8°C) between each use

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7. ADDITIONAL INFORMATION

How to dispose of used syringes, needles, and vials

It is important to follow your state and local laws regarding proper disposal of used syringes, needles, and vials. You should be provided a sharps disposal container with your Acthar shipment, but if it is not included, bring your container of used syringes, needles, and vials to your doctor's office or local hospital for proper disposal.

You should not:

- Reuse syringes, needles, or vials
- Throw the syringes, needles, and vials in household trash
- Recycle syringes, needles, and vials
- Use a clear plastic or glass container for disposal

To make your own sharps container:

- Place used supplies in a heavy plastic or metal container with a tight-fitting lid that is puncture-resistant and leak-proof; you can ask your pharmacist for a sharps container, or you can use a laundry detergent bottle
- Mark "Not for Recycling" on the container
- Reinforce the lid with heavy-duty tape
- Store the container in a secure place out of reach from children or pets

Visit [safeneedledisposal.org](https://www.safeneedledisposal.org) or call 1-800-643-1643 to find information about safely disposing used sharps in your state.

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When to call your doctor

Call your doctor right away if any of these potential risks concern you or if your child experiences any of these serious side effects during treatment:

- Increased risk of infections
- Increased blood pressure, salt and water retention, or low blood potassium levels
- Unpredictable response to vaccines
- Stomach or intestinal problems
- Changes in mood or behavior
- Worsening of other conditions, such as diabetes or muscle weakness
- Eye problems
- Allergic reactions
- Adrenal gland changes
- Problems with growth and physical development
- Bone density loss
- Masking other conditions



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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

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IMPORTANT SAFETY INFORMATION (continued)

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

- 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; 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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IMPORTANT SAFETY INFORMATION (continued)

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

- 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 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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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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