

ACTHAR FOR INFANTILE SPASMS

Commonly asked questions about treatment

Acthar is a prescription medicine that is used to treat infantile spasms in infants and children under 2 years of age.



IMPORTANT SAFETY INFORMATION

Acthar is given as an injection into the muscle. Do not inject it under the skin or into a vein, or give it to your child by mouth. Inject Acthar exactly as your doctor tells you, and keep all of your child's follow-up appointments.

Please see additional Important Safety Information throughout, as well as accompanying full Prescribing Information and Medication Guide.

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



INFANTILE SPASMS

What is infantile spasms (IS)?

IS is a rare seizure disorder that affects approximately 2500 children in the United States every year.

Children with IS generally have one or more of the following symptoms:

- A certain type of seizure (called “spasms”)
- A disorganized and chaotic brain-wave pattern called hypsarrhythmia (hips-a-rith-me-ya) as recorded on an EEG*
- Failure to meet developmental milestones

IS typically begins in the first year of life, most commonly between 4 and 8 months of age. Most of the time, IS is caused by an underlying disease or injury to the brain; however, in some children, no cause for IS can be found.

IS is a serious condition that requires immediate attention. Multiple treatments for IS are available. Studies have shown that early intervention may lead to fewer long-term effects.

Guidelines created by the American Academy of Neurology and Child Neurology Society say that treatment for IS has been successful when 2 conditions are met:

- The child no longer has spasms
- The child’s brain-wave pattern no longer shows signs of hypsarrhythmia

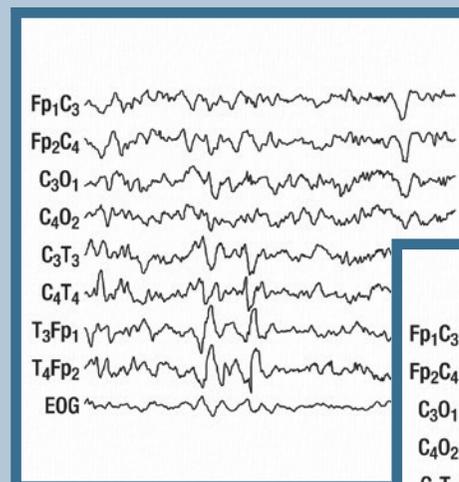
*An EEG, or electroencephalogram, is a test that measures and records the electrical activity of the brain.

IMPORTANT SAFETY INFORMATION (CONTINUED)

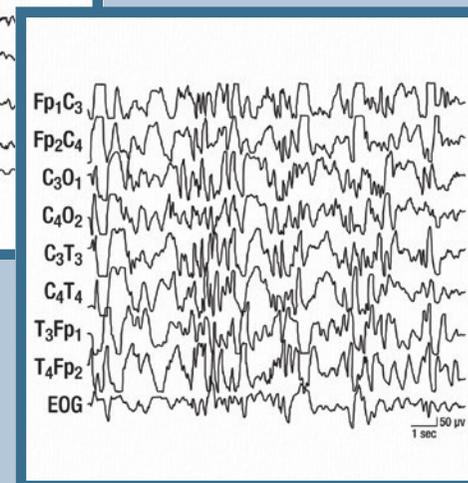
Your child should NOT use Acthar if they have:

A skin condition called scleroderma, bone density loss or osteoporosis, any infections (including suspected congenital infections in children under 2 years of age), eye problems, recent surgery, stomach ulcers or a history of ulcers, heart problems, high blood pressure, allergies to pig-derived proteins, been recently given a vaccine or are about to take one, certain adrenal conditions (such as Cushing’s or Addison’s disease).

2 Please see additional Important Safety Information throughout, as well as accompanying full Prescribing Information and Medication Guide.



Normal EEG pattern



Chaotic EEG pattern (hypsarrhythmia) in a child with IS

.....
IS is a serious condition that requires immediate attention.
.....



ACTHAR FOR INFANTILE SPASMS

What is Acthar?

Acthar is an injectable prescription medicine approved by the FDA more than 5 years ago to treat IS in infants and children under 2 years of age.

In a clinical study, 13 out of 15 children with IS had no spasms and no hypsarrhythmia after 2 weeks of treatment with Acthar.

What are the side effects of Acthar?

As with any medicine, your child may experience side effects during treatment with Acthar. These common side effects will likely go away as soon as treatment is over:

- Infections (like a cold)
- Change in behavior or mood (cranky or irritable)
- Change in appetite and weight gain
- Diarrhea and vomiting
- Increased blood pressure

Visit www.ActharIS.com for more information

IMPORTANT SAFETY INFORMATION (CONTINUED)

Acthar can cause side effects similar to those with steroid treatments. The risk of getting side effects may increase the longer your child is treated with Acthar. **Tell your doctor right away if your child has any of the following serious side effects:**

- **Increased risk of infections.** Your child may be more likely to get new infections. Also, old infections may become active. While taking Acthar, your child should stay away from people who are sick or have infections. Signs of infection are fever, cough, vomiting, or diarrhea. Other signs may be open cuts or sores on your child's body

4 Please see additional Important Safety Information throughout, as well as accompanying full Prescribing Information and Medication Guide.

.....
In a clinical study, 13 out of 15 children with IS had no spasms and no hypsarrhythmia after 2 weeks of treatment with Acthar.
.....



IMPORTANT SAFETY INFORMATION (CONTINUED)

- **Adrenal gland changes.** Taking Acthar long term may cause symptoms of Cushing's syndrome, such as upper body fat, rounded "moon" face, bruising easily, or bone weakness. When stopping Acthar, your child's body may not produce enough cortisol on its own (adrenal insufficiency). **Do not stop giving your child injections of Acthar without talking to your doctor first.** Call your doctor right away if your child appears pale, weak, or tired; loses weight or appetite; has stomach pain; or appears sick or feverish

H.P. **Acthar**[®] GEL
(repository corticotropin injection) 80 U/mL



INJECTION TRAINING AND SUPPORT

How do I give Acthar to my child?

Acthar is given as an intramuscular injection, which means Acthar is injected directly into a muscle, typically in the thigh. Acthar should not be injected under the skin or into a vein.

Your doctor or nurse will provide you with exact instructions on how to give Acthar to your child.

What if I've never given an injection before?

At first it may be scary to think about giving your child an injection. That's completely normal; however, other parents and caregivers learn to do it and you can, too.

You will have a lot of help as you learn how to give your child an injection, beginning with one-on-one training from your doctor or a nurse before you give Acthar to your child for the first time. Ask your doctor or nurse about available step-by-step training, which may include the opportunity to practice on an anatomical model. A starter kit is also available to help you prepare to give your child Acthar.

To get started, you can find more information about Acthar and view injection-instruction videos on

www.ActharInjectionTraining.com

IMPORTANT SAFETY INFORMATION (CONTINUED)

- **Increased blood pressure, too much water in the body, increased body salts, and low potassium in the blood.** Your doctor may check your child's blood pressure during treatment and discuss treatment choices if your child's blood pressure increases. Follow your doctor's instructions about if you need to decrease your child's salt intake or feed your child foods high in potassium
- **Unpredictable response to vaccines.** Talk to your doctor about which vaccines are safe for your child when taking Acthar

6 Please see additional Important Safety Information throughout, as well as accompanying full Prescribing Information and Medication Guide.

What support is available?

The company that manufactures Acthar—Mallinckrodt—created the Acthar Support & Access Program (A.S.A.P.) to make timely information and a variety of helpful services available to you at no cost.

- A.S.A.P. representatives can work with you to evaluate your insurance benefits and help qualified patients get co-pay assistance*
- A.S.A.P. will make arrangements to have Acthar shipped to your home from the specialty pharmacy

Expect a call. Someone from A.S.A.P. or the specialty pharmacy will call you to schedule the shipment of Acthar. **It is important that you do not miss this call.** Be sure to provide the best number at which to reach you.

For additional information, please visit the following websites:

[www.childneurologyfoundation.org/
disorders/infantile-spasms](http://www.childneurologyfoundation.org/disorders/infantile-spasms)
www.infantilespasmscenter.org
www.tsalliance.org



*Most insurance plans cover Acthar for infantile spasms.

IMPORTANT SAFETY INFORMATION (CONTINUED)

- **Masking other conditions.** Tell your doctor if your child has any infections, changes in weight, bloody or black tarry stool, vomiting, stomach pain, excessive tiredness, increased thirst, fast heart rate, or difficulty breathing. Additionally, infantile spasms sometimes hide (mask) other seizures your child may have. Once treated with Acthar, the spasms may disappear and allow other seizures to become visible for the first time. Tell the doctor right away if you see a change in your child's seizures or spasms
- **Stomach or intestinal problems.** Acthar may put your child at increased risk for bleeding from the stomach or intestine. Tell your doctor if your child has any pain in the stomach area, vomits blood, or has bloody or black stools
- **Changes in mood or behavior.** Your child may be irritable, have mood swings, be depressed, or have trouble sleeping

H.P. **Acthar**[®] GEL
(repository corticotropin injection) 80 U/mL

IMPORTANT SAFETY INFORMATION (CONTINUED)

- **Worsening of other medical conditions**, including diabetes
- **Eye problems**, such as cataracts, glaucoma, or optic nerve damage
- **Allergic reactions**. Tell your doctor if your child has a skin rash, swelling, or trouble breathing
- **Changes in growth and physical development**. Long-term use of Acthar may affect your child's growth and may weaken your child's bones
- **Enlarged heart**. Long-term use of Acthar may cause an increase in the size of your child's heart
- **Bone density loss**. Acthar may cause osteoporosis at any age

Before your child takes Acthar, tell your doctor if he or she has:

- An infection
- Diabetes
- Heart or kidney problems
- Stomach or intestinal problems
- Thyroid problems
- Liver problems
- Neuromuscular problems
- Convulsions or seizures
- Had exposure to someone with tuberculosis (TB)
- Had an allergic reaction to Acthar or to pork products
- Had recent surgery
- Had a recent vaccination or been scheduled to receive a vaccination
- A family member who is receiving vaccinations

Tell your doctor about all the medicines your child takes, including prescription and non-prescription medicines, vitamins, and herbal supplements. Do not start giving a new medicine to your child without first speaking to your doctor.

The most common side effects include:

- Infections
- Increased blood pressure
- Irritability and changes in behavior
- Changes in appetite and weight
- Diarrhea
- Vomiting

These are not all of the possible side effects of Acthar.

Tell your doctor if your child has any bothersome side effect or side effect that does not go away.

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 1-800-778-7898.

Please see additional Important Safety Information throughout, as well as accompanying full Prescribing Information and Medication Guide.



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