

December 20, 2019

Options to Access Acthar[®] Gel (repository corticotropin injection) to Treat Infantile Spasms

Infantile Spasms is a rare and potentially devastating disease for young children and their caregivers. Mallinckrodt is committed to helping appropriate infants with Infantile Spasms who are prescribed Acthar Gel receive treatment as quickly as possible.

To support patients with Infantile Spasms, Mallinckrodt offers several methods to help all eligible patients get access to Acthar Gel. They include:

- The Acthar Gel Commercial Starter Program, if eligible¹
- A Specialty Pharmacy², which would dispense Acthar Gel either to the patient at the treatment facility, or directly to the patient's home or place of convenience
- Hospital Direct Purchase, for inpatient use (the hospital will manage this; patients' families do not need to take action with this method).

Patients who lack insurance coverage for Acthar Gel may be eligible for additional assistance. For more information on how to access Acthar Gel, caregivers should call Mallinckrodt at 1-888-435-2284 to reach their Acthar Hub Case Manager.

Please see Important Safety Information for Acthar Gel below.

Acthar Gel Commercial Starter Program

¹ To be eligible for the Acthar Gel Commercial Starter Program, patients need to be Acthar Gel naïve, have a valid Acthar Gel prescription for Infantile Spasms, and have been verified to have commercial or private insurance. Government-insured patients are not eligible for this offering due to current government regulations. A patient who is participating in Medicare, Medicaid, or any government-funded healthcare plan is not eligible to participate in the Acthar Gel Commercial Starter Program. The Program is valid for one vial of Acthar Gel at a time as needed, up to four vials, prior to coverage approval by the patient's insurance. The patient will no longer receive vials under the Program when the patient receives insurance approval, a final denial of coverage, or the fourth vial. The patient may receive up to an additional three vials if the prescriber provides documentation of need and the patient has not received a final determination from the insurance company. The patient agrees not to seek reimbursement from any third-party payor for all or any part of Acthar Gel dispensed pursuant to the Program. The Program is void where prohibited by law. Mallinckrodt reserves the right to rescind, revoke, or amend the Program at any time without notice. By participating in the Program, the patient agrees to these eligibility terms and conditions.

² Dispensing method depends on the patient's insurance and the hospital's policy.

WHAT IS ACTHAR[®] GEL?

Treatment of infantile spasms in infants and children under 2 years of age.

Acthar is given as an injection into the muscle. Do not inject it under the skin, into a vein, or give it to your child by mouth.

IMPORTANT SAFETY INFORMATION

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

- 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
- Allergies to pig-derived proteins
- Have been given or are about to receive a live or live attenuated vaccine
- Suspected congenital infections (in children under 2 years of age)
- If you have been told that you have Cushing's syndrome or Addison's disease

Tell your doctor about any other health problems that you have. Give your doctor a complete list of medicines you are taking. Include all nonprescription medicines, vitamins, and herbal supplements that you are taking.

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

- Never inject Acthar directly into a vein, under the skin, or give it to your child by mouth
- Always inject Acthar 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

Acthar and corticosteroids have similar side effects.

- 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, or retain too much fluid. As a result of this, your doctor may recommend some changes to your diet, such as eating less salt and 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 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
- 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. Signs of allergic reaction are:
 - Skin rash and itching
 - Swelling of the face, tongue, lips, or throat
 - Trouble breathing
- 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 should not be given to adults who are pregnant or plan to become pregnant

What are the most common side effects of Acthar?

The most common side effects of Acthar are similar to those of steroids. They include:

- Fluid retention
- High blood sugar
- High blood pressure
- Behavior and mood changes
- Changes in appetite and weight

Specific side effects in children under 2 years of age include:

- Increased risk of infections
- High blood pressure
- Irritability
- Symptoms of Cushing's syndrome
- Thickening of the heart muscle (cardiac hypertrophy)
- Weight gain

The above side effects may also be seen in adults and children over 2 years of age.

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 www.fda.gov/medwatch. You may also report side effects by calling 1-800-844-2830.

Please see full Prescribing Information.

<http://www.acthar.com/pdf/Acthar-PI.pdf>

For parents and caregivers of IS patients, please also see Medication Guide.

http://www.acthar.com/pdf/IS_Medication_Guide.pdf

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