Acthar treatment calendar

Use the treatment calendar to make it easier for you and your family to keep track of your child’s treatment schedule and progress.

Use this convenient tool to keep track of when you give Acthar treatment, at what dose, and where the injection was given. The dose may change over time and the injection is given in different parts of the thigh, so it is helpful to record this information.

Calendar follows the FDA-recommended Acthar dosing regimen

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Initial dose  Tapered dose 1  Tapered dose 2  Tapered dose 3  Tapered dose 4

Please see full Prescribing Information including Medication Guide.
INDICATION

H.P. Acthar® Gel (repository corticotropin injection) 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.

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).

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

- 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

- 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

- 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

- 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 accompanying full Prescribing Information, including Medication Guide.

H.P. Acthar Gel (repository corticotropin injection) 80 U/mL
**How should I give H.P. Acthar Gel to my child?**

H.P. Acthar Gel 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.

- Inject H.P. Acthar Gel exactly as your doctor tells you. Your doctor will tell you where to give the injection, how much to give, how often and when to give it to your child.
- Do not use H.P. Acthar Gel until your doctor has taught you how to give the injection to your child.

- **To give H.P. Acthar Gel:**
  - Take the bottle from the refrigerator. Do not open the bottle or pry the cap (rubber stopper) off.
  - Warm the contents by rolling the bottle between your hands for a few minutes.
  - Wash your hands.
  - Prepare the skin where you are going to give the injection by wiping it with a new sterile alcohol wipe. Before giving the injection, look at the site prepared for the injection and make sure that it no longer looks wet. A wet site can cause burning.
  - Wipe the top of the vial rubber stopper with a new sterile alcohol wipe.
  - Use a new sterile needle and syringe to draw up the amount of H.P. Acthar Gel the doctor has told you to use.
  - Give the injection the way the doctor has instructed you.
  - Return the bottle to the refrigerator as soon as possible.

- **Keep all of your child’s follow-up appointments with your doctor**

  It is important for you to tell your doctor if your child’s spasms continue or change in any way during treatment or after treatment has stopped so that they can monitor your child’s progress.

Infantile Spasms sometimes hides (masks) other seizures your child or infant may have. Once treated with H.P. Acthar Gel, the Infantile Spasms symptoms may disappear. This may allow the other seizures to become visible for the first time. Tell your child’s doctor right away if you see a change in your child’s seizures/spasms.

**What are the possible side effects of H.P. Acthar Gel?**

H.P Acthar Gel can cause serious side effects.

- **Eye problems.** Your child can get cataracts, increased pressure in the eye (glaucoma), and possible damage to the optic nerve if treated with H.P. Acthar Gel for a long time.

- **Allergic reactions to H.P. Acthar Gel.** Your child may have an allergic reaction to H.P. Acthar Gel. Allergic reactions may not happen until your child has received several injections of H.P. Acthar Gel. Tell your doctor right away if your child has any of the following signs of an allergic reaction:
  - skin rash
  - swelling of the face, tongue, lips, or throat
  - trouble breathing

- **Changes in growth and physical development.** H.P. Acthar Gel may affect your child’s growth and physical development and may weaken his or her bones. This is more likely to happen with long term use of H.P. Acthar Gel.

- **Enlarged heart.** H.P. Acthar Gel may cause an increase in the size of your child’s heart. This is more likely to happen with long term use of H.P. Acthar Gel but usually goes away after H.P. Acthar Gel is stopped.

**Common side effects of H.P. Acthar Gel may include:**

- infections
- increased blood pressure
- irritability and changes in behavior
- changes in appetite and weight
- diarrhea
- vomiting

These are not all the possible side effects of H.P. Acthar Gel. Tell your doctor if your child has any side effect that bothers them or does not go away. For more information ask your child’s doctor or pharmacist.

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

*Please see accompanying full Prescribing Information, including Medication Guide.*