

MEDICATION GUIDE

Acthar® Gel (AK-thar jel) (repository corticotropin injection)

This Medication Guide provides information only about the use of Acthar Gel for the treatment of Infantile Spasms. If your doctor prescribes Acthar Gel for you or your child for any other reason, talk to your doctor for information about how this medicine is used to treat your medical condition.

Read this Medication Guide before your child receives Acthar Gel and each time you refill your child's prescription. There may be new information. This Medication Guide does not take the place of talking with your doctor about your child's medical condition or treatment.

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

Acthar Gel can cause serious side effects including:

1. Increased risk of infections.

Acthar Gel is a medicine that can affect your child's immune system. When your child is taking Acthar Gel, it can lower the ability of your child's immune system to fight infections.

Acthar Gel may:

- make your child more likely to get new infections
- worsen an infection that your child already has
- cause an inactive infection to become active, such as tuberculosis (TB)

Before starting Acthar Gel, tell your doctor if your child has:

- an infection or signs of an infection, such as:
 - fever
 - cough
 - vomiting
 - diarrhea
 - other signs of flu or illness
- a family member with an infection or signs of an infection

While taking Acthar Gel, your child should:

- stay away from people who are sick or who have infections
- tell your doctor right away if your child has any sign of infection such as:
 - fever (but your child may not have a fever with an infection)
 - cough
 - vomiting
 - diarrhea or
 - other signs of illness or flu and
 - any open cuts or sores on his or her body

2. Effects on the adrenal gland after stopping Acthar Gel.

When your child stops taking Acthar Gel, his or her body may not produce enough of a hormone called cortisol on its own (adrenal insufficiency). Your child may need to take steroid medicine to protect the body until the adrenal gland recovers and is working well again, especially to protect the body if they have surgery or trauma. **Do not stop giving your child injections of Acthar Gel without talking to your doctor first.**

Your doctor will tell you when and how to slowly stop giving the injections to avoid serious side effects.

While slowly stopping your child's injections of Acthar Gel or after you stop giving the injections, call your doctor right away if your child has any of the following:

- appears weak
- loses weight or has a decrease in appetite
- appears tired or lacking energy
- appears pale
- has stomach pain
- appears sick or is with a fever

3. Effects on the adrenal gland while taking Acthar Gel.

When your child is taking Acthar Gel, his or her adrenal gland may produce too much cortisol. This can cause symptoms of Cushing's syndrome. Cushing's syndrome is more common in children who take Acthar Gel for a long time.

Symptoms of Cushing's syndrome include:

- increased upper body fat around the neck, but not the arms and legs
- weight gain
- rounded or "moon" face
- thin skin, easy bruising, and stretch marks on thighs, belly and trunk
- slowed growth rates in children
- weak bones (osteoporosis)

While receiving treatment with Acthar Gel other side effects can happen that are like side effects that happen due to treatment with steroid medicines. The risk of getting side effects may increase the longer your child is treated with Acthar Gel. Side effects may include:

- **increased blood pressure.** Your doctor may check your child's blood pressure during treatment. If your child's blood pressure increases, your doctor may talk with you about possible treatment choices.
- **too much water in the body (water retention), increased amount of body salts, and low potassium in the blood.** Acthar Gel may cause your child to have an increased amount of body salts and water that stays in the body, and may lower the amount of potassium in your child's blood. Follow your doctor's instructions about if you need to decrease your child's salt intake or if you need to feed your child foods high in potassium.

4. Your child should not receive certain vaccines during treatment with Acthar Gel.

Your child may receive killed or inactivated vaccines while receiving Acthar Gel. Before your child receives any vaccines, talk to your doctor about which vaccines are safe for your child. Certain vaccines could cause your child to have serious side effects, or the vaccine may not be effective.

5. Hiding (masking) symptoms of other conditions or diseases.

It may be more difficult for your doctor to diagnose other conditions or diseases in your child during treatment with Acthar Gel. During treatment and after treatment ends, tell your doctor if your child has:

- any signs or symptoms of infection. See number 1 of this section in the Medication Guide.
- changes in body weight
- bloody or black tarry stool
- vomiting
- stomach pain
- excessive tiredness
- increased thirst
- fast heart rate
- difficulty breathing

6. Stomach and intestinal problems. Acthar Gel may cause bleeding of the stomach or intestine.

Your child has an increased risk for bleeding from the stomach or having a stomach ulcer. Tell your doctor if your child has any pain in the stomach area (abdominal pain), vomits blood, or has bloody or black stools.

7. Changes in mood and behavior.

During treatment with Acthar Gel your child may be irritable, have rapid changes in his or her mood, be depressed, have other changes in his or her behavior, or have trouble sleeping.

Tell your doctor if your child has any of the side effects or symptoms listed above.

What is Acthar Gel?

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

What should I tell my doctor before my child takes Acthar Gel?

Before your child takes Acthar Gel, read the section above "What is the most important information I should know about Acthar Gel?" and tell your doctor if your child has:

- an infection

- diabetes
- heart problems
- kidney problems
- stomach or intestinal problems
- thyroid problems
- liver problems
- neuromuscular problems
- convulsions or seizures
- had exposure to someone with Tuberculosis (TB)
- a previous allergic reaction such as hives, itching or trouble breathing, to Acthar Gel or pork products
- had recent surgery
- had a recent vaccination or is 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.

How should I give Acthar Gel to my child?

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 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 Acthar Gel until your doctor has taught you how to give the injection to your child.
- To give 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 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 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 Acthar Gel?

Acthar Gel can cause serious side effects.

- **See "What is the most important information I should know about Acthar Gel."**
- **Acthar Gel may make certain other medical conditions worse, such as diabetes (may increase blood sugar).**
- **Eye problems.** Your child can get cataracts, increased pressure in the eye (glaucoma), and possible damage to the optic nerve if treated with Acthar Gel for a long time.
- **Allergic reactions to Acthar Gel.** Your child may have an allergic reaction to Acthar Gel. Allergic reactions may not happen until your child has received several injections of 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.** 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 Acthar Gel.
- **Enlarged heart.** 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 Acthar Gel but usually goes away after Acthar Gel is stopped.

The most common side effects of Acthar Gel for patients with infantile spasms include:

- Infections
- muscle contractions that you cannot control (convulsions)
- increased blood pressure
- irritability and changes in behavior
- fever

These are not all the possible side effects of 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.

How should I store Acthar Gel?

- Store vials of Acthar Gel in the refrigerator between 36°F to 46°F (2°C to 8°C).

Throw away any vials after the expiration date printed on the label.

Keep Acthar Gel and all other medicines out of the reach of children

General information About Acthar Gel

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Acthar Gel for a condition for which it has not been prescribed. Do not give Acthar Gel to other people, even if they have the same symptoms. It may harm them.

This Medication Guide summarizes the most important information about Acthar Gel. If you would like more information, talk with your child's doctor. You can ask your child's doctor or pharmacist for information about Acthar Gel that is written for healthcare professionals. For more information, go to www.acthar.com or call 1-800-844-2830.

What are the ingredients in Acthar Gel?

Active ingredient: Corticotropin

Inactive ingredients: gelatin, phenol, cysteine, sodium hydroxide and/or acetic acid to adjust pH, and water for injection

Manufactured for:

Mallinckrodt ARD LLC
Bridgewater, NJ 08807

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