ACTHAR FOR INFANTILE SPASMS:
A guide to treatment for your child

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

Please see pages 10–13, as well as the accompanying full Prescribing Information and Medication Guide, for Important Safety Information.
You may have just learned your child has a condition called infantile spasms (IS), or your child may have just been prescribed Acthar. There is no doubt you have many questions about possible treatment for your child.

This brochure is intended to give you helpful information about IS and how treatment with Acthar may help. It may not cover everything you want to know, so after reading this information, write down any questions you have in the NOTES section at the back of this brochure as a reminder to ask your doctor or nurse.

Here is some important safety information you should know about Acthar:

- Acthar should never be given intravenously (into a vein) or by mouth. Acthar is given as an injection into the muscle.
- Patients should not receive certain vaccines during Acthar treatment. Talk to your doctor about which vaccines are safe.
- 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 or pork products.
- These are not all of the Warnings and Precautions for Acthar. Please see full Prescribing Information and pages 10–13 for additional Important Safety Information. For parents and caregivers of IS patients, please also see Medication Guide.

Please see pages 10–13, as well as the accompanying full Prescribing Information and Medication Guide, for Important Safety Information.
What is infantile spasms?

Infantile spasms is a rare and specific type of seizure disorder also known as West syndrome. IS usually begins within the first year of life. Children with IS typically have:

- A specific type of seizure (called spasms)
- A chaotic brain-wave pattern called hypsarrhythmia (hips-a-rith-me-ya)

The spasms are described as sudden, uncontrolled movements of the neck, body, arms, and legs that last only for a few seconds.

You may see the following:

- Repetitive forward head nodding or bobbing
- Bowing from the waist when sitting
- Drawing up of knees when lying down
- Extending or stiffening of the neck, trunk, arms, and legs
- Crossing arms across body as if self-hugging
- Thrusting arms to the side, elbows bent

Spasms are most common during the early morning or when your child wakes up from naps. Often, infantile spasms is mistaken for colic. Colic frequently begins at the same time each day. Children with colic will cry, tend to lift their legs repeatedly with their hands clenched, and may have a swollen stomach.

When making the diagnosis, your doctor will get a complete medical history and will want you to describe your child’s spasms. Some parents and caregivers find it helpful to take a video of the child’s spasms and record how often they happen in a journal as soon as they begin. Your doctor or nurse may find this information helpful when making the diagnosis and during treatment.

Your doctor may perform an electroencephalogram (EEG) to determine if your child has hypsarrhythmia. An EEG is a test of brain activity. Children with IS typically have EEGs that show hypsarrhythmia, a chaotic pattern of brain waves (see examples of EEGs on next page).
Normal EEG pattern

Example of an EEG pattern in a child with IS
What causes infantile spasms?

Once infantile spasms is diagnosed, your doctor may run several more tests to try to find out the cause of your child’s IS.

In some children, no cause for IS can be found. This is called cryptogenic, or idiopathic, infantile spasms. In most cases, infantile spasms is caused by an underlying disease or injury to the brain. Causes could include central nervous system infection, abnormal brain development, or brain injury.

No matter what the cause is, it is important to find and treat IS as quickly and effectively as possible. Be sure to talk to your child’s doctor about the potential effects of IS, as well as the available treatment options and when a follow-up EEG may be appropriate.

How is infantile spasms treated?

If children are thought to have IS, they may be sent to an epilepsy center to be diagnosed. Once infantile spasms is confirmed, treatment should be started as soon as possible.

The American Academy of Neurology and Child Neurology Society specify that successful treatment must stop both spasms and hypsarrhythmia.

Acthar is one clinically proven therapy that has been shown to help stop spasms and hypsarrhythmia in both children with idiopathic (cryptogenic) IS and those with symptomatic IS.
WHAT IS ACTHAR?

Acthar is a prescription medication containing the hormone adrenocorticotropic (“a-DRE-no-cor-ti-co-tro-pin”) that has been used for many years for children with infantile spasms.

Acthar provides a prolonged release of the medication after it’s injected. It is not a steroid.

One way Acthar may work to treat IS is by helping your child’s body produce natural hormones. Additional research is being done to learn more about how Acthar works.

How can Acthar help?

Acthar is an FDA-approved treatment for infantile spasms that has been shown to help stop both spasms and hypsarrhythmia. In a clinical study, 87% of children (n=15) had no spasms and no hypsarrhythmia at week 2.

Every child will respond to their Acthar treatment differently. Contact your doctor or nurse regarding any questions you may have about treatment with Acthar.

Acthar is proven to help:

- Stop spasms
- Stop hypsarrhythmia

How is Acthar given?

Acthar is given by an intramuscular (into the muscle) injection. Your doctor or nurse should provide detailed instructions about where to give the injection, how much to give, how often, and when to give Acthar to your child. In addition, Mallinckrodt has a brochure you can download and a step-by-step video you can watch at home on www.acthar.com to help guide you through the injection.

Contact your doctor or nurse if you have any questions about using Acthar.

Please see pages 10–13, as well as the accompanying full Prescribing Information and Medication Guide, for Important Safety Information.
Parents and caregivers often notice their child can be irritable when they are on Acthar. In addition to irritability, appetite changes and weight gain are commonly noticed with Acthar but are not considered harmful. These side effects of the medication will likely disappear after your child completes Acthar therapy.

The most common side effects of Acthar in infants include: infections, increased blood pressure, irritability and changes in behavior, changes in appetite and weight, diarrhea, and vomiting. Other adverse reactions reported in adults and children over 2 years of age included: abdominal bloating, anxiety, asthma, chest discomfort, congestive heart failure, dizziness, shortness of breath, redness of the face, fluid retention, flushing, headache, injection site pain, tiredness, muscle weakness, nervousness, rapid heart rate, and lack of energy. Tell your doctor if there is any side effect that bothers you or your child or that does not go away.
MEDICATION GUIDE
H.P. Acthar® Gel (repository corticotropin) Injection

This Medication Guide provides information only about the use of H.P. Acthar Gel for the treatment of Infantile Spasms. If your doctor prescribes H.P. 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 H.P. 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 H.P. ACTHAR GEL?

H.P. Acthar Gel can cause serious side effects including:

1. Increased risk of infections. H.P. Acthar Gel is a medicine that can affect your child’s immune system. When your child is taking H.P. Acthar Gel, it can lower the ability of your child’s immune system to fight infections. H.P. 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 H.P. 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 illness or flu
   - a family member with an infection or signs of an infection

While taking H.P. 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 H.P. Acthar Gel. When your child stops taking H.P. 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 H.P. 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 H.P. 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 H.P. Acthar Gel. When your child is taking H.P. 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 H.P. 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 H.P. 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 H.P. 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.** H.P. 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 H.P. Acthar Gel.** Your child may receive killed or inactivated vaccines while receiving H.P. 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 H.P. 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.**
   H.P. 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 H.P. 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 H.P. ACTHAR GEL?
H.P. 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 H.P. ACTHAR GEL?
Before your child takes H.P. Acthar Gel, read the section above “What is the most important information I should know about H.P. Acthar Gel?” and tell your doctor if your child has:
• an infection
• Diabetes
• heart problems

Please see accompanying full Prescribing Information and next page for additional Important Safety Information.
• 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 H.P. 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 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:
  o Take the bottle from the refrigerator. Do not open the bottle or pry the cap (rubber stopper) off.
  o Warm the contents by rolling the bottle between your hands for a few minutes.
  o Wash your hands.
  
  o 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.
  o Wipe the top of the vial rubber stopper with a new sterile alcohol wipe.
  o Use a new sterile needle and syringe to draw up the amount of H.P. Acthar Gel the doctor has told you to use.
  o Give the injection the way the doctor has instructed you.
  o 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.

• See “What is the most important information I should know about H.P. Acthar Gel.”
• H.P. 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 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.

How should I store H.P. ACTHAR GEL?
- Store vials of H.P. 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 H.P. Acthar Gel and all other medicines out of the reach of children

General information about H.P. Acthar Gel
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use H.P. Acthar Gel for a condition for which it has not been prescribed. Do not give H.P. 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 H.P. 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 H.P. Acthar Gel that is written for healthcare professionals. For more information, go to www.acthar.com or call 1-800-778-7898.

What are the ingredients in H.P. 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 Inc.
Hazelwood, MO 63042 USA
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Please see accompanying full Prescribing Information for additional Important Safety Information.
Help is available

Mallinckrodt is committed to helping children with infantile spasms get access to Acthar. The Acthar Support & Access Program (A.S.A.P.) was created for this purpose, and your child’s doctor or nurse will work directly with them and with you to help your child get started with Acthar.

Because Acthar is available only through what is called a Specialty Pharmacy—not your local pharmacy—the Acthar Support & Access Program coordinates the shipment of Acthar to your home, or to another location as chosen by you and your child’s doctor. This process can take a few days, and it is very important that you are able to be contacted for arrangements, whether by the Specialty Pharmacy team or your child’s doctor. Please be sure to provide your child’s doctor with the best phone number to reach you, and if you miss the call from the Specialty Pharmacy, call back as soon as you can.

When it comes to infantile spasms treatment, A.S.A.P. provides help coordinating:

- Reimbursement support, which includes working with the insurance company to determine coverage, as well as with charitable organizations and patient advocacy groups to provide other sources of assistance, if applicable.
- Copay Assistance Program, which covers up to 100% of copay costs for eligible patients. A.S.A.P. will refer patients to a third-party administrator based on copay amount or upon family/caregiver request. Patients must meet certain eligibility criteria.
- Patient Assistance Program, also administered by a third party, makes Acthar available at no cost to patients in financial need. This program is limited to patients who are uninsured or whose insurer does not cover Acthar. Patients must meet certain eligibility criteria.

Most insured patients who are prescribed Acthar for infantile spasms are covered. If prior authorization paperwork is required, A.S.A.P. provides information and assistance to help. You can find out more about access, reimbursement, and support at www.actharIS.com.
Use the space below to write down any questions you have for your doctor or nurse.