

Acthar is a prescription medicine for people with symptomatic sarcoidosis.

Is Acthar right for me?

Ask your doctor or healthcare provider these questions to help determine if Acthar may be right for you:

- Can Acthar help me treat my sarcoidosis symptoms?
- How often would I take Acthar?
- How might Acthar work for me?
- What are the most common side effects of Acthar?
- What kind of support will I get while on Acthar?
- I've never given myself an injection. Who will teach me?
- In your opinion, am I a candidate for Acthar?

You can even print this list and take it with you to your doctor's appointment.

Work with your doctor to decide whether Acthar may be the right treatment option for your symptomatic sarcoidosis. Remember that treatment should always be individualized. Not all treatments will work for everyone. **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.

Important Safety Information

Who should NOT take H.P. Acthar® Gel (repository corticotropin injection)?

You should **not take** Acthar if you have:

- A skin condition called scleroderma
- Bone density loss or osteoporosis
- Any infections, including fungal, bacterial, or viral
- Eye problems, such as ocular herpes simplex
- Had 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
- Suspected congenital infections (in children under 2 years of age)
- A condition where your adrenal glands produce either too much of certain hormones (as with Cushing's syndrome), or not enough (adrenal insufficiency)

Tell your doctor if you have any of these conditions or any other health problems. Also, share with your doctor what medicines you are taking. Don't forget to mention nonprescription medicines, vitamins, and herbal supplements.

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

- Never inject Acthar directly into a vein, and always take Acthar as prescribed by your doctor
- Never stop treatment suddenly unless your doctor tells you to
- Try not to miss any scheduled doctor's appointments, as it is important for the doctor to monitor you while taking Acthar

Acthar can cause side effects similar to those with steroid treatments. While taking Acthar, tell your doctor right away if you have any of the symptoms listed here:

- **Increased risk of infections.** You may be more likely to get new infections. Also, old infections may become active. Before and during treatment, 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
- **Adrenal gland changes.** When taking Acthar long term, your adrenal gland may produce too much of a hormone called cortisol, which may cause symptoms of Cushing's syndrome, such as upper body fat, rounded "moon" face, bruising easily, or muscle weakness

Sometimes when you stop taking Acthar long term, your body may not produce enough cortisol on its own. This is called "adrenal insufficiency." Your doctor may prescribe a steroid medicine to protect you until the adrenal gland recovers

Important Safety Information *(continued)*

- **Increased blood pressure, body salt, and fluid levels.** Your doctor may check your blood pressure while you are being treated with H.P. Acthar® Gel (repository corticotropin injection). He or she may recommend some changes to your diet, such as eating less salt and taking certain supplements
- **Unpredictable response to vaccines.** Talk to your doctor about which vaccines are safe to use when you are taking Acthar
- **Masking other conditions.** 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 put you at increased risk for bleeding from the stomach or getting 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
- **Changes in mood or behavior.** Taking Acthar can make you feel irritable or depressed. You may also have mood swings or trouble sleeping
- **Worsening of other medical conditions.** If you have other conditions, such as diabetes or muscle weakness, you may find they get worse
- **Eye problems.** It's possible that you may develop certain eye conditions, such as cataracts, glaucoma, or optic nerve damage
- **Allergic reactions.** Your body may develop antibodies or become sensitive when Acthar is used long term. Signs of allergic reaction in children are:
 - Skin rash
 - Swelling of the face, tongue, lips, or throat
 - Trouble breathing
- **Problems with growth and physical development.** Using Acthar long term can affect growth and physical development in children. This can be reversed when Acthar is no longer needed
- **Bone density loss.** Acthar may cause osteoporosis at any age
- **Potential harm to unborn baby.** Tell your doctor if you are pregnant or plan on becoming pregnant

Important Safety Information (continued)

What are the most common side effects of H.P. Acthar® Gel (repository corticotropin injection)?

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

- Fluid retention
 - Changes in blood sugar
 - Increased 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
 - Increased blood pressure
 - Irritability
 - Symptoms of Cushing's syndrome
 - Cardiac hypertrophy (thickening of the heart muscle)
 - 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 visit www.fda.gov/medwatch.** You may also report side effects by calling 1-800-778-7898.

Please see full Prescribing Information at <http://www.acthar.com/pdf/Acthar-PI.pdf>

H.P. Acthar® Gel (repository corticotropin injection) [H P AK-thar jel]

What is H.P. Acthar Gel?

Acthar is a prescription medicine for people with symptomatic sarcoidosis.

Acthar is injected beneath the skin or into the muscle.



Mallinckrodt, the "M" brand mark and the Mallinckrodt Pharmaceuticals logo are trademarks of a Mallinckrodt company. Other brands are trademarks of a Mallinckrodt company or their respective owners. © 2016 Mallinckrodt.