Acthar: Step-by-Step Self-Injection Instructions
WITH YOU EVERY STEP OF THE WAY

H.P. Acthar® Gel is a prescription medicine for people with symptoms of sarcoidosis.

SELECT IMPORTANT SAFETY INFORMATION
Acthar is injected beneath the skin or into the muscle. It should never be injected into a vein.

You should NOT take Acthar before talking to your doctor if you have any of these conditions: A skin condition called scleroderma, bone density loss, any infections, herpes simplex of the eye, had recent surgery, stomach ulcers or history of stomach ulcers, heart failure, uncontrolled high blood pressure, have been given, or are about to receive, a live or live attenuated vaccine, or have allergies to pig-derived protein. Tell your doctor if you are pregnant or plan on becoming pregnant.

Please see Important Safety Information throughout this brochure. Please see accompanying full Prescribing Information.
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Mallinckrodt intends this document to be informative, but you should remember the contents are general in nature and not meant to substitute for specific advice from professionals that may be necessary based on your individual questions and needs. We have made reasonable efforts to provide helpful and accurate information; however, we make no guarantees and you should not solely rely on the information included in this document.
The following sections provide easy step-by-step instructions for you or your caregiver on how to inject Acthar. The guide reviews all the items you will need when injecting, how to find areas on the body where Acthar can be injected, how to complete the injection itself, how to store Acthar, and how to throw it away. This guide is intended to be informational. Please consult with a healthcare provider prior to injection or for any questions.

Getting started with Acthar
Acthar is an injection given subcutaneously (under the skin) or intramuscularly (into the muscle). The steps included in this guide are intended only to supplement the detailed instructions and training provided to you in person by your doctor or nurse. If you have not received instructions or training on how to inject, do not proceed further without talking to your doctor.

Tell your healthcare provider about any other health problems you may have or medicines you are taking, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Home Injection Training is available
You can have a healthcare professional visit you in the comfort of your own home to provide Home Injection Training Services. This service is provided at no cost to patients and caregivers and can be scheduled more than once if needed.

The ActharPACT program also helps with your injections by offering injection reminders at no cost.

To find out more about these free Home Injection Training Services, you or your caregiver can call the Acthar Support & Access Program at 1.888.435.2284 or visit Acthar.com/SarcTraining.

SELECT 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.
Once you receive Acthar:

1. Check the vial to make sure that it’s Acthar

2. Check the expiration date on the Acthar vial to make sure you are using it before the date listed

3. Prior to each use, check for any signs of contamination (cloudiness, small flecks, etc)
   Do not use if:
   – the vial is expired
   – any signs of contamination are seen

4. Refrigerate Acthar as soon as you receive it and check that your refrigerator is set between 36°–46°F or 2°–8°C

5. Read this entire instruction guide before your first injection
Items you will need when injecting Acthar:

- Vial of Acthar
- A 23g or 25g needle
  - Some packages may include a 20g needle (not for injection), which can speed the process of drawing Acthar into the syringe
- Syringe
- Gauze pad
- Alcohol swabs
- Adhesive bandage
- Puncture-resistant container to safely dispose of syringe and needles after use

Understanding your dosage

Before you start to prepare the medication in the syringe for injection, check the dosage of Acthar that your doctor has prescribed. The prescribed amount is usually given as units, and will need to be converted to milliliters, or mL. The number of mL is the amount of medication you need to draw up in the syringe. Use the table below to help you with the conversion. Keep in mind that the values shown are not all of the possible dosages of Acthar. Dosage and frequency may vary. Your doctor has determined the best dose for you based on your medical history and condition.

<table>
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<th>Prescribed Units</th>
<th>Injection Amount (mL)</th>
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<tr>
<td>80 Units</td>
<td>1 mL</td>
</tr>
<tr>
<td>60 Units</td>
<td>0.75 mL</td>
</tr>
<tr>
<td>40 Units</td>
<td>0.5 mL</td>
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<tr>
<td>20 Units</td>
<td>0.25 mL</td>
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</table>
Preparing to inject

1. Gather all your needed supplies in a clean and quiet place that will be easy to access when injecting

2. Take the vial of Acthar out of the refrigerator. Recheck the expiration date to make sure the vial has not expired. Warm the vial to room temperature by rolling it between the palms of your hands or by holding it under your arm for a few minutes. Do not inject Acthar directly after removing it from the refrigerator. Make sure to refrigerate the vial after the injection is performed.
3. Wash your hands with soap and warm water for at least 15 seconds

4. Remove the cap of the vial and use an alcohol swab to wipe the rubber stopper on top of the vial

5. Attach either the wider (20g) or the thinner (23g or 25g) needle to the syringe. Follow these steps to avoid bubbles in your syringe. Before removing the cap of the needle, draw air into the syringe by pulling the syringe plunger to the exact amount your doctor has prescribed

6. Remove the needle cap. Insert the needle through the rubber stopper and inject air into the upright vial by pushing down on the plunger until it cannot be pushed farther
7. While the syringe is still in the vial, turn the vial and syringe upside down

8. While keeping the needle tip in the gel (medication), slowly pull back the plunger to the exact amount your doctor prescribed
9. To get rid of bubbles in your syringe, follow these steps. With the tip of the syringe upright and the needle still in the vial, tap the syringe with your finger until any air bubbles rise to the top. If bubbles are present, very slowly press the plunger until only the bubbles are pressed out of the syringe and a droplet starts to form at the needle tip. Check that you still have the amount your doctor prescribed in the syringe. If not, place the needle tip in the gel (medication) and draw in the amount you need and remove bubbles again.

10. If using the wider (20g) needle to draw Acthar into the syringe, replace the needle cap, detach the needle, and attach the thinner (23g or 25g) needle; continue to the following sections to find an injection site and learn how to inject Acthar. But remember, the 20g needle is not for injecting.

If using the thinner (23g or 25g) needle to draw Acthar into the syringe, continue to the following sections to find an injection site and learn how to inject Acthar. Before injecting, ensure that the needle remains sterile (ie, do not place on an unclean surface).
A few things to remember before injecting

- Ask your doctor or nurse which injection areas may be best for you. Common areas include upper arm or thigh.
- You may inject into the same area more than once a week, but rotate the injection sites in that area each time, keeping 1 inch between sites.
- Always defer to your doctor or nurse with any questions or concerns you may have, as this is only a general guide. See page 26 for more examples of when you should call your doctor.

Do not inject into:

- Same site (small area of the muscle) more than once a week
- An area that has skin irritation, including red, swollen, or painful areas
- An area that has hardened or is sensitive to touch
- Tattoos, warts, scars, or birthmarks
- Belly button
- Knee or groin area

Contact your doctor if you notice any injection site reactions, including redness, pain, and swelling.

If you are injecting subcutaneously, continue to page 11
If you are injecting intramuscularly, skip to page 20

To learn more about free Home Injection Training Services, please visit Acthar.com/SarcTraining

SELECT IMPORTANT SAFETY INFORMATION

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

- Never inject Acthar directly into a vein
- Always inject Acthar beneath the skin or 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
Injecting the upper thigh
The following instructions are for self-injections.

1. Sit comfortably on a firm chair to keep the thigh area relaxed

2. To locate the correct area, place one hand on your knee and one hand on your upper thigh near your hip. Draw an imaginary line down the center front of your thigh from hip to knee. The area between your hands and from the center of your thigh to the outer side of the leg is the area that should be injected

3. See “How to inject” on page 16 for additional instructions
Injecting the abdomen

The following instructions are for self-injections.

1. Sit comfortably on a firm chair

2. To locate the area, place your hands on your lower ribs. Injections should be done below where your hands are in any area that has enough tissue to pinch. However, it is important to not inject the belly button or the 1-inch area around it.

3. See “How to inject” on page 16 for additional instructions.
Injecting the upper arm

The upper arm is a common area used when injecting another person. Injections can be given on either the side or the back of the upper arm. The person receiving the injection can either sit or lie down, whichever is more comfortable, with his or her arm relaxed.

The following instructions are for the person giving the injection.

Side of the upper arm

1. Run your fingers along the collarbone until you reach the shoulder bone at the outermost tip of the shoulder

2. Place 4 fingers of your hand just below the shoulder bone
3. Now place 4 fingers of your other hand on the elbow. Draw an imaginary line down the center front and down the outer side of the upper arm from shoulder to elbow. Injections can be given between these imaginary lines and your hands if there is enough tissue to pinch.

4. See “How to inject” on page 16 for additional instructions.

**Back of the arm**

1. Run your fingers along the collarbone until you reach the shoulder bone.
2. Place 4 fingers of your hand behind the arm just below the shoulder bone.

3. Now place 4 fingers of your other hand on the back side of the elbow. Draw an imaginary line down the center back and down the outer side of the back upper arm from shoulder to elbow. Injections can be given between these imaginary lines and your hands if there is enough tissue to pinch.

4. See “How to inject” on page 16 for additional instructions.
How to inject

The steps are the same whether you are injecting yourself or someone else. The steps below should be done after the person receiving the injection has removed clothing around the area to be injected, an injection site has been found, and the person receiving the injection is ready for the injection (see previous instructions for more information).

1. Clean the area to be injected with an alcohol swab; let the alcohol dry before injecting

2. Press the plunger until a droplet forms at the tip of the needle

3. Pinch the skin around the injection site between the thumb and fingers of the hand that is not holding the syringe
4. Hold the syringe like a pencil or dart with your right hand if you are right-handed and your left if you are left-handed. Using a quick motion, insert the needle at a 90° angle through the skin.

5. Once the needle is fully in, draw back on the plunger to check for blood. It is important to make sure you are not injecting into a vein, and checking for blood will determine this:
   - **If no blood enters the syringe**, slowly push the plunger in until the syringe is empty.
   - **If blood enters the syringe**, withdraw the needle and, using a gauze pad, place pressure on the injection site. Start over with a new syringe and a new site for injection.

Please note that this step may not be necessary for all injections. Ask your doctor or nurse if or when you should check for blood.
6. Once the syringe is empty, pull the needle straight out. It may be helpful to hold a gauze pad over the injection site and use it to apply pressure once the needle has been removed. Use an ice cube if you feel pain at the injection site.

7. If there is any blood, wipe it off and, if necessary, apply an adhesive bandage.

8. Dispose of the used syringe, needle, and needle cap in a puncture-resistant container. Do not replace the needle cap prior to disposal (see the following section for more information about proper disposal of syringes, needles, and vials).

9. Wash your hands with soap and warm water.
How to dispose of used syringes, needles, and vials

It is important to follow state and local laws regarding proper disposal of used syringes, needles, and vials. Your doctor, nurse, or pharmacist will provide instructions to you.

You should:

• Place used supplies in a heavy plastic or metal container with a tight-fitting lid that is puncture resistant and leakproof; you can ask your pharmacist for a “sharps container” or you can use a laundry detergent bottle
• Mark “Not For Recycling” on the container
• Reinforce the lid with heavy-duty tape
• Store the container in a secure place out of the reach of children or pets

You should not:

• Reuse syringes, needles, and vials once empty
• Throw the syringes, needles, and vials in household trash
• Recycle syringes, needles, and vials once empty
• Use a clear plastic or glass container

How to store Acthar

• Acthar should be kept refrigerated (36°–46°F; 2°–8°C) between uses

Watch instructional videos about self-injection of Acthar at Acthar.com/SarcInjection

SELECT IMPORTANT SAFETY INFORMATION

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

• 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
Injecting the upper-outer thigh muscle

The following instructions are for self-injections.

1. Sit comfortably on a firm chair to keep the muscle relaxed

2. To locate the correct muscle, place your fingertips on the middle of the thigh and gently press down to locate the thigh bone. The muscle that runs along the upper-outer edge of the thigh bone is the muscle that should be injected

3. It is best to inject into the middle third of that muscle. To find the middle third, place the fingertips of one hand on your knee and rest the palm of that hand on your thigh. Place the fingertips of your other hand behind the first hand. The outer area under your second hand is the area to inject

4. See “How to inject” on page 22 for additional instructions
Injecting the upper-arm muscle

NOTE: In some patients, the muscle may not be well developed and would not be a suitable area for injections. Consult your doctor or nurse for further guidance. The person receiving the injection can either sit or lie down, whichever is more comfortable, with his or her arm relaxed. The following instructions are for the person giving the injection.

1. Run your fingers along the collarbone until you reach the shoulder bone at the outermost tip of the shoulder

2. Inject in the area 3 fingertip widths directly below the shoulder bone

3. See “How to inject” on page 22 for additional instructions
How to inject

The steps are the same whether you are injecting yourself or someone else. The steps below should be done after the person receiving the injection has removed clothing around the area to be injected, an injection site has been found, and the person receiving the injection is ready for the injection (see previous instructions for more information).

1. Clean the area to be injected with an alcohol swab; let the alcohol dry before injecting

2. Press the plunger until a droplet forms at the tip of the needle

3. Stretch and hold the skin around the injection site between the thumb and fingers of the hand that is not holding the syringe. Steady the muscle by grasping it on each side
4. Hold the syringe like a pencil or dart with your right hand if you are right-handed and your left if you are left-handed. Using a quick motion, insert the needle at a 90° angle through the skin.

5. Once the needle is fully in (about 1/8" of the needle should still be visible above the skin), draw back on the plunger to check for blood. It is important to make sure you are not injecting into a vein, and checking for blood will determine this.
   – If no blood enters the syringe, slowly push the plunger in until the syringe is empty.
   – If blood enters the syringe, withdraw the needle and, using a gauze pad, place pressure on the injection site. Start over with a new syringe and a new site for injection.

Please note that this step may not be necessary for all injections. Ask your doctor or nurse if or when you should check for blood.
6. Once the syringe is empty, pull the needle straight out. It may be helpful to hold a gauze pad over the injection site and use it to apply pressure once the needle has been removed. Use an ice cube if you feel pain at the injection site.

7. If there is any blood, wipe it off and, if necessary, apply an adhesive bandage.

8. Dispose of the used syringe, needle, and needle cap in a puncture-resistant container. Do not replace the needle cap prior to disposal (see the following section for more information about proper disposal of syringes, needles, and vials).

9. Wash your hands with soap and warm water.
How to dispose of used syringes, needles, and vials
It is important to follow state and local laws regarding proper disposal of used syringes, needles, and vials. Your doctor, nurse, or pharmacist will provide instructions to you.

You should:
• Place used supplies in a heavy plastic or metal container with a tight-fitting lid that is puncture resistant and leakproof; you can ask your pharmacist for a “sharps container” or you can use a laundry detergent bottle
• Mark “Not For Recycling” on the container
• Reinforce the lid with heavy-duty tape
• Store the container in a secure place out of the reach of children or pets

You should not:
• Reuse syringes, needles, and vials once empty
• Throw the syringes, needles, and vials in household trash
• Recycle syringes, needles, and vials once empty
• Use a clear plastic or glass container

How to store Acthar
• Acthar should be kept refrigerated (36°–46°F; 2°–8°C) between uses

To learn more about self-injection of Acthar, please visit Acthar.com/Sarclnjection

SELECT IMPORTANT SAFETY INFORMATION
What is the most important information I should know about Acthar? (continued)
• 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 might harm an unborn baby. Therefore, tell your doctor if you are pregnant or plan on becoming pregnant
Questions?
If you have a question that is not answered in this brochure, please ask your doctor or nurse. You can also speak with a personal Nurse Coach from ActharPACT to help review the steps with you and provide helpful tips. Nurse Coaches are available 24/7 at no cost to you. You or your caregiver can call 1.877.546.PACT.
Feel free to use the space below to write down any questions or notes you’d like to remember.

Mallinckrodt intends this document to be informative, but you should remember the contents are general in nature and not meant to substitute for specific advice from professionals that may be necessary based on your individual questions and needs. We have made reasonable efforts to provide helpful and accurate information; however, we make no guarantees and you should not solely rely on the information included in this document. Always refer to your doctor or nurse for specific questions or concerns.

When to call your doctor
You should call your doctor right away if you have any of the following:
• Problems that keep you from giving yourself the injection
• Needle that breaks off in the injection site
• Medication injected into the wrong area
• Bleeding at the injection site that doesn’t stop
• Rash, redness, or swelling at the injection site
• A lot of pain
• Shortness of breath
• Fever or chills
• Allergic reaction
• Any other side effect or concern
Home Injection Training Services
You can have a healthcare professional visit you at your home to provide Home Injection Training Services. This service is provided at no cost to patients and caregivers and can be scheduled more than once if needed.
To find out more about these free Home Injection Training Services, you or your caregiver can call the Acthar Support & Access Program at 1.888.435.2284 or visit Acthar.com/SarcTraining.

SELECT IMPORTANT SAFETY INFORMATION
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 visit www.fda.gov/medwatch.
You may also report side effects by calling 1.800.778.7898.
Please see accompanying full Prescribing Information.

Reference
H.P. Acthar® Gel (repository corticotropin injection) prescribing information, Mallinckrodt ARD, Inc.