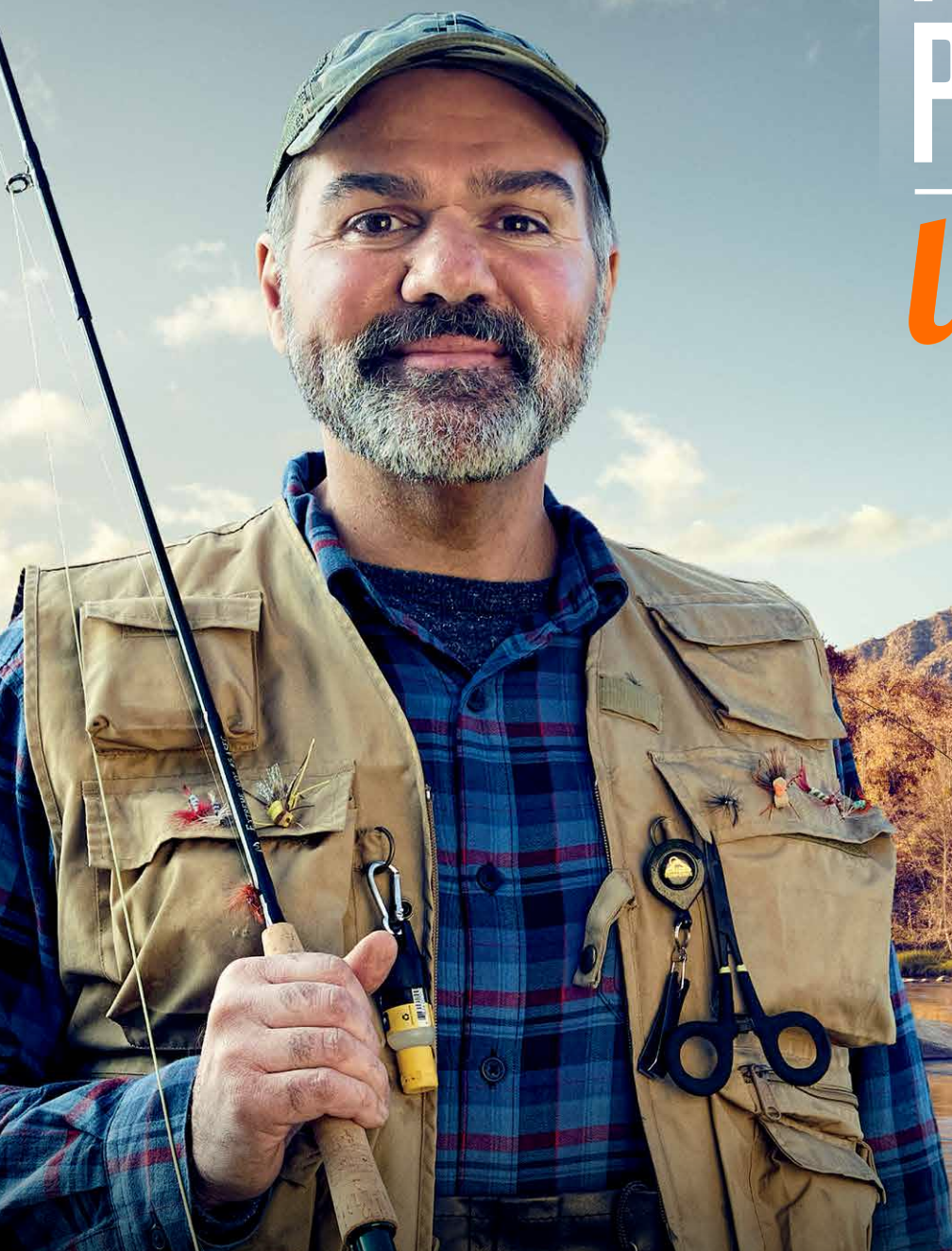


RELIEF IS POSSIBLE

let's go



H.P. **Acthar**® GEL
(repository corticotropin injection) 80 U/mL

What is H.P. Acthar® Gel?

- A prescription medicine for flares or on a regular basis (maintenance) in people with dermatomyositis or polymyositis (DM-PM), or systemic lupus erythematosus (lupus)
- A prescription add-on medicine for the short-term administration (to tide patients over an acute episode or exacerbation) in: psoriatic arthritis (PsA); rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis

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

Please see additional Important Safety Information on pages 26-27 and throughout this guide, and accompanying full Prescribing Information.

RELIEF IS POSSIBLE

let's go

SELECT IMPORTANT SAFETY INFORMATION

DO NOT take Acthar until you have talked to your doctor if you have any of the following conditions:

- Eye infections, such as ocular herpes simplex
- Had recent surgery
- Stomach ulcers or a history of stomach ulcers
- Heart failure
- Uncontrolled high blood pressure

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Important Safety Information

Important Safety Information	26-27
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Please see additional Important Safety Information on pages 26-27 and throughout this guide, and accompanying full Prescribing Information.

This guide provides step-by-step instructions on how to inject Acthar and reviews all the items you will need when injecting. This includes:

- How to find areas on the body to inject Acthar
- How to complete the injection itself
- How to store Acthar
- How to dispose of Acthar and injection supplies

GETTING STARTED WITH ACTHAR

The instructions below explain how to prepare and inject Acthar. If you need support, a caregiver can give you the injection or you can schedule an appointment with your doctor.

You are also eligible to have a registered nurse provide Acthar Injection Training at your home. If you are interested in this service, please discuss it with your doctor. For more information, see page 24.

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.

Acthar is given by a subcutaneous (under the skin) or intramuscular (into the muscle) injection. Acthar should never be given intravenously (into a vein) or by mouth.

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
 If you have any questions, contact your doctor.
4. Refrigerate Acthar as soon as you receive it and check that your refrigerator is set between 36°F–46°F or 2°C–8°C.
5. Read this entire instruction guide before your first injection.

Items you will need when injecting Acthar:



A 23g or 25g needle can be used to draw Acthar into the syringe and it should be used to inject Acthar. If your kit includes a 20g needle, this should be used only to draw up Acthar into the syringe, not to inject.

- 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
- Alcohol swabs
- Gauze pad
- Adhesive bandage
- Puncture-resistant container to safely dispose of syringe and needles after use

Preparing to inject:

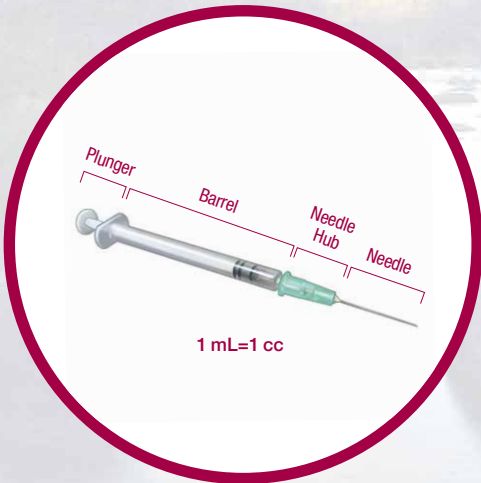


1. Gather all your supplies in one place so they will be easy to access when injecting.

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. Confirm the dose you are instructed to take.
- 5. Remove the cap of the vial and use an alcohol swab to wipe the rubber stopper on top of the vial.
- 6. Attach either the wider (20g) or the thinner (23g or 25g) needle to the 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.



7. 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.



8. While the syringe is still in the vial, turn the vial and syringe upside down.



9. While keeping the needle tip in the gel (medication), slowly pull back the plunger to the exact amount your doctor prescribed.



Keep needle tip in gel (medication) at all times.

10. 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.



11. If you used 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 you used 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).

SELECT IMPORTANT SAFETY INFORMATION

DO NOT take Acthar until you have talked to your doctor if you have any of the following conditions:

- 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.

A few things to remember before injecting

- Ask your doctor or nurse which injection areas may be best for you. Common areas include the upper arm or thigh
- If a caregiver is performing the injection, the upper arm may be best
- You may inject into the same area (eg, upper-right thigh) more than once a week, but you need to rotate (change) the injection sites in that area each time, keeping 1 inch of distance between sites

Do not inject into:

- A vein
- The same site (small area of the muscle) more than once a week. You must keep at least 1 inch of distance between sites when injecting into an area 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
- The belly button
- A knee or the groin area

If you are injecting subcutaneously, **continue to page 10.**

If you are injecting intramuscularly, **skip to page 18.**

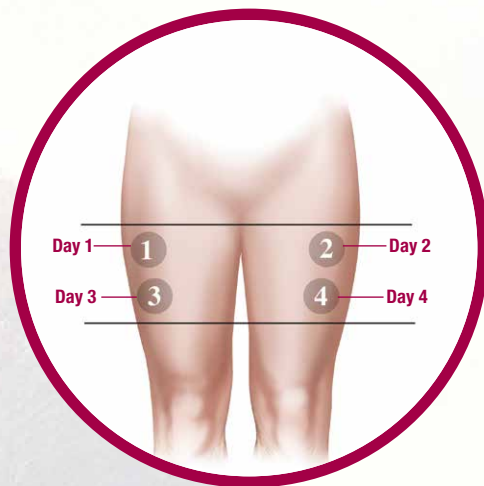
Contact your doctor if you notice any injection-site reactions, including redness, pain, and swelling.

SUBCUTANEOUS INJECTION ONLY

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 14 for additional instructions.



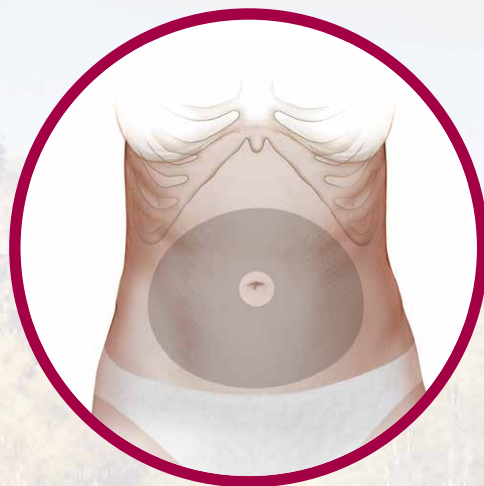
You may inject into the same area more than once in a week, but rotate the injection sites in that area each time, keeping 1 inch between sites.



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 14 for additional instructions.



SUBCUTANEOUS INJECTION ONLY

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.



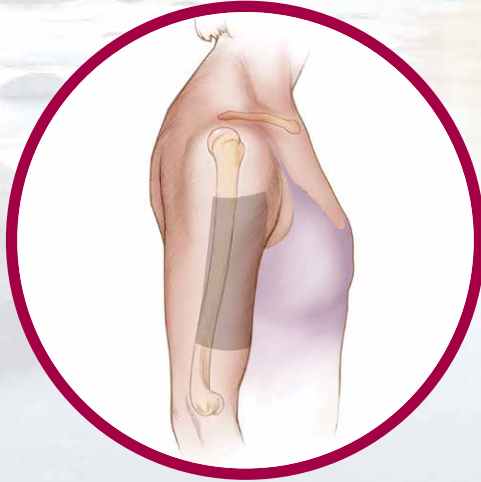
2. Place 4 fingers of your hand just below the shoulder bone.



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 14 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 14 for additional instructions.



SUBCUTANEOUS INJECTION ONLY

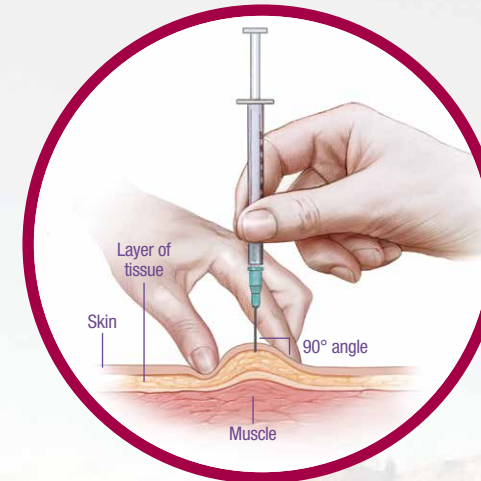
How to inject

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: This step may not be necessary for all injections. Ask your doctor or nurse if or when you should check for blood.



SUBCUTANEOUS INJECTION ONLY

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 facing page 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 leak-proof; you can ask your pharmacist for a sharps container or you can use a laundry detergent bottle
- If you are using a laundry detergent bottle or other puncture-resistant and leak-proof container, please remember the following:
 - Affix the sharps container label included with your **Acthar Starter Kit**
 - Mark **“Not for Recycling”** right 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 and needles
- 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

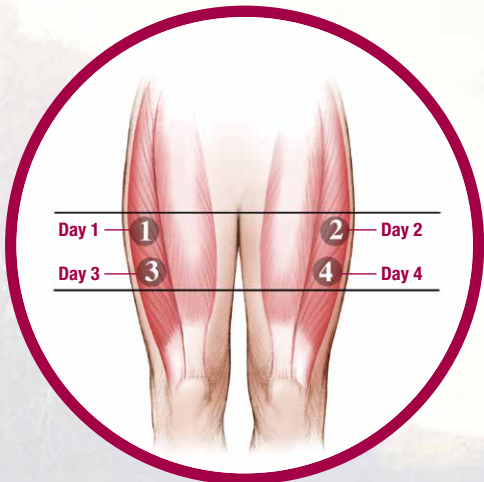
- Acthar should be kept refrigerated (36°F–46°F; 2°C–8°C) between uses

INTRAMUSCULAR INJECTION ONLY

Injecting the upper-outer thigh muscle

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 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 20 for additional instructions.



You may inject into the same muscle more than once in a week, but rotate the injection sites in that muscle each time, keeping 1 inch between sites.

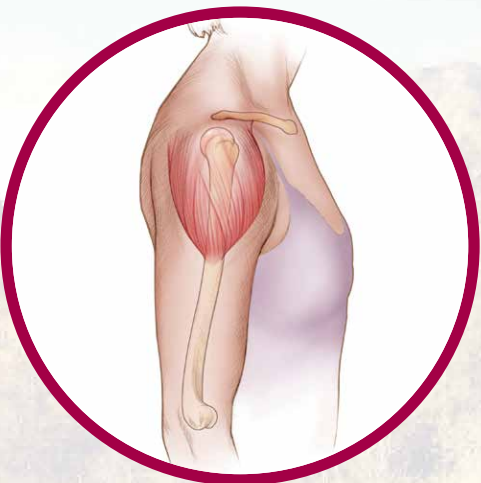


Injecting the upper-arm muscle

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 20 for additional instructions.



INTRAMUSCULAR INJECTION ONLY

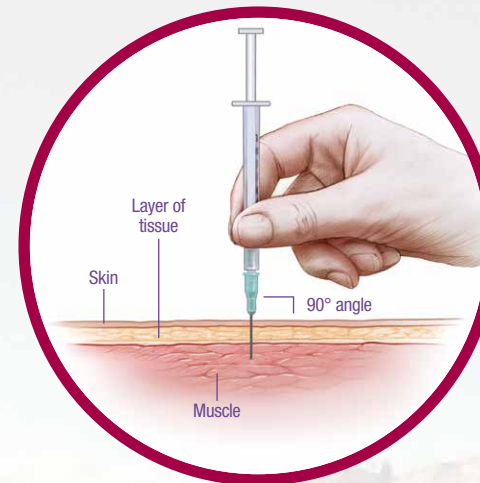
How to inject

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: This step may not be necessary for all injections. Ask your doctor or nurse if or when you should check for blood.



INTRAMUSCULAR INJECTION ONLY

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 facing page 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 leak-proof; you can ask your pharmacist for a “sharps container” or you can use a laundry detergent bottle
- If you are using a laundry detergent bottle or other puncture-resistant and leak-proof container, please remember the following:
 - Affix the sharps container label included with your **Acthar Starter Kit**
 - Mark “**Not for Recycling**” right 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 and needles
- 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°F–46°F; 2°C–8°C) between uses

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 severe side effect or concern

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.

Acthar Injection Training in the privacy of your home

You can have a registered nurse visit you at home, work with you online, or speak to you by phone to teach you how to inject Acthar. Mallinckrodt, the maker of Acthar, offers this service at no cost to you. During your welcome call, your Acthar Case Manager will tell you about injection training and ask if you would like to have this service.

Once you or your doctor requests training, the injection training nurse will:

- Contact you to schedule your training. This typically occurs within 48 hours after you receive Acthar from the Specialty Pharmacy
 - You must receive Acthar before the nurse can train you
- Review injection materials and supplies with you, including needles, syringes, alcohol wipes, etc
- Prepare the medication and supplies for your Acthar injection
- Show you or your care partner how and where to administer Acthar. (You or your care partner actually perform the injection)
- Review how to store Acthar and dispose of used needles and syringes
- Answer any questions about your injection and treatment with Acthar

If you are interested in Acthar Injection Training, please call your Case Manager at the Acthar Hub at 1-888-435-2284 Monday through Friday from 8 AM to 9 PM ET, and Saturday from 9 AM to 2 PM ET.

Questions?

If you have a question that is not answered in this brochure, please ask your doctor or nurse. Feel free to use the space below to write down any questions or notes you'd like to remember.

Notes from your office visit

ADDITIONAL INFORMATION

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.

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
- 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
- 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

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**.



Get more information about Acthar and helpful support resources. Visit ActharRheumatology.com.

Please see Important Safety Information on pages 26-27 and throughout this guide, and accompanying full Prescribing Information.



H.P. **Acthar**[®] GEL
(repository corticotropin injection) 80 U/mL

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