

Acthar[®] GEL
(repository corticotropin injection) 80 U/mL

Patient Support

Your Acthar Gel Treatment Journal

Abby,
taking Acthar Gel.
Individual results may vary.

A tool to help you record
your injections and stay on track
with your treatment plan

Please see Important Safety Information on pages 18-20,
and the full [Prescribing Information](#).

What is Acthar Gel?

Acthar® Gel is a prescription medicine used for:

- Reduction of proteinuria in people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or that due to lupus erythematosus (lupus)
- Treatment of infantile spasms in infants and children under 2 years of age
- Treatment for adults with acute relapses or flares of multiple sclerosis (MS). Studies have shown Acthar to be effective in speeding recovery from an MS relapse. However, there is no evidence that it affects the ultimate outcome or natural history of the disease
- Treatment of severe acute and chronic allergic and inflammatory conditions affecting different parts of the eye. This can include the front part of the eye such as the cornea and iris, or the back part of the eye such as the optic nerve and retina
- Treatment for people with symptoms of sarcoidosis
- Treatment for flares or on a regular basis (maintenance) in people with systemic lupus erythematosus (lupus)
- Treatment for flares or on a regular basis (maintenance) in people with dermatomyositis or polymyositis (DM-PM)
- Add-on therapy for short-term administration (to tide patients over an acute episode or exacerbation) in: psoriatic arthritis (PsA); rheumatoid arthritis (RA), including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis

Acthar is injected beneath the skin or into the muscle.

SELECT IMPORTANT SAFETY INFORMATION

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

- Have been given or are about to receive a live or live attenuated vaccine
- A skin condition called scleroderma
- Bone density loss or osteoporosis
- Any infections, including fungal, bacterial, or viral
- Eye infections, such as ocular herpes simplex

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, which 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. This journal should not be used for patients with Infantile Spasms. For caregivers of IS patients, please see Acthar.com.

Staying on track starts here

This journal can help you stay motivated as you go through your treatment plan. Bring it to all of your doctor's appointments so together, you and your doctor can review your progress and discuss any treatment goals or questions you may have.

Inside you will find tools to help you:

- ✓ Record your treatment schedule
- ✓ Monitor your progress
- ✓ Track injections and how you are feeling
- ✓ Write down treatment goals and questions for your doctor

Gary,
taking Acthar Gel.
Individual results may vary.

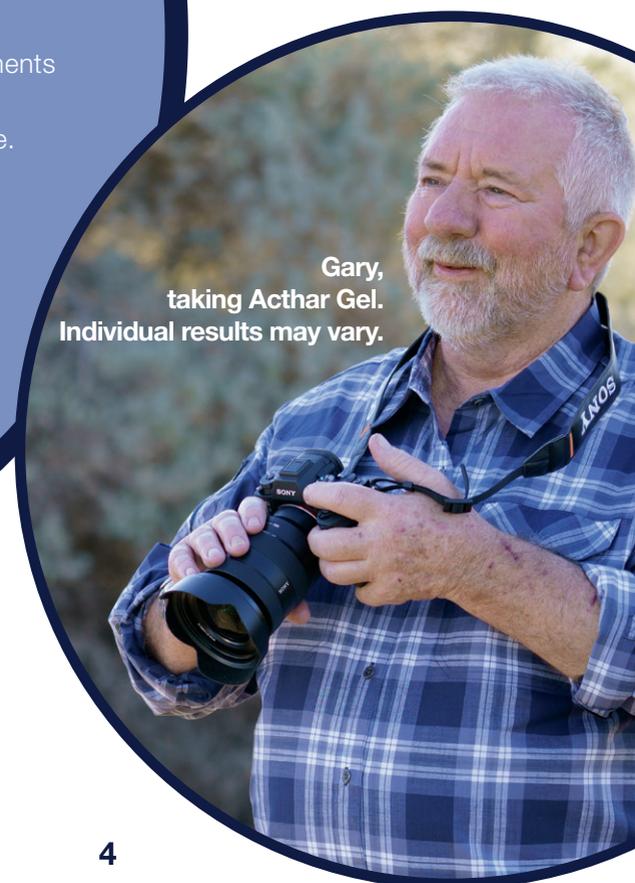


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Your support starts here

With Acthar Patient Support, you have a dedicated Nurse Navigator* who will:

- Answer questions about your condition and Acthar Gel, and guide you to support resources
- Coordinate free, one-on-one injection training to take place in your home, online, or by phone—when you are starting Acthar Gel and if you need additional training at a later date



*Nurse Navigators do not give medical advice and will direct you to your doctor for answers to medical questions.

Working side by side with your Nurse Navigator, your Case Manager offers ongoing support and will help you with:

- Insurance coverage
- Assistance options

For more information, visit Acthar.com

SELECT IMPORTANT SAFETY INFORMATION (continued)

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

- Had recent surgery
- Stomach ulcers or a history of stomach ulcers
- Heart failure
- Uncontrolled high blood pressure
- Addison’s disease or Cushing’s syndrome
- Allergies to pig-derived proteins
- Suspected infections at birth (in infants under 2 years of age)

Tell your doctor about any other health problems that you have. Give your doctor a complete list of medicines you are taking, including all prescription and nonprescription medicines, vitamins, and herbal supplements.

Please see additional Important Safety Information on pages 18-20, and the full [Prescribing Information](#).

Building your support team

Having people to support you when managing a health condition is an important part of your care. It can be helpful to identify who makes up your support team, what type of support each person can provide, when they’re available, and the best way to contact them.

Sources of support

List the support you would like to have during treatment and write down who you can ask to help.

TYPE OF SUPPORT	NAME	AVAILABILITY	PHONE/EMAIL
Comes with me to my appointments			
Helps me inject			
Helps me stay on track			
In case of emergency			

Be sure to add the best phone numbers for your Nurse Navigator and Case Manager to “Important phone numbers” on page 9.



Need support? We’re here to help
Call Acthar Patient Support at **1-888-435-2284**

Monday through Friday, 8 AM to 9 PM ET
Saturday, 9 AM to 2 PM ET

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Making the most of your doctor's appointments

Preparing ahead of time can ensure that the time you spend with your doctor is productive and helpful. Here are some tips to help you get ready for appointments:



READ

about your condition and your treatment options.



RECORD

both your prescription and over-the-counter medicines (including vitamins and herbal supplements), along with your dose for each and any side effects you may have experienced. Be sure to share with your doctor.



WRITE

down any questions or concerns you want to talk about with your doctor.



ASK

a family member or friend to go with you for support, help you make sure important questions are addressed, and help you remember or write down what your doctor says.

Questions to ask your doctor

It can be helpful to have questions prepared prior to your doctor's visits, especially if you feel rushed during appointments. Below is a list of questions you may find helpful to take to your next doctor visit.

QUESTIONS	ANSWERS
What are the goals of my Acthar Gel treatment?	
What is my Acthar Gel dose?	
How and when should I take my Acthar Gel dose?	
How will I know if Acthar Gel is working?	
How long will I have to take Acthar Gel?	
What side effects might I experience? What should I do if I experience them?	
Are there any support resources to help me manage my condition?	

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

Appointment tracker

It is important to write down how you are doing, what your doctor tells you, and any treatment goals you discuss with your doctor. You can use the space below to help you keep a record.

APPOINTMENT DATE/TIME	ITEMS TO DISCUSS
	Treatment Goals:

Important phone numbers

Add and update important phone numbers for members of your support team. Add nurses, physician assistants, and others as needed.

CONTACT	NAME	PHONE
Specialist		
Primary Care Doctor		
Nurse		
Nurse Navigator		
Case Manager		
Specialty Pharmacy		

SELECT IMPORTANT SAFETY INFORMATION

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

- 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

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How to convert your Acthar Gel dose

You may need to convert your prescribed dose of Acthar Gel from units to milliliters (mL). This is because the amount of medicine you will draw up into the syringe for injection is measured in mL.

The table at the right can help with the conversion. You should speak to your doctor if you have any questions about converting your prescribed dose of Acthar Gel.

PRESCRIBED UNITS	INJECTION AMOUNT
80 units	1 mL
60 units	0.75 mL
40 units	0.5 mL
20 units	0.25 mL

The values shown are provided as examples only. This is not a list of all the possible prescribing doses.

Remember to take Acthar Gel exactly as prescribed by your doctor. He or she has prescribed the correct dose for you based on your medical history and condition.

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. These effects are reversible once Acthar therapy is stopped
- 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; these allergies may be severe. Signs of allergic reaction include:
 - Skin rash and itching
 - Swelling of the face, tongue, lips, or throat
 - Trouble breathing
- The effects of Acthar may be intensified if you have an underactive thyroid or cirrhosis of the liver
- 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 to become pregnant

Please see additional Important Safety Information on pages 18-20, and the full [Prescribing Information](#).

Your Acthar Gel routine

Use the table below to keep track of the dosing instructions provided by your doctor.

Type of injection (check one):		How often:	
<input type="checkbox"/> Subcutaneous (under the skin)	<input type="checkbox"/> Intramuscular (into a muscle)		
# of units of Acthar Gel prescribed:	# of mL of Acthar Gel for injection:		
units	mL (See conversion chart on page 12.)		
Acthar Gel is taken on:			
<input type="checkbox"/> Monday	<input type="checkbox"/> Tuesday	<input type="checkbox"/> Wednesday	<input type="checkbox"/> Thursday
<input type="checkbox"/> Friday	<input type="checkbox"/> Saturday	<input type="checkbox"/> Sunday	
Time of day that I take Acthar Gel:			
<input type="checkbox"/> Morning	<input type="checkbox"/> Afternoon	<input type="checkbox"/> Evening	
My supplies should include:			
<input type="checkbox"/> Acthar Gel vial	<input type="checkbox"/> Syringe	<input type="checkbox"/> Needle for injecting	<input type="checkbox"/> Needle for drawing up
<input type="checkbox"/> Alcohol swabs	<input type="checkbox"/> Adhesive bandage/gauze (if needed)	<input type="checkbox"/> Acthar Gel injection instructions	<input type="checkbox"/> Sharps container
<input type="checkbox"/> Injection placemat			
Reminders I will use to take Acthar Gel:			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reminders I will use to refill Acthar Gel:			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Take some time right now to note on your calendar your Acthar Gel start date, the days of your injections, your next doctor's appointment, when to order refills, and any events (such as vacations, holidays, special events) that you may need to plan around during your treatment.



Do not stop taking Acthar Gel without speaking with your doctor.

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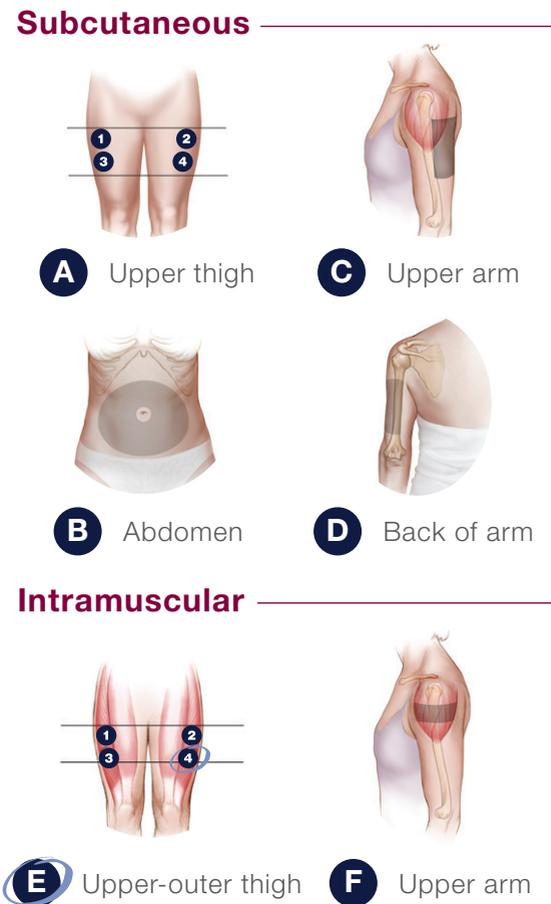
Using the Acthar Gel calendar

Use the calendar starting on page 17 to help you stay on track by recording your Acthar Gel injections. Share this information with your doctor at your next appointment.

Use it to record important information, including:

- When and where you have injected Acthar Gel
- Amount injected
- Upcoming travel plans or changes to your schedule that might affect your injections

Record where you have injected Acthar Gel by circling the injection area (A to F) that you use for each injection. If you use injection area A or E and rotate the site of your injection, you should also circle the number (1 to 4) that corresponds with the site you used. See example on next page.



SELECT IMPORTANT SAFETY INFORMATION

What are the most common side effects of Acthar?

Commonly reported side effects of Acthar include:

- Injection site reaction
- Fatigue, physical weakness, and lack of energy
- Fluid retention
- Insomnia (difficulty sleeping)
- Headache
- High blood sugar

Please see additional Important Safety Information on pages 18-20, and the full [Prescribing Information](#).

Acthar Gel calendar example

Sample content below. Not actual patient information.

SUN	MON	TUES	WED	THURS	FRI	SAT
	1	2	3	4	5	6
A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4
	1 mL			1 mL	Call Case Manager	
7	8	9	10	11	12	13
A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4
1 mL			1 mL			1 mL
14	15	16	17	18	19	20
A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4
		1 mL				1 mL
21	22	23	24	25	26	27
A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4
	1 mL			1 mL	Reorder Acthar Gel!!	
28	29	30	31			
A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4
1 mL			1 mL			

Notes:

Notes: Adjust schedule so injections don't fall on a Saturday when traveling next time.

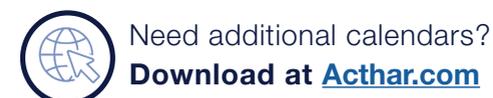
Notes:

Notes:

Successes, challenges, side effects, and notes for my doctor:

Ask doctor about taking Acthar Gel on a different day of the next trip.

Ask doctor what we can do to relieve joint swelling.



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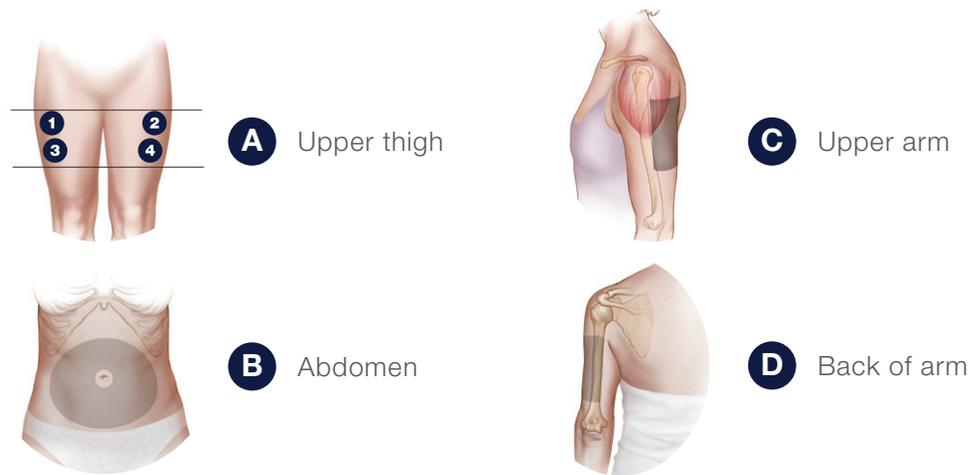
Patient Support

Your Acthar Gel calendar

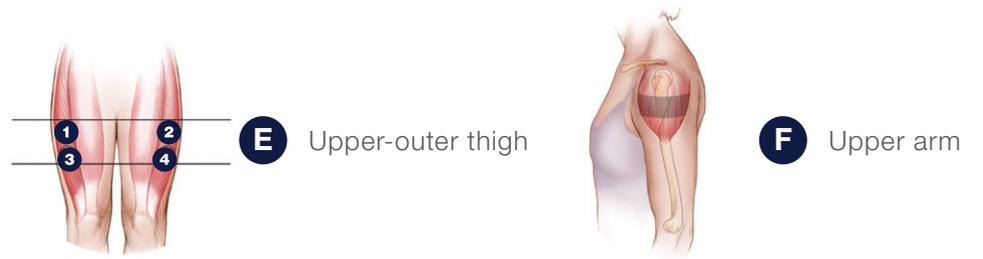
Keep track of the date, area, and site of each Acthar Gel injection.

Record where you have injected Acthar Gel by circling the injection area (A to F) that you use for each injection. If you use injection area A or E and rotate the site of your injection, you should also circle the number (1 to 4) that corresponds with the site you used.

Subcutaneous



Intramuscular



Do you need to reorder Acthar Gel?

Call Acthar Patient Support at **1-888-435-2284**

Please see Important Safety Information on pages 18-20, and the full [Prescribing Information](#).

Month: _____

SUN	MON	TUES	WED	THURS	FRI	SAT
A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4
Notes:						
A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4
Notes:						
A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4
Notes:						
A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4
Notes:						
A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4	A B C D E F 1 2 3 4
Notes:						

Successes, challenges, side effects, and notes for my doctor:

Need additional calendars?
 Download at Acthar.com

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IMPORTANT SAFETY INFORMATION

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

- Have been given or are about to receive a live or live attenuated vaccine
- 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
- Addison's disease or Cushing's syndrome
- Allergies to pig-derived proteins
- Suspected infections at birth (in infants under 2 years of age)

Tell your doctor about any other health problems that you have. Give your doctor a complete list of medicines you are taking, including all prescription and nonprescription medicines, vitamins, and herbal supplements.

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
- 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, retain too much salt and water, or have low blood potassium levels. As a result of this, your doctor may recommend some changes to your diet, such as eating less salt or 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 and 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. These effects are reversible once Acthar therapy is stopped
- 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; these allergies may be severe. Signs of allergic reaction include:
 - Skin rash and itching
 - Swelling of the face, tongue, lips, or throat
 - Trouble breathing
- The effects of Acthar may be intensified if you have an underactive thyroid or cirrhosis of the liver
- 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 to become pregnant

IMPORTANT SAFETY INFORMATION (continued)

What are the most common side effects of Acthar?

Commonly reported side effects of Acthar include:

- Injection site reaction
- Fatigue, physical weakness, and lack of energy
- Fluid retention
- Insomnia (difficulty sleeping)
- Headache
- High blood sugar

The most common side effects for the treatment of infantile spasms (IS) are:

- Increased risk of infections
- Convulsions
- High blood pressure
- Irritability
- Fever

The above side effects may also be seen in adults and children over 2 years of age. Some children with IS progress to other forms of seizures; IS sometimes masks these seizures, which may become visible after treatment for IS has been completed.

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 1-800-844-2830.



Need additional calendars?
Download at Acthar.com



More questions?

- How do I teach someone else to inject Acthar Gel for me?
- My Acthar Gel delivery didn't arrive when scheduled. What should I do?
- What happens if I lose my insurance or my insurance changes?

Don,
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We're here to help!

Call **1-888-435-2284**

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Saturday, 9 AM to 2 PM ET

Acthar.com



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