

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 24-25, and accompanying full Prescribing Information.

STAYING ON TRACK

starts now

This journal can help you stay motivated as you go through your treatment plan. Bring it to all of your doctor visits. 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



Table of Contents

Making your doctor's appointment more productive	4
Appointment tracker	6
Converting your Acthar dose	7
My Acthar routine	8
Building your Acthar team	g
Medication list	10
Personalized support from a registered nurse	12
Your Acthar calendar	13
My calendar	14
Notes from my office visit	22
Acthar patient support services	22
My phone numbers	23
Important Safety Information	24-25

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

If you'd like to learn more about your condition or Acthar treatment, visit ActharRheumatology.com.

Making your doctor's appointment more productive

Getting ready for your appointments ahead of time can help make them more productive. It will also make it easier to talk with your doctor and help you better understand your treatment plan. Below are some tips to help you prepare.



READ up on your condition and your treatment options.



ASK a family member or friend to go with you to help you remember what your doctor says and make sure important questions are addressed.



RECORD your prescription and over-the-counter medications, along with your dose for each, and any treatment effects you may experience. Be sure to share with your doctor.



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

It can be helpful to have questions prepared prior to doctor 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 (you may want to write them down)
What are the goals of my Acthar treatment?	
How and when should I take my Acthar dose?	
How long will I have to take Acthar?	
How will I know Acthar is working?	
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?	
What is my Acthar dose?	
Add new:	Maria Comment
Add new:	



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	Notes
	Joint pain and morning stiffness has worsened
4/20/18	Treatment goals: Be ready to treat symptom flares when they happen
	Treatment goals:
GRANT SE	
	Treatment goals:
	Treatment goals:

Converting your Acthar dose

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

The table at the right can help with the conversion. You can also check your Step-by-Step Injection Guide or speak to your doctor if you have any questions about converting your prescribed dose of Acthar.

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

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

Prescribed units	Injection amount
80 units	1 mL
60 units	0.75 mL
40 units	0.5 mL
20 units	0.25 mL

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



My Acthar routine

Writing down your dose and how often you should inject will help you take Acthar as instructed by your doctor. Use the table below to keep track of your dosing instructions.

Make a plan for your Acthar treatment

As schedules can change, it's a good idea to plan ahead so that you can keep up with your injections if your routine changes.

# of units of Acthar I was prescribed:	units	# of mL of Acthar I inject:	m
Duration of Acthar I was prescribed:		Days of the week I take Acthar:	
Time of day/existing routine to link to:			
My supply container should include:	Syringe/needlesAlcohol swabsSharps container	Acthar injection instructionsAdhesive bandage/gauze (if needed)	Injection placematActhar via
Reminders I will use to remember to take Acthar:			
Reminders I will use to refill Acthar:			

Take some time right now to note on your calendar your Acthar 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, etc) that you may need to plan around during your treatment.

Do not stop taking Acthar without speaking with your doctor.

Building your Acthar team

Getting support to cope with and manage any health condition is an important part of your care. It's important to identify who can provide support, what kind of support they can provide, and when they can help. Fill out the sections below to help plan to ask for support.

Sources of support

List the types of support you would like to have during treatment and write down the names of people you could ask for help.

Type of support	Name	Phone/Emai
Come with me to my appointments		
Help me inject		
Help me stay on track		
In case of emergency		
Please use spa	ce below for additional	types of support



Tell your doctor about all the medications you are taking. List below all prescription treatments (including infusions) you are prescribed.

Prescription medication list

Medicine	Dosage	Schedule	I take this medicine for:
Salar .			
Land Control			
			No.

For injection instructions, please see the Step-by-Step Injection Guide included in your Acthar Starter Kit. List below all over-the-counter medications (vitamins, supplements, and herbs) you are currently taking.

Non-prescription medication list

Medicine	Dosage	Schedule	I take this for:
The state of the s			
	9 3 3		

Visit ActharRheumatology.com to learn more about Acthar and helpful support resources.



Personalized support from a registered nurse

ActharPACT (Patient & Acthar Coaching Team) is a no-cost resource to help guide you through your treatment.

This specialized support allows you to schedule recurring calls with a registered nurse who is trained to answer questions about Acthar. If you choose, your nurse can also send you personalized information and/or text messages. There is no cost to you for this support, and you can stop it at any time.



Call 1-877-546-7228 for 24-hour nurse support, or visit ActharPACT.com.



What can the Nurse Coach do for me?

Your registered Nurse Coach can provide:



- Information about your condition and Acthar
- Reimbursement and financial support services information
- Support for managing your treatment
- Treatment reminders and useful materials
- Assistance with staying on track, and help with setting up injection reminders by text

Always direct specific questions about your symptoms or your care to your doctor. For example, your Nurse Coach can talk to you about general side effects, but only your doctor can offer specific advice on your condition.

Your Acthar calendar

On the following pages you'll find a calendar to help you keep track of your Acthar injections. Use it to record a number of items, including:

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

My calendar example

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
					Doctor Appt. 10:00 am	2	3
October	4	5	6	7 Injection training 9:30 am	8	9	Injection (right arm)
		12	13	Id Injection Itelt orgal	AmharPACT	16	Injection (right thigh)
Month:	18	Out-of-town	20 Out-of-town	21 Injection (left thigh)	22	23	24 Injection (right arm)
Ī	<u>25</u>	26	27	28 Injection (left arm)	29 ActharPACT II:30 am	Call pharmacy to order refill of Acthar	31 Injection (right thigh)

Symptom	Start date	End date	Comments	My doctor's instructions	What can I do
Pain in left knee	October 5	Still have it	Gets worse on workdays		
		EXAR	APLE		

Successes, challenges, side effects, and other notes:

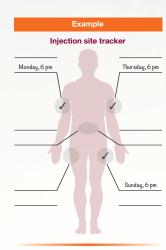
Ask doctor about taking Acthar at a different time of the day on the next trip. Talk with Acthar PACT nurse about suggestions for traveling with Acthar. Ask doctor what we can do to help relieve joint swelling.

Sunday	Monday	Tuesday	Wednesday
_			

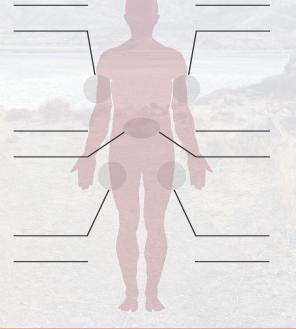
Symptom	Start date	End date	Comments	My doctor's instructions	What can I do
				V ₁	

Successes, challenges, side effects, and other notes:

Thursday Friday Saturday



Injection site tracker





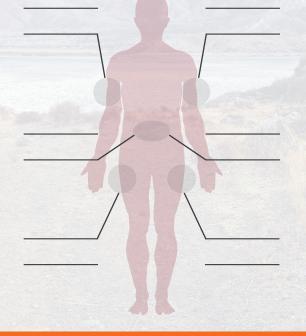
Sunday	Monday	Tuesday	Wednesday
_			
_			

Symptom	Start date	End date	Comments	My doctor's instructions	What can I
	LANG				
				Marine,	

Successes, challenges, side effects, and other notes:

Thursday	Friday	Saturday

Injection site tracker





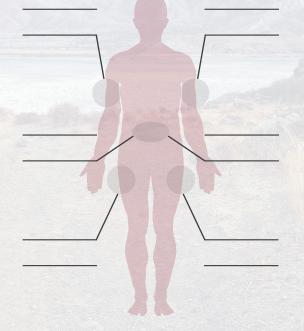
Sunday	Monday	Tuesday	Wednesday
_			
_			
_			
_			

Symptom	Start date	End date	Comments	My doctor's instructions	What can I do
	Lands				

Successes, challenges, side effects, and other notes:

Thursday	Friday	Saturday

Injection site tracker





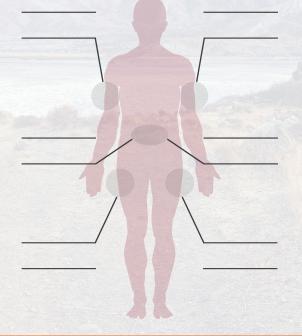
Sunday	Monday	Tuesday	Wednesday
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Symptom	Start date	End date	Comments	My doctor's instructions	What can I d
				Marco.	

Successes, challenges, side effects, and other notes:

Thursday	Friday	Saturday

Injection site tracker





Notes from my office visit	t	

Acthar patient support services

Mallinckrodt, the maker of Acthar, offers the support services listed below.



Acthar Hub

1-888-435-2284 Monday through Friday from 8 AM to 9 PM ET, and Saturday from 9 AM to 2 PM ET.

A resource that supports you from prescription through treatment, including help with insurance coverage, financial assistance options, and injection training.



ActharPACT (Patient & Acthar Coaching Team)

1-877-546-PACT • ActharPACT.com

- Access a 24-hour nurse hotline when you have questions or concerns about your condition or treatment
- Receive regular calls from a registered Nurse Coach to help you manage your Acthar treatment

My phone numbers

Rheumatologist	
Name:	
Phone:	
Primary Care Doctor	
Name:	
Phone:	
Nurse	
Name:	
Phone:	
Specialty Pharmacy	
Name:	
Phone:	
Acthar Injection Training Nurse	
Name:	
Phone:	
ActharPACT Nurse Coach	
Name:	
Phone:	
Other	
Name:	
Phone:	
Other	
Name:	
Phone:	
Personal contact information	
If found, please contact	
Name:	
Phone:	
Email:	

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.

Notes	Notes

Get more information about Acthar and helpful support resources. Visit ActharRheumatology.com. Please see Important Safety Information on pages 24-25, and accompanying full Prescribing Information. Mallinckrodt Pharmaceuticals H.P. Acthar GEL (repository corticotropin injection) 80 U/mL 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. © 2018 Mallinckrodt. ARDUS/01-06/0518/0041 07/18 Printed in USA.