

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 22-23 and throughout this guide, and accompanying full Prescribing Information.

RELIEF IS POSSIBLE

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WELCOME

This guide offers information to help you get started with Acthar treatment. You'll learn about how FDA-approved Acthar may provide relief from your symptoms, as well as what you can expect during the Acthar approval process.

Inside you'll find:

About Acthar	Page 4
Dermatomyositis and polymyositis	Page 6
Systemic lupus erythematosus	Page 8
Rheumatoid arthritis	Page 10
Psoriatic arthritis	Page 12
Ankylosing spondylitis.....	Page 14

How Acthar May Work	Page 16
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Acthar Support	Pages 18-21
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Important Safety Information	Pages 22-23
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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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ABOUT ACTHAR

Acthar is an FDA-approved injectable medication. Acthar is used to treat symptoms of a number of rheumatic conditions:

- Dermatomyositis and polymyositis (DM-PM)
- Systemic lupus erythematosus (Lupus)
- Rheumatoid arthritis (RA)
- Psoriatic arthritis (PsA)
- Ankylosing spondylitis (AS)

Depending on your condition, Acthar may be prescribed for:

- Short-term use when symptoms do not improve
- Long-term use (only for certain patients) as a maintenance treatment to help manage disease activity

How Acthar may help treat your condition

Acthar may be an effective treatment option to reduce disease activity and provide symptom relief.

If you have DM-PM or lupus, your doctor may be able to lower your steroid dose with Acthar.

Why has your doctor prescribed you Acthar?

Your doctor may have prescribed Acthar as another treatment option because you continue to experience disease activity or flares.

If your disease has remained active and you need another treatment option, Acthar may be right for you.



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.

For information about Acthar support resources, visit [Acthar.com/approval](https://acthar.com/approval).



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DERMATOMYOSITIS AND POLYMYOSITIS (DM-PM)

Understanding Your Condition

DM and PM are rheumatic diseases that affect about 75,000 people in North America. They occur when your immune system attacks your body's own healthy tissue. Symptoms may include:

- Inflammation and weakness in the skeletal muscles (found in the thighs, torso, shoulders, hips, and upper arms)
- A rash around the eyes and on the skin of the joints (DM only)



Acthar Clinical Experience

Acthar may help reduce disease activity and provide symptom relief. Read about Acthar results below.

Dr. Aggarwal Study

*In an **open-label, prospective study**, 10 patients were treated with Acthar. Six of them had DM and 4 had PM. (An 11th patient dropped out due to an unrelated condition.) DM and PM patients did not differ in their response to treatment.*

- Seven out of the 10 patients saw an improvement in their condition:
 - All patients decreased or discontinued steroid use
 - Two patients saw some improvement, but this improvement did not continue to the end of the study. Another patient saw no improvement
- Serious side effects reported were viral infections, bone loss, and chest pain

Dr. Patel Study

*In a **retrospective case series**, a total of 4 patients —2 with DM and 2 with PM—were treated with Acthar.*

- Three patients saw an improvement, while 1 patient saw no change:
 - Two patients with PM experienced an improvement in muscle strength and a decrease in muscle pain
 - One of the 2 patients with DM saw her rash improve; the other saw no change
 - Steroid dose was lowered for the 3 patients who saw improvement
- One patient had blurry vision during Acthar treatment, but it resolved before treatment was stopped

Please see additional Important Safety Information on pages 22-23 and throughout this guide, and accompanying full Prescribing Information.

Acthar is not a cure. Though Acthar has been shown to help some patients, not all patients may experience the same results. Keep in mind that patients in these clinical settings were on several treatments in addition to Acthar. The results seen in these patients may not all be due to Acthar.

Acthar is a prescription medicine for flares or on a regular basis (maintenance) in people with dermatomyositis or polymyositis (DM-PM).

Acthar is injected beneath the skin or into the muscle.

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

Glossary Terms

Open-label study: A type of clinical trial to research how effective a treatment may be. Since the trial is "open," both doctors and patients are aware of which treatment is being researched.

Prospective study: A type of research that observes a group of patients for certain outcomes, such as the development of a disease or the impact of treatment on a disease.

Retrospective case series: A type of research study in which doctors look back in time to compare patients' medical records.



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SYSTEMIC LUPUS ERYTHEMATOSUS (LUPUS)

Understanding Your Condition

Lupus is a rheumatic disease affecting about 1.5 million people in the United States today, with 10 times as many women living with lupus as men. Lupus occurs when your immune system overreacts, causing your body to produce antibodies that destroy healthy tissues. This attack can lead to inflammation, pain, and damage to your body. Symptoms can vary from one person to another and may include:

- Butterfly-shaped rash across the cheeks and nose
- Fluid retention and swelling in the feet and legs
- Headaches
- Chest pain with deep breathing
- Painful or swollen joints

Acthar Clinical Experience

Acthar may help reduce disease activity and provide symptom relief. Read about Acthar results below.

Dr. Fiechtner Study

*Acthar was assessed in a **single-site, open-label study** of 10 patients diagnosed with lupus.*

- Acthar provided symptom relief to all 10 patients, including:
 - Improvement in joint and active skin problems
- There were no serious side effects reported during this study. One patient had swelling in the legs and ankles; however, 2 weeks after Acthar had been stopped, the swelling was gone. Another patient was treated for a sinus infection



Acthar is not a cure. Though Acthar has been shown to help some patients, not all patients may experience the same results. Keep in mind that patients observed in clinical settings were on several treatments in addition to Acthar. The results seen in these patients may not all be due to Acthar.

Acthar is a prescription medicine for flares or on a regular basis (maintenance) in people with systemic lupus erythematosus (lupus).

Acthar is injected beneath the skin or into the muscle.

SELECT IMPORTANT SAFETY INFORMATION

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

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

Glossary Terms

Open-label study: A type of clinical study to research how effective a treatment may be. Since the trial is "open," both doctors and patients are aware of which treatment is being researched.

Single-site study: A type of medical research study. It takes place at a single clinic, and information is collected and processed at a single data center.



RHEUMATOID ARTHRITIS (RA)

Understanding Your Condition

RA is a common rheumatic disease affecting about 1.5 million people in the United States today, with 3 times as many women living with RA as men. RA occurs when your body's immune system attacks healthy bone and tissues, which can cause joint damage. It is a chronic condition, and its symptoms may include:

- Inflammation
- Pain
- Swelling

RA

Acthar Clinical Experience

Acthar may help reduce disease activity and provide symptom relief. Read about Acthar results below.

Dr. Brown Study

In a *case series*, a total of 5 patients with RA were treated with Acthar.

- Four of the 5 patients experienced improvements in their condition during treatment, including:
 - A decrease in disease-related inflammation (based on lab results)
 - Reduced symptoms, such as pain, joint swelling, and tenderness
- The fifth patient saw short-term improvements
- Side effects included changes or an increase in blood pressure, rash on the upper chest, weight gain, and high blood sugar

Dr. Wei Study

In an *open-label study*, a total of 8 patients with RA were treated with Acthar.

- All patients in this study experienced a decrease in their RA disease activity while taking Acthar. This included:
 - Significant reduction in joint pain and swelling
- Side effects included skin reaction at the injection site and low blood sugar. One patient experienced blood clots

Acthar is not a cure. Though Acthar has been shown to help some patients, not all patients may experience the same results. Keep in mind that patients in these clinical settings were on several treatments in addition to Acthar. The results seen in these patients may not all be due to Acthar.

Acthar is a prescription add-on medicine for short-term administration (to tide patients over an acute episode or exacerbation) in rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy).

Acthar is injected beneath the skin or into the muscle.

SELECT IMPORTANT SAFETY INFORMATION

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

- 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

Glossary Terms

Case series: A study that reports on the outcomes for a group of patients who were given similar medical treatments.

Open-label study: A type of clinical study to research how effective a treatment may be. Since the trial is "open," both doctors and patients are aware of which treatment is being researched.



H.P. **Acthar** GEL
(repository corticotropin injection) 80 U/mL 11

Please see additional Important Safety Information on pages 22-23 and throughout this guide, and accompanying full Prescribing Information.

PSORIATIC ARTHRITIS (PSA)

Understanding Your Condition

PsA is a rheumatic condition that affects up to 2.25 million Americans. The exact cause is not known, but it occurs when your immune system attacks healthy tissue. This can lead to inflammation of your joints and can trigger an overproduction of skin cells, causing your skin to become red and irritated with flaky white scales. Symptoms may include:

- Red and swollen fingers and toes
- Stiff, painful joints
- Fatigue (tiredness)



Acthar Clinical Experience

Acthar may help reduce disease activity and provide symptom relief. Read about Acthar results below.

Dr. Brown Study

*In a **case series**, a total of 9 patients with PsA were treated with Acthar.*

- A majority of patients in this study saw some type of improvement in joint and skin symptoms:
 - Eight of 9 patients experienced fewer joint problems during treatment
 - Six of 8 patients achieved relief from active skin problems, including skin disease that “mostly cleared” in 1 patient
- Side effects included high blood pressure, weight gain, high blood sugar, and facial flushing

Dr. Fiechtner Study

*In an **open-label study**, a total of 15 patients with PsA were treated with Acthar. Out of the original 15 patients, 8 remained on Acthar through 12 weeks of treatment.*

- All 8 remaining patients saw their PsA symptoms improve by 20%. This included:
 - Reduced joint pain and swelling
- Three of the original 15 patients left the study due to side effects, which included worsening psoriasis and depression

Acthar is not a cure. Though Acthar has been shown to help some patients, not all patients may experience the same results. Keep in mind that patients in these clinical settings were on several treatments in addition to Acthar. The results seen in these patients may not all be due to Acthar.

Acthar is a prescription add-on medicine for short-term administration (to tide patients over an acute episode or exacerbation) in psoriatic arthritis (PsA).

Acthar is injected beneath the skin or into the muscle.

SELECT IMPORTANT SAFETY INFORMATION

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

- 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

Glossary Terms

Case series: A study that reports on the outcomes for a group of patients who were given similar medical treatments.

Open-label study: A type of clinical study to research how effective a treatment may be. Since the trial is “open,” both doctors and patients are aware of which treatment is being researched.



ANKYLOSING SPONDYLITIS (AS)

Understanding Your Condition

AS is a type of arthritis that affects about half a million people in the United States. It is more common in men than women and occurs most often in Caucasians, Asians, and Hispanics.

The exact cause of AS is not known, but researchers believe a type of gene and heredity may play a role in its development.

AS typically affects your spine (backbone), causing your ligaments and joints to become inflamed. As time goes by, AS may also cause the bones and joints of your spine to fuse (grow together). Symptoms may include:

- Pain and stiffness, beginning in the lower back and hips, then moving up the spine
- Neck pain and fatigue
- Loss of flexibility in the spine, leading to a hunched-forward posture

Acthar may be an appropriate treatment option to help reduce disease activity and provide symptom relief.

In some patients, Acthar may also help fight inflammation.

Acthar has been shown to help some patients manage their symptoms. This includes patients who were taking other treatments for their condition.



Acthar is not a cure. Though Acthar has been shown to help some patients, not all patients may experience the same results. Keep in mind that patients in these clinical settings were on several treatments in addition to Acthar. The results seen in these patients may not all be due to Acthar.

Acthar is a prescription add-on medicine for short-term administration (to tide patients over an acute episode or exacerbation) in ankylosing spondylitis.

Acthar is injected beneath the skin or into the muscle.

SELECT IMPORTANT SAFETY INFORMATION

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

- 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



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HOW ACTHAR MAY WORK



Acthar is not a steroid. It is believed to work differently than steroids. The active ingredient in Acthar is ACTH, a natural hormone. Acthar is designed to work by helping your body produce its own natural hormones.*

Acthar may help your body by*:

- Regulating your immune system
- Targeting inflammation in your body caused by your condition

***The exact way Acthar works in the body is not fully understood. Further studies are being carried out. The above information is based on lab and scientific data, and how it relates to patient benefits is not completely known.**

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

These are not all of the possible side effects of Acthar.



Please see additional Important Safety Information on pages 22-23 and throughout this guide, and accompanying full Prescribing Information.

H.P. **Acthar** GEL
(repository corticotropin injection) 80 U/mL 17

ONE-ON-ONE SUPPORT FOR YOU, RIGHT FROM THE START

Mallinckrodt is committed to helping you from prescription to treatment

From the moment your doctor prescribes Acthar, you'll be supported every step of the way. Your doctor will send your Acthar prescription to the Acthar Hub.

Here's how the Acthar Hub may help you:

Insurance support:

- Works directly with your doctor and insurance company to help determine insurance coverage and work through any plan requirements and/or approvals



Financial assistance:

- Acthar Commercial Co-pay Program, which provides a \$0 co-pay per prescription of Acthar for eligible patients with commercial or private insurance—and no government insurance (see Terms and Conditions to the right)
- Information on Independent Charitable Foundations that may be able to provide funding for government-insured patients seeking financial support*
- Acthar Patient Assistance Program, which provides Acthar at no cost for eligible uninsured, underinsured, or rendered uninsured patients†‡



Acthar Injection Training:

- Schedules injection training with a registered nurse at home, online, or by phone
- Helps you get comfortable with the injection process
- Includes training a care partner if you are not going to self-inject



Get support from ActharPACT

Registered nurses with ActharPACT (Patient and Acthar Coaching Team) are here to support you with treatment. ActharPACT offers:

- Your own registered Nurse Coach who can provide personalized support and education over the phone
- Connections to other helpful resources
- Access to a 24/7 nurse hotline to help answer questions

Call 1-877-546-PACT (1-877-546-7228).
You can also visit [Acthar.com/PACT](https://acthar.com/PACT).

Terms and Conditions:

- The Acthar Commercial Co-pay Program provides drug co-pay assistance of up to \$25,000 per calendar year for each eligible patient
- This program is valid for eligible privately and commercially insured patients. Uninsured patients are not eligible for this program
- This program is not valid for prescriptions for which payment may be made in whole or in part under federal or state health programs, including, but not limited to, Medicare or Medicaid, or where prohibited by law
- Patient must have a valid Acthar prescription for an FDA-approved, on-label indication
- Patient must be a permanent US resident. This program is not valid outside of the United States
- Patient (or patient's legal representative) must be 18 years of age or older to opt in to program
- This program offer is limited to 1 membership per person and is not transferable
- Patients should consult their insurance provider concerning any limitations that may apply to this program under their insurance policy
- This program does not constitute prescription drug coverage or insurance and is not intended to substitute for such coverage
- Patients are responsible for any co-payment or coinsurance costs above and beyond the program's annual maximum benefit
- Absent a change in Massachusetts law, effective July 1, 2019, the Acthar Commercial Co-pay Program will no longer be valid for residents of Massachusetts
- Mallinckrodt ARD, Inc. reserves the right to terminate or modify this program at any time without notice

*Mallinckrodt does not determine Independent Charitable Foundations' fund eligibility criteria, or have any influence over the patients chosen or types of assistance provided.

†Acthar Patient Assistance Program eligibility criteria:

- Valid Acthar prescription for an FDA-approved indication
- Permanent US resident
- Household income at or below 700% of the Federal Poverty Level
- Patients may be subject to random income verification to determine eligibility

‡Program administered via a third-party organization.



H.P. **Acthar**® GEL
(repository corticotropin injection) 80 U/mL 19

Please see Important Safety Information on pages
22-23 and throughout this guide, and accompanying
18 full Prescribing Information.

WHAT TO EXPECT DURING THE ACTHAR APPROVAL PROCESS

Through the Acthar Hub, you'll get your own personal Acthar Case Manager to support you throughout the process

AFTER YOU HAVE BEEN PRESCRIBED ACTHAR:

1. You receive a welcome call from your Case Manager at the Hub.
– If you miss the call, please call back at **1-888-435-2284**
2. Your Case Manager discusses the process for obtaining insurance coverage, your co-pay or coinsurance, and injection training.
3. An Acthar Welcome Letter and the Rheumatology Treatment Guide arrive at your home.
4. Your Case Manager works with your doctor and insurance company to determine coverage. If you hear from your insurance company, please let your Case Manager know.
– Responding to the plan requirements may take some time, but your Case Manager will help you through this process

AFTER YOU HAVE BEEN APPROVED FOR ACTHAR:

1. Your Specialty Pharmacy calls to schedule delivery.
2. An Acthar Starter Kit arrives at your home.
3. Acthar is shipped to your home in a refrigerated container.
4. A registered nurse can help you or your care partner learn to inject Acthar on your own. If you are interested in this service, talk to your Case Manager.

The Acthar Hub is available at
**1-888-435-2284 Monday through Friday from
8 AM to 9 PM ET, and Saturday from 9 AM to 2 PM ET.**



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H.P. **Acthar** GEL
(repository corticotropin injection) 80 U/mL 21

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



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Mallinckrodt
Pharmaceuticals

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