# **UVEITIS • KERATITIS • RETINAL VASCULITIS**AND OTHER INFLAMMATORY EYE CONDITIONS

# Relief is possible with Acthar® Gel

Ask your doctor if FDA-approved Acthar Gel may be right for you



Gerolyn, treated with Acthar Gel. Individual results may vary.

#### What is Acthar Gel?

Acthar Gel is a prescription medicine for 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.

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

Please see additional Important Safety Information throughout and the accompanying full Prescribing Information.

- Bone density loss or osteoporosis
- Any infections, including fungal, bacterial, or viral



# Could Acthar® Gelbe right for you?

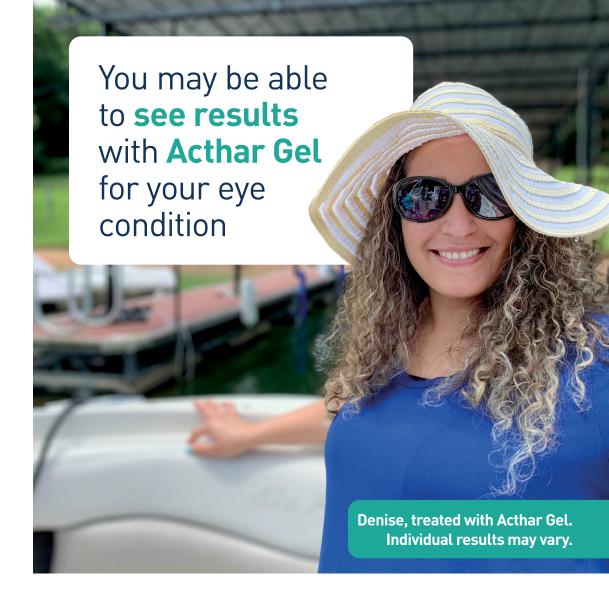
Acthar Gel is an **FDA-approved medication** that may help if you are still looking for symptom relief.

Acthar Gel is not a steroid. Acthar Gel is thought to work differently from steroids, but it can have similar side effects in some people. Talk to your doctor about what to expect.

#### **SELECT IMPORTANT SAFETY INFORMATION**

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

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



# In this brochure, you will learn about:

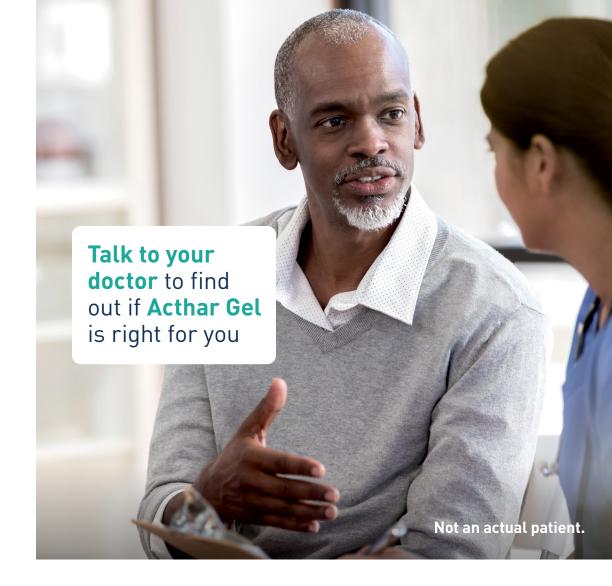
| <b>Symptoms</b> of inflammatory eye conditions                                       |
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#### SELECT IMPORTANT SAFETY INFORMATION

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

- 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.



# Are you struggling with these common symptoms of your inflammatory condition?

|                           | <b>UVEITIS</b> | <b>KERATITIS</b> | <b>RETINAL VASCULITIS</b> |
|---------------------------|----------------|------------------|---------------------------|
| Blurred vision            | <b>/</b>       | <b>✓</b>         |                           |
| Eye redness               | <b>/</b>       | <b>✓</b>         |                           |
| Floaters                  | <b>/</b>       |                  | <b>✓</b>                  |
| Eye pain                  | <b>/</b>       | <b>✓</b>         |                           |
| Sensitivity to light      | <b>/</b>       | <b>✓</b>         |                           |
| Decreased vision          |                | <b>✓</b>         | <b>✓</b>                  |
| Tearing                   |                | <b>/</b>         |                           |
| Difficulty opening eyelid |                | <b>✓</b>         |                           |

#### **SELECT IMPORTANT SAFETY INFORMATION**

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

- Never inject Acthar directly into a vein
- Acthar is injected beneath the skin or into the muscle.
   Always inject Acthar with SelfJect beneath the skin
- Follow your doctor's instructions for injecting Acthar

# Ask your doctor about Acthar® Gel

Acthar Gel may be able to ease the symptoms of your inflammatory eye condition.



# What is Acthar® Gel?

Acthar Gel is a prescription medicine for 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.



# **SELECT IMPORTANT SAFETY INFORMATION**

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

- 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

### How is Acthar Gel believed to work?

- It's not a steroid—Acthar Gel is believed to work differently from steroids
- It's thought to work with the immune system to help **reduce inflammation**
- It's a blend of proteins and natural hormones, like those already found in your body

The way Acthar Gel works is not fully understood. Further studies are being done. The information above is based on studies done in labs and with healthy volunteers. How the information relates to patient benefits is unknown. Acthar Gel can have similar side effects to steroids. Ask your doctor what you should expect from treatment with 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

# How well did Acthar® Gel work in people with uveitis?

In one study, doctors reviewed medical records to see whether Acthar Gel was effective in treating people with uveitis. The records of 91 people who took Acthar Gel over the past 12 months were included.

# In this study:



<sup>\*</sup>Doctors rated uveitis symptoms as improved.

# SELECT IMPORTANT SAFETY INFORMATION

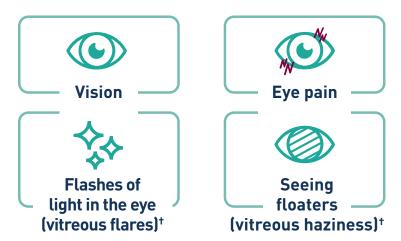
## What is the most important information I should know about Acthar? (continued)

- When taking Acthar long-term, your adrenal gland may produce too much of a hormone called cortisol. This can result in symptoms of Cushing's syndrome. This may cause increased upper body fat, a rounded "moon" face, bruising easily, or muscle weakness
- Sometimes when you stop taking Acthar long-term, your body may not produce enough natural cortisol. This is called "adrenal insufficiency." Your doctor may prescribe a steroid medicine to protect you until the adrenal gland recovers

and the accompanying full Prescribing Information.

Please see additional Important Safety Information throughout

# People experienced improvements in the following symptoms:



The safety of Acthar Gel was not studied. Remember that Acthar Gel can have similar side effects to what you may experience with steroids.

There were limits to this study, including the possibility of incomplete medical records and doctors having different definitions of "improved." Many people were taking other treatments along with Acthar Gel. The exact role Acthar Gel had in the improvements is not known.

<sup>†</sup>Vitreous is the jelly-like material in the middle of the eye.

• 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



# How well did Acthar® Gel work in people with keratitis?

A study looked at whether Acthar Gel was safe and effective in treating people with severe keratitis. There were 31 people in the study who took Acthar Gel for 16 weeks.\*

# In this study:



people saw improvements 1 in 2 after 12 weeks of treatment with Acthar Gel

There were limits to this relatively small and shorter study. People could have been taking other treatments along with Acthar Gel. The exact role Acthar Gel had in the improvements is not known.

#### SELECT IMPORTANT SAFETY INFORMATION

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

- 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

# People experienced improvements in the following symptoms:







Twelve patients reported at least 1 medical event that was not present at the start of treatment. Some of these included high blood pressure, blurred vision, double vision, and irritability. One person reported a serious medical event (intentional overdose) that was not related to Acthar Gel treatment. The doctors who conducted the study did not observe any notable increases in eye pressure.

• 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

<sup>\*</sup>Symptom changes were captured for 34 people after 12 weeks.

# How well did Acthar® Gel work in people with retinal vasculitis?

A study looked at whether Acthar Gel was effective in treating people with retinal vasculitis. There were **18 people** who took Acthar Gel for **24 weeks**.

# In this study:



3 in 5

people saw improvements after treatment with Acthar Gel

Some patients experienced side effects that were not present before taking Acthar Gel, including insomnia, palpitations, mood changes, injection site reactions, appetite changes, and hypertension. One patient discontinued the study due to adverse effects. The doctors who conducted the study did not observe any notable increases in eye pressure.

There were limits to this study, including that people could have been taking other treatments along with Acthar Gel. The exact role Acthar Gel had in the improvements is not known.



#### **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



# How can you take Acthar® Gel?

Acthar Gel is available to take in **2 ways**. Talk to your doctor to see which way could work for you.

# The Acthar® Gel Single-Dose Pre-filled SelfJect™ Injector

A device designed to help people take a 40- or 80-unit dose of Acthar Gel under the skin (subcutaneously). It may be helpful to people who have vision impairment or issues with grip.

SelfJect is only to be administered by people 18 years of age and older.



# New to injections?

Don't worry, a nurse educator will provide the injection **training you need**, whether it's in your home, online, or by phone.

# **Vial and Syringe**

An option for people who take any dose of Acthar Gel. The vial and syringe can be used to inject under the skin or into a muscle (intramuscularly).



Acthar Gel is injected in the upper thigh, abdomen, or back of the arm. Avoid injecting within 1 inch of the belly button, knee, or groin area. It IS NOT injected into the eye.

#### **SELECT IMPORTANT SAFETY INFORMATION**

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

- Your body may develop allergies to Acthar; these allergies may be severe. Signs of allergic reaction include:
  - o Skin rash and itching o Trouble breathing
  - o Swelling of the face, tongue, lips, or throat

Please see the accompanying full <u>Prescribing Information</u> and the <u>40-unit</u> and <u>80-unit</u> SelfJect Instructions for Use. If you've been prescribed SelfJect, please see the Quick Reference Guide in the SelfJect carton.

- 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



# Support from the start

If Acthar® Gel is right for you, **Acthar Patient Support** is here to help you on your treatment plan.

You are automatically enrolled in **Acthar Patient Support** when your doctor submits your prescription. The support program helps with **navigating insurance coverage** and with **injection training**.



# **Acthar Patient Support will provide:**



A **Nurse Navigator** to partner with you throughout your time taking Acthar Gel who can answer questions and provide support\*



Free injection training, based on your needs



Support for insurance coverage questions. Your Case Manager is ready to help **review your options** and create a plan

### You won't be starting this care journey alone

You have a dedicated care team available to support you every step of the way.

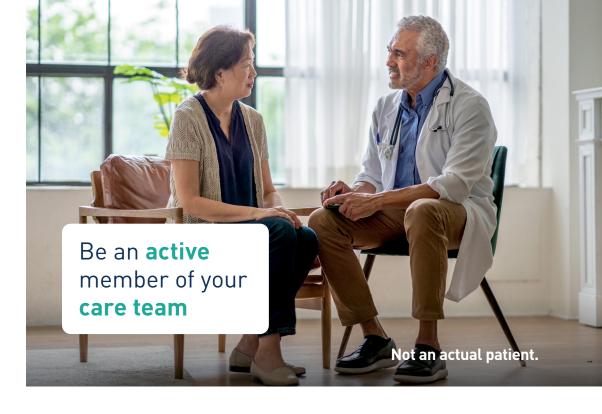
\*Nurse Navigators do not give medical advice and will direct you to your healthcare provider for any treatment-related questions, including further referrals.



# Start the conversation about Acthar® Gel with your doctor today

You and your doctor can **work together** to decide if Acthar Gel is the right treatment for you. Here are a few **questions** to help you get the conversation started:

| Is Acthar Gel an appropriate treatment option for my condition?       |
|---|
| What side effects have your patients experienced while on Acthar Gel? |
| What benefits have your patients experienced using Acthar Gel?        |



#### **SELECT IMPORTANT SAFETY INFORMATION**

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

- 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

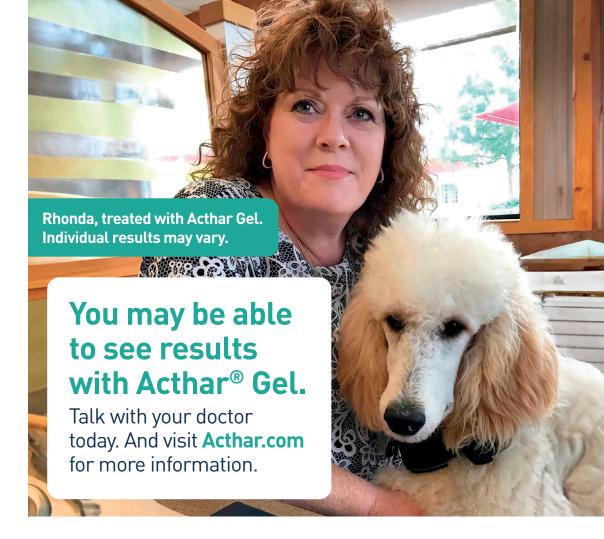
# What are the most common side effects of Acthar?

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

| Notes _ |  |  |  |
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### SELECT IMPORTANT SAFETY INFORMATION

## What are the most common side effects of Acthar? (continued)

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

- Increased risk of infections
   Irritability

Convulsions

- Fever
- High blood pressure

#### 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 pigderived 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
- Acthar is injected beneath the skin or into the muscle.
   Always inject Acthar with SelfJect beneath the skin
- 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.
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- 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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- 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

# IMPORTANT SAFETY INFORMATION (continued) 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:
  - o Skin rash and itching
  - o Swelling of the face, tongue, lips, or throat
  - o 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

### What are the most common side effects of Acthar?

Commonly reported side effects of Acthar include:

- Injection site reaction
- Fatique, 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.

Please see the accompanying full Prescribing Information for additional Important Safety Information.

# See if Acthar® Gel may be able to ease your symptoms

Hear about real patient experiences and ask your doctor if Acthar Gel could be right for you.



Visit Acthar.com/patient-stories.

#### For the treatment of:

- Uveitis
- Keratitis
- Pemphigoid

- Conjunctivitis
- Retinal vasculitis
- Other inflammatory conditions

### **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 throughout and the accompanying full <u>Prescribing Information</u>.

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