#### FDA-APPROVED TO TREAT: RHEUMATOID ARTHRITIS (RA), PSORIATIC ARTHRITIS (PSA), ANKYLOSING SPONDYLITIS (AS)

## Relief is possible with Acthar® Gel

Ask your doctor if Acthar Gel may be right for you

> Gloria, treated with Acthar Gel. Individual results may vary.

#### What is Acthar Gel?

Acthar Gel is a prescription add-on medicine 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); and 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
- Please see additional Important Safety Information throughout and the accompanying full <u>Prescribing Information</u>.



## Could Acthar<sup>®</sup> Gel be right for you?

Acthar Gel is an **FDA-approved medication to treat rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS)** 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
- Addison's disease or Cushing's syndrome
- Allergies to pig-derived proteins
- Suspected infections at birth (in infants under 2 years of age)

Please see additional Important Safety Information throughout and the accompanying full <u>Prescribing Information</u>.

You may be able to see and feel results with Acthar Gel for your RA, PsA or AS

Jacqueline, treated with Acthar Gel for an autoimmune disease. Individual results may vary.



## In this brochure, you will learn:

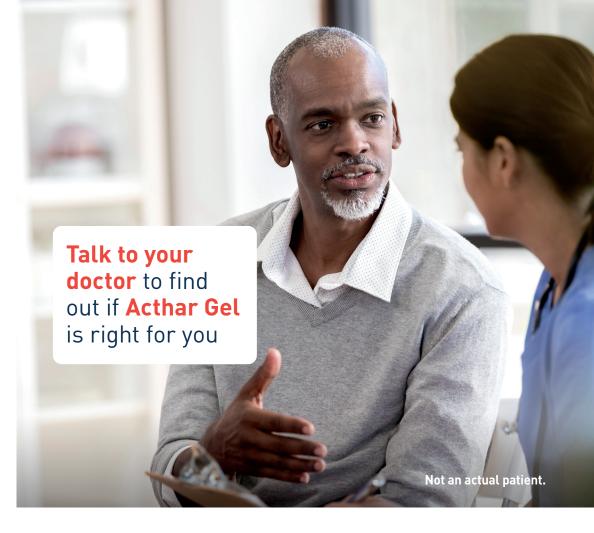
<b>Symptoms</b> of rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS)6
What is Acthar <sup>®</sup> Gel?
How well Acthar Gel worked in people with RA and PsA .10
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Your support team
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## SELECT IMPORTANT SAFETY INFORMATION

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. Other signs may be flu or any open cuts or sores



# Are you struggling with symptoms of RA, PsA or AS?

RA is a type of autoimmune disease. In autoimmune diseases, the immune system attacks healthy body tissues and cells, causing inflammation and damage to parts of the body.

In RA, the immune system mistakenly attacks the lining of the joints. The exact cause of RA is unknown; however, many genetic and environmental factors may be involved.

PsA is another autoimmune condition that causes pain, swelling and stiffness in the joints. In addition, people with PsA typically have psoriasis, which is characterized by scaly, flaky patches of skin. While there is significant overlap in symptoms, PsA and RA are distinctly different conditions. In fact, PsA is more similar to conditions like ankylosing spondylitis (AS) which mainly affects the spine and lower back.

## - Ask your doctor about Acthar<sup>®</sup> Gel -

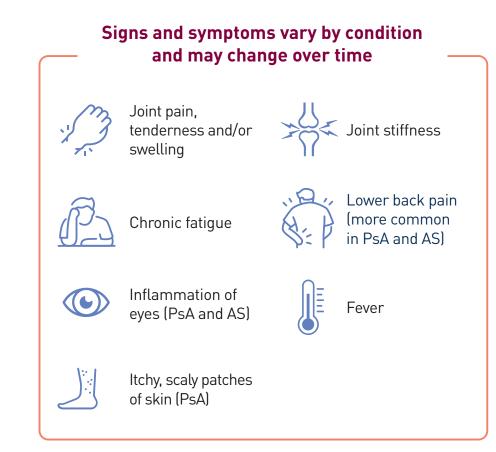
Acthar Gel may be able to **ease the** symptoms of your of RA, PsA or AS

#### **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

Please see additional Important Safety Information throughout and the accompanying full <u>Prescribing Information</u>.



## Symptoms may flare up suddenly

When symptoms suddenly worsen, this is known as a flare. A flare can consist of one, or several, symptoms. Flares can be triggered by things like stress, weather changes, overexertion, poor sleep, or infection.

When a flare occurs, it's important to let the doctor know right away to determine if additional steps should be taken.



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## What is Acthar<sup>®</sup> Gel?

Acthar Gel is a prescription medicine that is FDA-approved as a short-term add-on treatment for flares of rheumatoid arthritis (RA), including juvenile RA; psoriatic arthritis (PsA) and ankylosing spondylitis (AS). Selected patients with RA may need low-dose maintenance therapy.



disease. Individal results may vary.

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

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

## 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

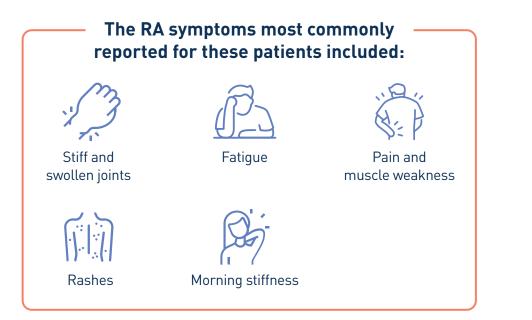
Acthar Gel can have similar side effects to steroids. Ask your doctor what you should expect from treatment with Acthar. The way Acthar Gel works is not fully understood. Further studies are being done. The information above is based on studies done in labs and with healthy volunteers. How the information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

- 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



## How well did Acthar<sup>®</sup> Gel work on the symptoms of RA?

Medical records of 54 people with RA were reviewed for the period 12 months before and up to 12 months after the first prescription date for Acthar Gel added to their treatment plan



There were limitations 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 seen is not known.



\*Of the 32 people who reported changes in their symptoms, doctors also rated 4 people with symptom changes as worsened and 3 people with no change in symptoms. There were no results reported for 22 of the 54 people included in the study.

Fourteen people with RA reported side effects. Common side effects included abdominal pain, bruising, and sweating. One person reported serious side effects (inflammation in the pancreas and urinary tract infection).

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

- 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



## How well did Acthar® Gel work in patients with treatment-resistant RA?

259 people who had persistently active RA despite treatment with a steroid and 1 or 2 disease-modifying antirheumatic drugs began a 2-part clinical trial. Roughly 60% participated in both parts.

**In Part 1,** where 235 patients added Acthar Gel to their treatment plan:

63%

saw improvement after 12 weeks, including: Fewer swollen joints Fewer tender joints

19%

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achieved remission at Week 12\*

## SELECT IMPORTANT SAFETY INFORMATION

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

- 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

Please see additional Important Safety Information throughout and the accompanying full <u>Prescribing Information</u>.

**In Part 2,** where 77 improved patients continued treatment for another 12 weeks and 77 were switched to placebo

61%

sustained their improvement with Acthar Gel vs 42 percent who were switched to placebo

**In part 1** of the study, 98 people reported side effects. Common side effects included urinary tract infections, headache, and sore throat. Three people reported serious side effects (chest pain, traumatic brain injury, and pneumonia).

**In part 2** of the study, 25 of 77 people taking Acthar Gel reported side effects. Common side effects included headache, high blood sugar, and high blood pressure. No patients reported serious side effects.

There were limits to this study. Patients were aware they were taking Acthar Gel and not all ethnicities were equally represented in the trial. In addition, people could have been taking other treatments along with Acthar Gel. The exact role Acthar Gel had in the improvements seen is not known.

\* Remission was defined as achieving a DSA28-ESR score (which measures the number of tender and swollen joints, as well as a standard laboratory indicator of inflammation) of less than 2.6.



## How well did Acthar<sup>®</sup> Gel work for patients with PsA?

15 patients with moderately-to-severely active PsA despite treatment enrolled in a 28-week, unblinded study of Acthar Gel



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## **ALL 8 PATIENTS**

who completed 12 weeks of treatment

had 20% improvement in disease activity (ACR20)

## **ALL 7 PATIENTS**

who completed 24 weeks of treatment\*,

had 70% improvement in disease activity (ACR70)

had 75% improvement in extent and severity of psoriasis (PASI75)

Of the 7 patients who withdrew prior to Week 12, 3 experienced potential treatment-related adverse events: 2 had psoriasis that worsened and 1 had depression

Please see additional Important Safety Information throughout and the accompanying full <u>Prescribing Information</u>.

The remaining 4 patients withdrew for other reasons unrelated to adverse events. There were no other potentially treatment-related adverse events identified during this study.

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

#### 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:
  - Skin rash and itching
  - Swelling of the face, tongue, lips, or throat
  - Trouble breathing



# Ways to take

## How can you take Acthar<sup>®</sup> Gel?

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

## 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.

## The Acthar<sup>®</sup> Gel Single-Dose Pre-filled SelfJect<sup>™</sup> 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.

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The exterior configuration of the drug delivery device is owned by West Pharmaceutical Services, Inc. and is used with permission.

## 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 arm. Avoid injecting within 1 inch of the belly button, knee, or groin area.

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

• The effects of Acthar may be intensified if you have an underactive thyroid or cirrhosis of the liver

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

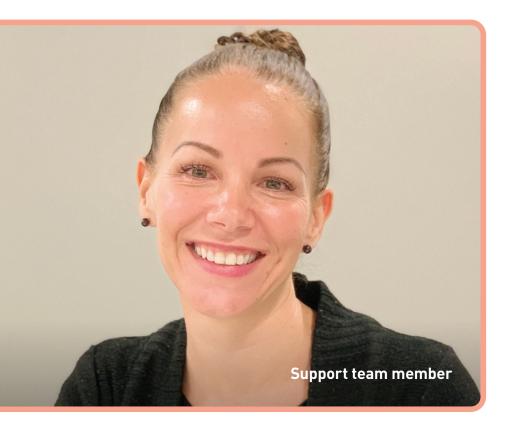
- Long-term Acthar use can affect growth and physical development in children. This can be reversed when Acthar is no longer needed
- Acthar may cause osteoporosis (weak bones)
- Acthar might harm an unborn baby. Therefore, tell your doctor if you are pregnant or plan to become pregnant



## Support from the start

If Acthar<sup>®</sup> 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 **learning** to give injections.



## 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<sup>®</sup> 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 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

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- Insomnia (difficulty sleeping)
- Headache
- High blood sugar

Please see additional Important Safety Information throughout and the accompanying full <u>Prescribing Information</u>.



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.



You may be able to feel results with Acthar Gel. Ask your doctor if Acthar Gel may be right for you

Gerolyn, treated with Acthar Gel for an autoimmune disease. Individual results may vary.

Please see additional Important Safety Information throughout and the accompanying full <u>Prescribing Information</u>.



## See if Acthar<sup>®</sup> 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.

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

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 additional Important Safety Information throughout and the accompanying full <u>Prescribing Information</u>.

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