#### FDA-APPROVED TO TREAT SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

### Relief is possible with Acthar<sup>®</sup> Gel

Ask your doctor if Acthar Gel may be right for you

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

#### What is Acthar Gel?

Acthar Gel is a prescription medicine used for treatment 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

**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
- Bone density loss or osteoporosis
- A skin condition called scleroderma
- Any infections, including fungal, bacterial, or viral

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



## Could Acthar® Gel be right for you?

Acthar Gel is an **FDA-approved medication to treat SLE** 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)

You may be able to see and feel results with Acthar Gel for your SLE

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

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

Acthar<sup>®</sup>GEL (repository corticotropin injection) 80 U/mL 3

## In this brochure, you will learn:

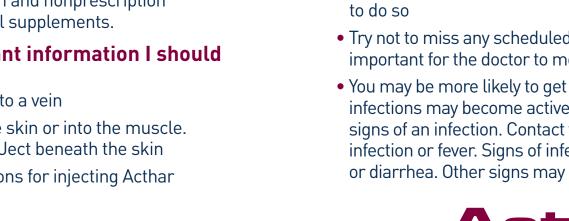
Symptoms of Systemic Lupus Erythematosus (SLE) 6
What is <b>Acthar® Gel? 8</b>
How well Acthar Gel worked in people with SLE10
Ways to take Acthar Gel14
Your support team16
Starting a conversation with your doctor18

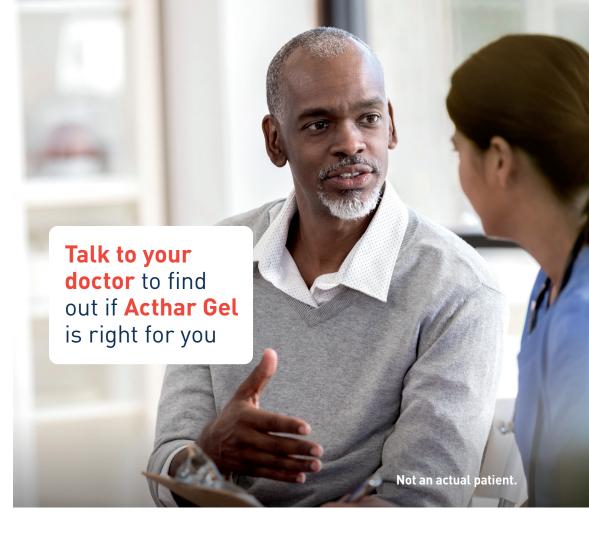
#### SELECT IMPORTANT SAFETY INFORMATION

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
- 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 SLE?

SLE is the most common type of lupus. It's a chronic and complex autoimmune condition that can affect joints, skin, blood vessels, brain, lungs, and kidneys. The exact cause of SLE is not known. Most likely, both family history and factors in the environment are involved.

No two cases of SLE are the same and the disease may affect people differently at different times.

#### These are some common signs and symptoms:

- Fatigue, often the primary symptom
- Butterfly-shaped rash that covers the cheeks and bridge of the nose
- Unexplained fevers
- Swollen or painful joints

#### **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

#### SLE can flare up unpredictably



When symptoms suddenly appear or worsen, you might be having a flare. Flares may involve a single symptom or a group of symptoms. The course of flares can be unpredictable, with symptoms coming and going.

## Even with treatment, SLE symptoms may persist or worsen

Unfortunately, treatment doesn't always eliminate symptoms or prevent flares. If you're experiencing ongoing symptoms—or having a flare—despite treatment, let your rheumatologist know. There may be something else that can help.

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

Acthar Gel may be able to ease the symptoms of your SLE



## What is Acthar<sup>®</sup> Gel?

Acthar Gel is a prescription medication used to treat SLE flares, as well as for regular use as maintenance therapy.



#### 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

#### 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**, similar to 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 still uncertain. Acthar Gel can have similar side effects to steroids. Ask your doctor what you should expect from treatment with Acthar.

- 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® Gel work in people experiencing SLE flares?

10 patients who were experiencing flares and treated with Acthar Gel were evaluated in a 28-day, unblinded study





Other effects of Acthar Gel were observed, including improvements in day-to-day activities.

\*These symptoms are among those that had been reported by patients before the study and/or assessed by standard measures of SLE disease activity.

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

- Two people experienced side effects
  - One person reported swelling in the legs and ankles. Another person reported a sinus infection
  - No one reported serious or unexpected side effects

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

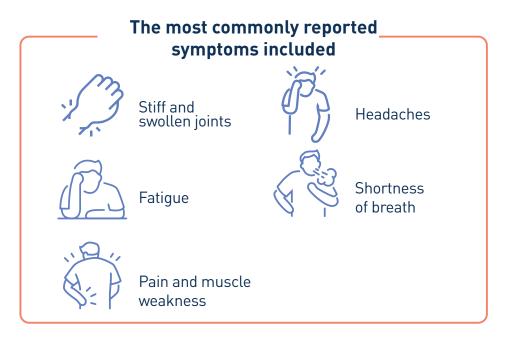
#### SELECT IMPORTANT SAFETY INFORMATION What is the most important information I should know about Acthar? (continued)

- 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



## Did patients treated with Acthar<sup>®</sup> Gel experience long-lasting symptom relief?

 In a review of medical records 12 months before and 12 months after treatment with Acthar Gel,\* 19 of 30 patients with SLE had changes in their symptoms reported.



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 seen is not known.

12

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

of the 19 patients with changes in their symptoms were rated as improved by their doctors\*\*

\*Acthar Gel was added to other SLE treatment for some patients. <sup>†</sup>Of the 19 people who reported changes in their symptoms, 1 person was rated as worsened. The remaining 11 patients did not have data reported on physician's impression of change.

- Five people reported side effects
  - Side effects included diarrhea, upset stomach, swelling, nerve pain, pneumonia, and weight gain
  - Four people reported serious side effects (muscle pain, dehydration, adrenal insufficiency, pneumonia, kidney failure, and mini stroke)

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



### 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.

#### 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.

14



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

#### 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 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.

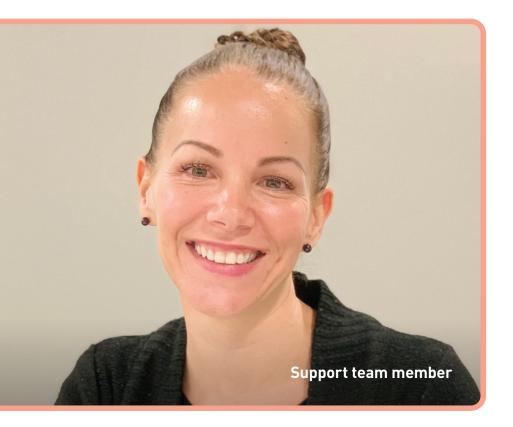
- Long-term Acthar use can affect growth and physical development in children. This can be reversed when Acthar is no longer needed
- Acthar may cause osteoporosis (weak bones)
- Acthar might harm an unborn baby. Therefore, tell your doctor if you are pregnant or plan to become pregnant



### 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® 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

18

- 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
- High blood pressureIrritability

Convulsions

• 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.



# 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>.

Mallinckrodt, the "M" brand mark, SelfJect, and the Mallinckrodt Pharmaceuticals logo are trademarks of a Mallinckrodt company. Other brands are trademarks of a Mallinckrodt company or their respective owners. © 2025 Mallinckrodt. US-2500047 03/25



