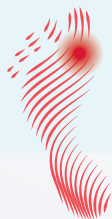


The **ONLY** FDA-approved
ACTH therapy for appropriate
patients with acute gouty
arthritis flares

 **Purified
Cortrophin® Gel**
repository corticotropin
injection USP 80 U/mL

A potential option for the next step of your treatment journey

Purified Cortrophin Gel is a prescription medicine that is injected under the skin or into the muscle. It is used for short-term add-on therapy to help manage acute episodes or flares in acute gouty arthritis.



This brochure provides important information about the medication you have been prescribed and where to find helpful resources.

ACTH=adrenocorticotropic hormone.

Important Safety Information

DO NOT use Cortrophin Gel if you have any of the following conditions:

- A skin condition called scleroderma
- Bone density loss or osteoporosis
- Fungal infections
- Ocular herpes simplex (an eye infection)
- A recent surgery
- Stomach ulcers or a history of stomach ulcers
- Heart failure
- High blood pressure
- Allergies to pig-derived proteins

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



MEET CARL

- 55 years old; contractor
- Living with acute gouty arthritis for 5 years
- Has been experiencing frequent flares
- Previously treated his flares with colchicine, but did not respond as his doctor had hoped

*“Is there anything else I can try?
I need additional options.”*

GOUT “FLARES” (ALSO CALLED “ATTACKS”) ARE EPISODES OF PAIN AND SWELLING IN AT LEAST ONE JOINT. IN SOME CASES, THE AFFECTED JOINT CAN ALSO FEEL WARM TO THE TOUCH.

Hypothetical Patient

Important Safety Information (continued)

DO NOT use Cortrophin Gel if you have any of the following conditions (continued):

- Adrenal glands that do not make enough of the hormone cortisol (primary adrenocortical insufficiency) or
- An adrenal cortex that makes too much of the hormones cortisol and aldosterone (adrenocortical hyperfunction)

Tell your doctor if you:

- Have or have had any other health problems
- Are taking any prescription or over-the-counter medicines, including aspirin, vitamins, and herbal or dietary supplements

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

Learning about acute gouty arthritis flares



Gout flares are more likely to occur during the night or in the early morning hours



Although the majority of gout flares typically resolve within a week, some can last 2 weeks or longer



Some people may have frequent flares (2 or more flares per year), while others may not have another flare for years. However, over time, if left untreated, your flares may happen more often and last longer



Gout flares typically affect a single joint (eg, a toe) but can sometimes affect multiple joints at the same time

Where Cortrophin Gel may fit into your treatment plan

Cortrophin Gel is the ONLY ACTH therapy available only by prescription as a short-term add-on therapy option for appropriate patients with acute gouty arthritis flares. Your healthcare provider may have prescribed Cortrophin Gel as an additional therapy because you may have tried other medicines to treat your gout flares and did not experience optimal results.

You'll get specific instructions from your healthcare provider on how to use Cortrophin Gel based on your specific condition and therapy needs.

Important Safety Information (continued)

Tell your doctor if you (continued):

- Have any allergies
- Are about to receive any vaccine
- Are pregnant or plan to become pregnant. Cortrophin Gel may harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if Cortrophin Gel passes into your breast milk and if it can harm your baby.

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

MEET THOMAS

- 52 years old; firefighter
- Living with acute gouty arthritis for 6 years
- Also suffers from obesity
- On a uric acid-lowering therapy, but needs an additional option when he experiences a flare

“Is there something else you can recommend? I want to try everything I can.”



Hypothetical Patient

Important Safety Information (continued)

What important information do I need to know about Cortrophin Gel?

Be sure to take Cortrophin Gel exactly as your doctor has directed. Always inject Cortrophin Gel under the skin or into the muscle. **Do not inject Cortrophin Gel directly into the vein.**

- You may be more likely to get infections. Contact your doctor at the first sign of an infection or fever.
- Your body may not produce enough natural cortisol after you stop taking Cortrophin Gel long term. This is called adrenal insufficiency. Your doctor may try to reduce your dosage gradually or prescribe a steroid medicine to protect you until the adrenal gland recovers.
- 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.

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

Understanding the role of ACTH

Cortrophin Gel contains a naturally sourced, purified hormone called corticotropin. Corticotropin is a complex mixture of proteins, one of which is adrenocorticotrophic hormone, or “ACTH” for short. One way ACTH may reduce inflammation is by boosting the body’s production of cortisol. This may help regulate the immune system and reduce inflammation.

ACTH may also interact with certain receptors that play a role in regulating inflammation, among other functions. These receptors are located in different organs and parts of the body.

The exact way Cortrophin Gel works is not fully known. The information above is not based on clinical data, and how it relates to patient benefits is unknown.

Important Safety Information (continued)

What important information do I need to know about Cortrophin Gel? (continued)

- Corticotropin therapy 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.
- Taking Cortrophin Gel can make you feel irritable or depressed. You may also have mood swings or trouble sleeping.
- You might develop certain eye conditions, such as cataracts, glaucoma, or optic nerve damage.
- You may develop allergies to Cortrophin Gel. These allergies may be severe. Signs of an allergic reaction include dizziness, nausea and vomiting, skin reactions (rash or itching), swelling of the face, tongue, lips or throat, and trouble breathing.
- The effects of Cortrophin Gel may be intensified if you have an underactive thyroid or cirrhosis of the liver.

Side effects of Cortrophin Gel include fluid or salt retention; weight gain; muscle weakness; osteoporosis, stomach ulcers with possible bleeding; injection site reactions; impaired wound healing; high blood pressure; convulsions; headache; development of Cushingoid state (a hormonal condition often characterized by facial puffiness and weight gain); suppression of growth in children; and allergic reactions that may be severe.

These are not all of the possible side effects of Cortrophin Gel. Call your doctor or pharmacist for medical advice about side effects. You may report side effects to ANI Pharmaceuticals, Inc. at 1-800-308-6755 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout and full [Prescribing Information](#).



Designed to support you during your treatment journey

Once you're prescribed Cortrophin Gel, the *Cortrophin In Your Corner** program can provide you with support and educational information throughout your treatment.

*Not all patients will be eligible for all services offered by *Cortrophin In Your Corner*.



A TEAM OF EXPERTS DEDICATED TO YOU



Call 1-800-805-5258
Monday-Friday,
8 AM to 8 PM ET



Visit www.cortrophin.com/savings-and-support or scan this QR code.

[†]Copay Assistance is for eligible, commercially insured patients for FDA-approved indications only. Restrictions, limitations, and/or eligibility requirements apply. Assistance is not valid for patients who are government beneficiaries or whose prescription drugs are covered, in whole or in part, under Medicare, Medicare Part D or Medicare Advantage, Medigap, Medicaid, TRICARE, VA, DoD, Puerto Rico Government Health Insurance Plan, or any other state or federal health care programs. Patients must be residents of the United States or a US territory. The maximum financial assistance provided to eligible patients is \$25,000 per calendar year. The patient will be responsible for any remaining out-of-pocket costs for Cortrophin Gel for that calendar year.

Helpful resources

The organizations below offer information about acute gouty arthritis as well as other rheumatic disorders for patients, family members, and caregivers.* Use your smartphone to scan the different QR codes below to access each organization's information.



Mayo Clinic:
Gout Overview



**American College
of Rheumatology:**
Gout Overview



**Arthritis
Foundation®:**
Gout

*ANI Pharmaceuticals, Inc. is not affiliated with the organizations shown above.

Find additional information at cortrophin.com

Use your smartphone to scan the QR code below to access additional resources, like the *Using Cortrophin Gel* step-by-step video, customizable injection calendar, and downloadable injection guide located on the Cortrophin website.



Access patient resources on cortrophin.com

**YOUR HEALTHCARE PROVIDER IS ALWAYS YOUR
BEST RESOURCE FOR INFORMATION.**

Important Safety Information (continued)

DO NOT use Cortrophin Gel if you have any of the following conditions (continued):

- Stomach ulcers or a history of stomach ulcers
- Heart failure
- High blood pressure
- Allergies to pig-derived proteins
- Adrenal glands that do not make enough of the hormone cortisol (primary adrenocortical insufficiency) or
- An adrenal cortex that makes too much of the hormones cortisol and aldosterone (adrenocortical hyperfunction)

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

Discover Cortrophin Gel



Purified Cortrophin Gel is a prescription medicine that is injected under the skin or into the muscle. It is used for short-term add-on therapy to help manage acute episodes or flares in acute gouty arthritis.

You can inject Cortrophin Gel yourself, get help from a family member, or go to your healthcare provider.

Store Purified Cortrophin Gel vials and prefilled syringes in the carton provided in the refrigerator between 36° to 46°F (2° to 8°C). Purified Cortrophin Gel vials and prefilled syringes **may** be stored at room temperature between 68° to 77°F (20° to 25°C) **for up to 24 hours**.

Cortrophin In Your Corner is a dedicated program* designed to support you and help you access treatment.

*Not all patients will be eligible for all services offered by *Cortrophin In Your Corner*.

Multiple-dose vials

For injection into a muscle (intramuscular)
or under the skin (subcutaneous).



1 mL



5 mL

Vial sizes are not to scale.

Single-dose prefilled syringes

For injection under the skin (subcutaneous) only.



0.5 mL



1 mL

Prefilled syringe sizes are not to scale.

Important Safety Information (continued)

Tell your doctor if you:

- Have or have had any other health problems
- Are taking any prescription or over-the-counter medicines, including aspirin, vitamins, and herbal or dietary supplements
- Have any allergies
- Are about to receive any vaccine
- Are pregnant or plan to become pregnant. Cortrophin Gel may harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if Cortrophin Gel passes into your breast milk and if it can harm your baby.

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

You can also scan this QR code to see the full Prescribing Information.



Learn more about Cortrophin Gel at cortrophin.com.



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US-CG-2600033 04/2026