



For severe
inflammatory
eye diseases



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

Cortrophin Gel is a prescription medicine that is injected under the skin or into the muscle. It's used as a treatment 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.

The next steps of your treatment journey

This brochure provides important information about what to expect next now that you have been prescribed this medication.

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**.



Hypothetical Patient

Where Cortrophin Gel may fit into your treatment plan

Cortrophin Gel is an FDA-approved injection therapy that may be a potential next step in your treatment journey. Your healthcare provider may have prescribed Cortrophin Gel because you are on other medicines and are in need of an additional therapy option.

Cortrophin Gel can be used to treat 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. Conditions may include:

- Allergic conjunctivitis
- Anterior segment inflammation
- Chorioretinitis
- Choroiditis
- Dry eye disease (keratoconjunctivitis sicca)
- Eyelid inflammation
- Iritis
- Iridocyclitis
- Keratitis
- Keratoconjunctivitis
- Lacrimal gland disorders
- Optic neuritis
- Orbital inflammation
- Orbital myositis
- Panuveitis
- Posterior cyclitis
- Retinal vasculitis
- Scleritis

Your healthcare provider will determine if Cortrophin Gel is an appropriate treatment option for your specific condition.

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)

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)

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

Multiple-dose vials

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



1 mL

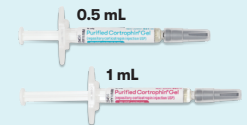
5 mL

Vial sizes are not to scale.

ALSO AVAILABLE

as Single-Dose Prefilled Syringes
0.5 mL and 1 mL:
for Injection Under the Skin (Subcutaneous) Only.

Providing the option for you to receive Purified Cortrophin Gel, with less steps to administer.



Prefilled syringe sizes are not to scale.

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)

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](#).



We're in your corner, every step of the way

SUPPORT THAT'S DESIGNED TO HELP YOU THROUGHOUT THE TREATMENT PROCESS



Cortrophin In Your Corner is a dedicated program designed to support you and help you access treatment. Once you are prescribed Cortrophin Gel, the *Cortrophin In Your Corner* program* can provide you with support and educational information throughout your treatment.

Learn more about *Cortrophin In Your Corner* and what you may expect next by reviewing this step-by-step overview on page 5

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

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**.

Here is what to expect next



Step 1: Enroll in Cortrophin In Your Corner

- Your doctor will ask for your signature on an Enrollment Form
- Your **signature** is required to receive patient support services* (including access to a Nurse Access Specialist [NAS], a free training session, and more)
- Enrollment in *Cortrophin In Your Corner* is not required for access to the medication



Step 3: Your doctor's office will work with your NAS on the authorization process

- Your insurance company will make a determination on coverage
- If coverage is denied, the decision can be appealed
- Your doctor's office can help guide you through the process and may reach out for additional information
- Your NAS will also reach out to discuss available copay assistance programs and to coordinate the shipment of your medication

The authorization process may take several weeks or more, but knowing the steps involved can help you stay prepared as you wait for your medication.



Step 5: Your NAS will coordinate training

- If needed, your NAS will schedule a training session with a certified nurse to help you and/or your caregiver learn how to inject your medication*



Step 6: Stay in contact with your doctor regarding refills

- It will be important to stay in contact with your healthcare team
- The specialty pharmacy will need to speak with you to confirm each delivery
- Your NAS may also follow up with you*

If you have questions, please call *Cortrophin In Your Corner* at 1-800-805-5258, Monday-Friday, 8 AM-8 PM ET or visit cortrophin.com/support



Step 2: Answer a welcome call from an NAS

- Be ready for a welcome call from your NAS.*† If you do not answer the call after a few attempts, the process will be paused
- Your NAS will verify your information and discuss next steps



Step 4: Your prescription is approved and sent to a specialty pharmacy

- The **specialty pharmacy** will call to confirm your prescription and let you know when you can expect delivery
- You will need to be home to receive your medication because it must be refrigerated as soon as you receive it
- A signature will be required for delivery

! **IMPORTANT:** The pharmacy call may come from a toll-free or unknown number, and it will be important to answer the call to avoid a delay in receiving your medication. Your medication cannot be delivered until the specialty pharmacy has confirmed your prescription with you. If you receive a voicemail, it's important to call the pharmacy back as soon as possible.

? **WHAT IS A SPECIALTY PHARMACY?** Sometimes, medications for specific conditions are not commonly found in regular pharmacies. A specialty pharmacy's focus is stocking these types of medications, so they're easily accessible to patients like you.

? **WHY IS MY MEDICATION BEING SHIPPED?** In most cases, your medication will ship directly to your home, so you (or a caregiver) can administer Cortrophin Gel yourself. In a few cases, your doctor may administer your medication in-office. Talk to your doctor to see how your treatment will be administered.

*Not all patients will be eligible for all services offered by *Cortrophin In Your Corner*.
†Nurse Access Specialists do not give medical advice and will direct patients to their healthcare professional for any treatment-related questions.

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

Helping you access your treatment

ANI Pharmaceuticals is committed to patient access for Cortrophin Gel. The *Cortrophin In Your Corner* program is here to help figure out what coverage and financial support options are available to you.



FOR PATIENTS WITH COMMERCIAL INSURANCE PLANS

Cortrophin In Your Corner can help eligible, commercially insured patients get Cortrophin Gel for as little as \$0 per prescription fill, if receiving through a pharmacy.* If receiving medication in your physician's office, copay assistance is also available through your doctor. The Copay Savings Program is for approved indications only.

*Restrictions, limitations, and/or eligibility requirements apply. 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.



If you have questions about signing up for the Copay Savings Program, call 1-800-805-5258, Monday-Friday, 8 AM to 8 PM ET.



FOR PATIENTS WITH GOVERNMENT INSURANCE PLANS

Patients may be eligible for financial support through an independent foundation.

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.

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



FOR PATIENTS WITH LIMITED OR NO INSURANCE

If you lack insurance and meet certain financial requirements, you may be eligible for the ANI Pharmaceuticals Patient Assistance Program.

If you wish to apply for the Patient Assistance Program, download an application from cortrophin.com/support, fill it out, and mail or fax the application to see if you qualify.



Important Safety Information (continued)

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

- 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.

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Getting started with Cortrophin Gel treatment

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*.

Important Safety Information (continued)

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

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](#).



Learn more about getting started with Cortrophin Gel and access helpful resources, including a step-by-step injection training video.



Learn more about Cortrophin Gel at cortrophin.com.



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