

**For multiple sclerosis
(MS) flares**

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

Purified Cortrophin Gel is a prescription medicine that is injected under the skin or into the muscle. It is used for acute attacks or flares of multiple sclerosis.

A potential option for the next step of your treatment journey

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

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

MEET CATHY

- 52 years old; tour guide
- Diagnosed with MS 6 years ago
- She was on treatment to help stabilize her condition and then experienced a flare
- She was prescribed a high dose of steroids
- Cathy called into the office reporting that her flare continues and she's looking to see if there's anything else that may help

"I'm worried about this disease and want to know about all of my options."

**"FLARES" ARE WHEN SYMPTOMS
SUDDENLY BECOME WORSE**



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
- Have any allergies
- Are about to receive any vaccine

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

About MS flares

If your MS symptoms keep coming back, even after or on treatment, you're not alone.

Nearly 3 in 4 patients with MS experience occasional flare-ups of symptoms, including fatigue, numbness or tingling, and walking or balance issues.



MS flares are characterized by the **occurrence of new symptoms or the worsening of old symptoms**



A flare is defined as at least 24 hours of symptom presence, with **at least 30 days of separation since your previous flare**



Both **unresolved flares** and the **frequency of flares** in the first 1-2 years of the disease can **impact progression of disability**

Where Cortrophin Gel may fit into your treatment plan

Cortrophin Gel is an FDA-approved therapy available only by prescription as an additional treatment option for appropriate patients. Your healthcare provider may have prescribed Cortrophin Gel because you are on other medicines and are in need of an additional therapy option.

Your healthcare provider may have prescribed Cortrophin Gel for acute attacks or flares of multiple sclerosis.

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):

- 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 ANDREW

- 46 years old; elementary school teacher
- Diagnosed with MS 12 years ago
- His doctor has prescribed him a biologic and he continues to experience a flare

“Is there something additional 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

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.

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



Questions? Call us at 1-800-805-5258

**Or for more information about *Cortrophin In Your Corner*, visit
cortrophin.com/support.**

Working together to help you every step of the way



STEP 1

Our team of experts is here to help you

- Obtain information on insurance coverage and financial support, including copay assistance
- Coordinate shipments with the specialty pharmacy supplying your medication (if applicable)
- Get access to useful resources and answers to questions you may have
- A dedicated Nurse Access Specialist* may help you navigate the treatment process and facilitate additional injection training for you
- A support center is available to answer your questions and provide educational information

*Nurse Access Specialists do not give medical advice and will direct you to your healthcare professional for any treatment-related questions.



STEP 2

Receiving your treatment

Your medication will be delivered to your home or administered in-office by your healthcare provider. If being delivered to your home, once your prescription is approved, the specialty pharmacy providing your medication will reach out to coordinate a time to deliver your medication. 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 Safety Information (continued)

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- Bone density loss or osteoporosis
- Fungal infections
- Ocular herpes simplex (an eye infection)
- A recent surgery

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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.



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.

Helpful resources

The organizations below offer information about MS for patients, family members, and caregivers.* Use your smartphone to scan the different QR codes below to access each organization's information.



**National Multiple
Sclerosis Society**



**Multiple Sclerosis
Association of
America**



**Multiple Sclerosis
Foundation**

*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)

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Discover Cortrophin Gel



Purified Cortrophin Gel is a prescription medicine that is injected under the skin or into the muscle. It is used for acute attacks or flares of multiple sclerosis.

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.**

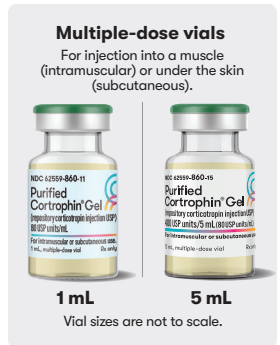
Cortrophin In Your Corner is a dedicated program* designed to support you and help you access treatment.

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

Important Safety Information (continued)

Tell your doctor if you:

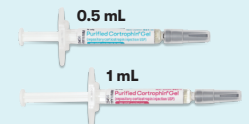
- Have or have had any other health problems
- Are taking any prescription or over-the-counter medicines, including aspirin, vitamins, and herbal or dietary supplements
- Have any allergies
- Are about to receive any vaccine
- Are pregnant or plan to become pregnant. Cortrophin Gel may harm your unborn 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.



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.



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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