For reduction of protein in the urine due to certain types of nephrotic syndrome

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 reduction of protein in the urine of people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or due to lupus.

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

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

MEET PETER

- 59 years old; engineer
- Recently diagnosed with membranous nephropathy (MN), a type of kidney disease
- Is on other medication and his excess urinary protein (proteinuria) levels remain unchanged
- He's also struggling with swelling and weight gain

"Is there something else you could recommend? I want to try everything I can."

REDUCING PROTEINURIA IS A KEY GOAL WHEN TREATING NEPHROTIC SYNDROME

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.

What is proteinuria?

Proteinuria is an elevated level of protein in the urine. Common symptoms of proteinuria include foamy urine and swelling of the hands, feet, face, and/or abdomen.

Proteinuria is not a disease, but is often a symptom of an underlying kidney problem called nephrotic syndrome. There are different kinds of nephrotic syndrome, including:

- **Membranous nephropathy** (MN), a disease that attacks and damages the glomeruli, or the tiny filters in your kidney where blood is cleaned
- **Focal segmental glomerulosclerosis** (FSGS), a disease that causes scarring to some of a person's glomeruli filters

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.

Cortrophin Gel can be used for reduction of protein in the urine of people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or due to lupus.

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.

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

MEET BILL

- 61 years old; mason
- Diagnosed with focal segmental glomerulosclerosis (FSGS) 12 years ago
- Initially, Bill reduced his proteinuria through 8 months of high-dose glucocorticoids. He was able to taper off steroids and for many years successfully managed his FSGS through a combination of diet and other medications
- Recently started to experience weight gain and swelling
- After starting steroids again, his latest lab results showed that his proteinuria has only improved slightly

"What additional options are out there?"

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 adrenocorticotropic 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.

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

Cortrophin In Your Corner™

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)

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

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

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

Helping you access your treatment

Cortrophin In Your Corner™

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 organization below offers information about nephrotic syndrome for patients, family members, and caregivers.* Use your smartphone to scan the QR code below to access information.

National Kidney Foundation®

*ANI Pharmaceuticals, Inc. is not affiliated with the National Kidney Foundation.

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
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 reduction of protein in the urine of people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or due to lupus.

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.

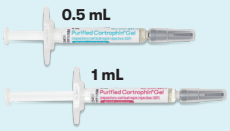
Multiple-dose vials
For injection into a muscle (intramuscular) or under the skin (subcutaneous).

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.

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.

ani Pharmaceuticals, Inc.

© Copyright 2025 ANI Pharmaceuticals, Inc. All Rights Reserved.
Cortrophin is a registered trademark of ANI Pharmaceuticals, Inc.
Cortrophin In Your Corner is a trademark of ANI Pharmaceuticals, Inc.
All other trademarks are property of their respective owner.
US-CG-2300144 09/2025