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

Cortrophin In Your Corner™

To enroll your patient in the *Cortrophin In Your Corner* program, fax completed form to 1-844-FLARE-NOW (1-844-352-7366) with copies of the front and back of all medical and prescription insurance cards. Questions? Call 1-800-805-5258.

*Indicates required field.

1 Patient Information (Including Patient Authorization of pages 2 and 3)

*First Name | *M.I. | *Last Name | *Date of Birth (mm/dd/yyyy) | Sex ☐ M ☐ F | Email (May be emailed for additional authorizations or information regarding this form)

*Shipping Address | *Apt/Bldg/Fl | *City | *State | *ZIP Code | *Phone # | ☐ Permission to Leave Voicemail

Alternative Contact Name | Contact Phone # | Contact Email (May be emailed for additional authorizations or information regarding this form) | Relationship to Patient | Preferred Language of Patient if Other Than English

2 Insurance Information (Please attach copies [front and back] of all medical and prescription insurance cards)

Policyholder: ☐ Self ☐ Other (Please complete policyholder details below) **Policy Type:** ☐ Commercial/Private ☐ Government ☐ Not Insured (If uninsured, visit cortrophinhcp.com/support to learn about patient assistance)

Policyholder First Name | Policyholder Last Name | Relationship to Patient

Primary Medical Insurance Name | Insurance Phone # | Subscriber ID # | Group #

Pharmacy Insurance Name | Insurance Phone # | Subscriber ID # | Rx Group # | Rx BIN # | Rx PCN #

Secondary Insurance Name | Insurance Phone # | Subscriber ID # | Group #

3 Prescriber Information (Please include supervising MD or DO, where applicable)

*First Name | *Last Name | Specialty/Sub-specialty | *Phone # | *Fax #

Practice Name | *Address | *City | *State | *ZIP Code

*Prescriber NPI | Group NPI (If applicable) | Prescriber State License # | Tax ID # | Office Contact Name

*Office Contact Phone # | *Office Contact Email | Preferred Method of Communication: ☐ Phone ☐ Email ☐ No Preference

4 Prescription: Purified Cortrophin Gel (repository corticotropin injection USP)

*ICD-10 Diagnosis Code _____ For a list of possible relevant ICD-10 diagnosis codes associated with FDA-approved use, visit cortrophinhcp.com/ICD10.

Please only fill out prescription information for either prefilled syringe or vial.

Purified Cortrophin Gel Single-Dose Prefilled Syringe
For subcutaneous injection only

Please select dose
- ☐ 40 USP units/0.5 mL NDC#62559-861-35
- ☐ 80 USP units/mL NDC#62559-861-11

Frequency
- ☐ 40 units twice weekly
- ☐ 80 units twice weekly
- ☐ Other: _____

Duration: _____

*Quantity of prefilled syringes: _____

*Refills: _____

☐ **Sharps container**

OR

Purified Cortrophin Gel Multiple-Dose Vial
For intramuscular or subcutaneous injection

Please select dose
- ☐ 1-mL vial containing 80 USP units/mL NDC#62559-860-11
- ☐ 5-mL vial containing 80 USP units/mL NDC#62559-860-15

Route of administration (injection)
- ☐ Subcutaneous ☐ Intramuscular

Please select dose
- ☐ 40 units ☐ 80 units ☐ Other: _____

Frequency
- ☐ 2 times per week ☐ 3 times per week ☐ Other: _____

Duration: _____

*Quantity of multiple-dose vials: _____

*Refills: _____

Supplies needed for prescription (for SP dispense only)

Pharmacy to dispense sufficient supplies for therapy
- ☐ Yes, I would like the pharmacy to dispense sufficient supplies for therapy
- ☐ No, I would like the pharmacy to dispense the quantity of supplies as written below

Syringe size: 1 mL

Needle size for drawing: 20 G needle, 1"

Needle size for injection: ☐ 23 G needle, 1" ☐ 25 G needle, 5/8"

Sharps container

☐ **Other:** _____

Special instructions, titration schedule, or taper dose, if applicable

Allergies ☐ NKDA (no known drug allergies)

☐ **Patient virtual injection training for administering Cortrophin Gel:** By checking here, I request that virtual injection training be arranged for my patient at no cost.

I verify that the patient and prescriber information on this enrollment form was completed by me or at my direction and that the information contained herein is complete and accurate to the best of my knowledge. I authorize the *Cortrophin In Your Corner* program to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy. By signing below, I agree to the Prescriber Certification and Statement of Medical Necessity on page 2.

_____ _____ **OR** _____ _____

DISPENSE AS WRITTEN **DATE** **SUBSTITUTIONS ALLOWED** **DATE**

Prescriber signature required for consent and to validate prescriptions. Prescriber attests that this is her/his signature. No stamps allowed.

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Patient Name: _____ **Date of Birth (mm/dd/yyyy):** _____

For Prescriber

Prescriber Certification and Statement of Medical Necessity (Signature on Page 1 Required for Documentation)

I certify that the information contained herein is complete and accurate to the best of my knowledge; the above therapy (the "Product") is medically necessary for this patient and I have made the decision to prescribe the Product; I have received an appropriate written authorization from the patient, in accordance with applicable federal and state privacy law(s), and any other applicable requirements, to release the patient's information to ANI Pharmaceuticals, the *Cortrophin In Your Corner* program (the "Program"), and their agents for purposes of assessing the patient's insurance coverage and participation in the Program and for other purposes outlined in the Patient Authorization for Use and Disclosure of Personal Health Information. I acknowledge that patient's potential participation in the Program is not contingent on or a reward for any past or future requirement to prescribe, purchase, or utilize the Product or any other ANI Pharmaceuticals product. The full value of any Program benefit shall apply to the patient. I have not received and will not receive any price concession or other value from the Program or any other ANI Pharmaceuticals program. If my patient or I decide the patient should discontinue treatment with the Product, neither the patient nor I will incur any financial penalty or consequence from the Program. Any Product provided at no charge to the patient is provided on a complimentary basis, and I will not submit any claims for payment or reimbursement for such Products to any third-party payor, including any federal healthcare program. If I am or become in possession of such Product, I will not resell or attempt to resell the Product. I understand that I must comply with my practicing state's specific prescription requirements, such as e-prescribing, state-specific prescription form, fax language, etc. I agree that the Program may contact me about the information in this form as needed to facilitate my patient's enrollment in the Program.

For Patient

Patient Authorization for Use and Disclosure of Protected Health Information (continued on page 3)

I authorize my healthcare providers (including pharmacy providers) and health plans to release, disclose, or re-disclose my protected health information ("PHI") (as such term is defined in the Health Insurance Portability and Accountability Act of 1996 ["HIPAA"] and its regulations), including my personal contact and other information on this form, all medical records, financial information, and other information (collectively, "Information") relevant to my enrollment, participation, or receipt of assistance under the *Cortrophin In Your Corner* program (the "Program"), to ANI Pharmaceuticals and its affiliates, and any third parties engaged to assist in administering the Program, in order to: (1) establish my benefit eligibility; (2) communicate with my healthcare providers and health plans about my eligibility for Program support, my benefit and coverage status, and/or my medical care; (3) provide support through the Program, including facilitating the provision of the Cortrophin Gel ("Product") to me, as well as any information or materials related to such support or Product, including marketing, promotional, or educational communications; (4) evaluate the effectiveness of Product support programs; (5) contact me regarding this enrollment form or my use or potential use of the Product and providing me with related patient support communications, including through messages left for me that disclose that I take or may take the Product; (6) facilitate or assist on copayment, coinsurance, and patient assistance program ("PAP") matters, as applicable; and (7) administer, evaluate, and improve the Program, including by analyzing the usage patterns and the effectiveness of ANI Pharmaceuticals products, services, and programs; helping to develop new products, services, and programs; and for other ANI Pharmaceuticals general business and administrative purposes.

I understand that certain entities may receive remuneration for the use or disclosure of my Information and providing support services as authorized above, and that, once my Information has been disclosed under this Authorization, my Information may not be subject to all of the protections and safeguards provided by HIPAA or other federal and state privacy laws. I also understand, however, that the Program plans to use and disclose my Information only for the purposes described above or as required by law.

Patient Name: _____ **Date of Birth (mm/dd/yyyy):** _____

Patient Authorization for Use and Disclosure of Protected Health Information (continued)

I understand that I may refuse to sign this Authorization and that my refusal to sign this Authorization will not affect my right to treatment or payment of benefits for healthcare. I understand that if I refuse to sign, I will not be eligible to receive support through the Program. I may later withdraw this Authorization by sending written notice of my withdrawal from the Program to Serva Health LLC Attn CIYC, 1000 Bishops Gate Blvd, Suite 201, Mount Laurel, NJ, 08054. Withdrawal of this Authorization will end further uses and disclosures of my Information by my healthcare providers and health plans under this Authorization, except to the extent those uses and disclosures have been made in reliance on this Authorization and as permitted by applicable law. I am entitled to receive a copy of this signed Authorization, which expires 5 years after the date it is signed by me unless otherwise specified by state or other applicable law or revoked by me earlier in writing. MARYLAND HEALTHCARE PROVIDERS, under Md. Code HG § 4-303(b)(4) this authorization expires ONE YEAR from the date of signature.

By signing below, I have read and agree to the Patient Authorization for Use and Disclosure of Protected Health Information above and on page 2.

PATIENT NAME OR LEGAL REPRESENTATIVE	SIGNATURE	DATE

IF LEGAL REPRESENTATIVE, EXPLAIN AUTHORITY TO ACT ON BEHALF OF PATIENT AND RELATIONSHIP*

*By signing on behalf of the patient as representative or guardian, I attest that I am legally able to sign such documents on the patient's behalf and am properly acting in my capacity in doing so. Proof of such guardian's or representative's authority to act for the patient may be requested such as power of attorney or legal court order.

☐ **By checking this box, I agree to receive marketing and other communications from ANI Pharmaceuticals regarding Cortrophin Gel, in compliance with the Telephone Consumer Protection Act Consent below. I understand that not checking this box does not impact my enrollment in the *Cortrophin In Your Corner* support program.**

Patient Telephone Consumer Protection Act Consent to Receive Additional Information From ANI Pharmaceuticals or *Cortrophin In Your Corner*

I agree to receive marketing and other communications, including, but not limited to, transactional communications, offers, clinical trial opportunities, and educational materials and information related to my medical condition, treatment, and/or my prescription medication by autodialed SMS text messages and cell or other telephone calls. I understand that opting-in to receive these communications is not required as a condition of purchasing any goods or receiving a copay or other support from the Program. Message and data rates may apply. Message frequency may vary. Reply STOP to cancel and HELP for help. By checking the box to receive communications above, you consent to receive disclosures electronically instead of in paper form. You can withdraw your consent to receive these disclosures at any time without penalty, and you can request a paper copy for no fee by calling us at 1-800-805-5258. You can also call us at that number to update your contact information. To ensure you receive and can retain the necessary disclosures, you must have a device (such as your mobile phone) with internet access, and either a printer or storage space to save the disclosures.

This authorization will remain in effect until I cancel it, which I may do at any time by calling ANI Pharmaceuticals at 1-800-434-1121 or *Cortrophin In Your Corner* at 1-800-805-5258 Monday–Friday, 8 AM–8 PM ET. I may request a copy of this signed authorization.

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

Cortrophin In Your Corner™

To enroll your patient in the *Cortrophin In Your Corner* program, fax completed form to 1-844-FLARE-NOW (1-844-352-7366) with copies of the front and back of all medical and prescription insurance cards. Questions? Call 1-800-805-5258.

Patient Name: _____ **Date of Birth (mm/dd/yyyy):** _____

5 Specialty Pharmacy Prescription Submission

Please select one:

☐ I **HAVE NOT** submitted the prescription to a specialty pharmacy. *Note: A Cortrophin In Your Corner case manager will contact you to provide information on all potential specialty pharmacy options.*

☐ I **HAVE** already submitted the patient's prescription **to the following specialty pharmacy:**

Name of specialty pharmacy: _____ Phone: _____ Fax: _____

A complete list of specialty pharmacies for your acute gouty arthritis where Cortrophin Gel is available can also be found by scanning this QR code or visiting cortrophinhcp.com/goutspecialtypharmacies

Clinical Documentation

☐ I will be submitting the prior authorization request via covermymeds.com

NOTE: Many prior authorization processes require a patient's relevant treatment history. Sections 6-10 of the Enrollment Form can be sent to the specialty pharmacy and/or payer as prior authorization support.

☐ **Please forward this clinical documentation to payer for review on my behalf.**

☐ **Please request expedited review because patient is currently experiencing an acute flare.**

Prescribed in consultation with a ☐ rheumatologist ☐ nephrologist

6 History of Corticosteroid Use (Check all that are applicable)

The following responses were seen during prior corticosteroid use:

- ☐ Patient had inadequate response or the use of corticosteroids failed and Cortrophin Gel is considered another potential treatment option
- ☐ Patient became intolerant to corticosteroids
- ☐ Patient was contraindicated for treatment or had a known corticosteroid intolerance
- ☐ Patient had no IV access
- ☐ Other: _____

If a corticosteroid was previously used, which agent was prescribed?

- ☐ IV or oral methylprednisolone
- ☐ IV or oral dexamethasone
- ☐ Oral prednisone
- ☐ Oral prednisolone
- ☐ Other: _____

7 Recent Relevant Treatment History (Include corticosteroid history)

Medication	Dose	Start Date	Stop Date (if applicable)	Treatment Details/Outcome

Important Safety Information

Contraindications

- Cortrophin Gel is contraindicated for intravenous administration.
- Cortrophin Gel is contraindicated in patients who have any of the following conditions: scleroderma; osteoporosis; systemic fungal infections; ocular herpes simplex; recent surgery; history of or the presence of a peptic ulcer; congestive heart failure; hypertension; primary adrenocortical insufficiency; adrenocortical hyperfunction; or sensitivity to proteins derived from porcine sources.

Please see Indications and Important Safety Information on pages 4-6 and full Prescribing Information or visit cortrophinhcp.com.

Patient Name: _____ **Date of Birth (mm/dd/yyyy):** _____

8 Acute Gouty Arthritis Medical Information

How many acute gout flares has this patient experienced in the past 12 months? _____

Urate-lowering therapies (ULTs)

Is the patient currently on a ULT? If so, which agent was prescribed?

- ☐ Xanthine oxidase inhibitors (allopurinol or febuxostat)
- ☐ Uricosuric agent (e.g., probenecid)
- ☐ Other: _____

If a ULT was previously used, which agent was prescribed?

- ☐ Xanthine oxidase inhibitors (allopurinol or febuxostat)
- ☐ Uricosuric agent (e.g., probenecid)
- ☐ Other: _____

The following responses were seen during ULT use:

- ☐ Patient currently on ULT
- ☐ Patient had inadequate response
- ☐ Patient became intolerant to ULTs
- ☐ Other: _____

What concurrent medication(s) is the patient taking?

Nonsteroidal anti-inflammatory drugs (NSAIDs)

- ☐ Indomethacin Dose: _____ Start Date: _____ Stop Date: _____
- ☐ Other: _____ Dose: _____ Start Date: _____ Stop Date: _____

The following responses were seen during NSAID use:

- ☐ Patient had inadequate response or the use of NSAIDs failed and Cortrophin Gel is considered another potential treatment option
- ☐ Patient became intolerant to NSAIDs
- ☐ Patient was contraindicated for treatment or had a known NSAID intolerance
- ☐ Other: _____

Colchicine, USP tablets

- ☐ Colcrys® (colchicine, USP) tablets Dose: _____ Start Date: _____ Stop Date: _____
- ☐ Other: _____ Dose: _____ Start Date: _____ Stop Date: _____

The following responses were seen during colchicine use:

- ☐ Patient had inadequate response or the use of colchicine failed and Cortrophin Gel is considered another potential treatment option
- ☐ Patient became intolerant to colchicine
- ☐ Patient was contraindicated for treatment or had a known colchicine intolerance
- ☐ Other: _____

Important Safety Information (continued)

Warnings and Precautions

- **Infections:** Corticotropin therapy may increase susceptibility to infections and may mask the symptoms of infections.
- **Adrenal insufficiency:** Prolonged corticotropin therapy can increase the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by gradually reducing the corticotropin dosage. Hormone therapy should be reinstituted if stressful situations arise during discontinuation.
- **Elevated blood pressure, salt and water retention, and hypokalemia:** Corticotropin can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium or calcium.
- **Masking symptoms of other diseases:** Corticotropin may only suppress signs and symptoms of chronic disease without altering the natural course of disease.
- **Psychiatric reactions:** Psychic derangements may appear when corticotropin is used, ranging from euphoria, insomnia, mood swings, personality changes, and depression to psychosis. Existing conditions may be aggravated.
- **Ophthalmic reactions:** Prolonged use of corticotropin may produce posterior subcapsular cataracts and glaucoma with possible damage to the optic nerves.
- **Immunogenicity potential:** Prolonged administration of Cortrophin Gel may increase the risk of hypersensitivity reactions. Cases of anaphylaxis have been reported in the postmarketing setting. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH and Cortrophin Gel activity.
- **Vaccination:** Patients should not be vaccinated against smallpox while on corticotropin therapy. Other immunizations should be undertaken with caution due to possible neurologic complications and lack of antibody response.
- **Use in patients with hypothyroidism and cirrhosis:** There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis.
- **Use in patients with latent tuberculosis or tuberculin reactivity:** Closely observe for reactivation of the disease.
- **Comorbid diseases:** Corticotropin should be used with caution in patients with diabetes, abscess, pyogenic infections, diverticulitis, renal insufficiency, and myasthenia gravis.
- **Growth and development:** Carefully observe growth and development of infants and children on prolonged corticotropin therapy.

Patient Name: _____ **Date of Birth (mm/dd/yyyy):** _____

9 FOR RHEUMATIC DISORDERS AND COLLAGEN DISEASES: Medical Information

Indicated Use Based on Diagnosis

If diagnosis is rheumatoid arthritis, including juvenile rheumatoid arthritis, Cortrophin Gel is prescribed as:

- ☐ Adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation)
- ☐ Low-dose maintenance therapy (in select cases)

For collagen diseases (systemic lupus erythematosus and systemic dermatomyositis/polymyositis), Cortrophin Gel is prescribed:

- ☐ During an exacerbation
- ☐ As maintenance therapy (in select cases)

☐ Other:

Organ Involvement (eg, lungs, bones, skin, etc)

10 Additional Information to Include With Enrollment Form

Please attach all relevant clinical notes (including any allergies and all concurrent medications) and any other information pertinent to your rationale for treatment with Cortrophin Gel, or write that information in the space below.

- ☐ I am attaching a separate document of relevant clinical notes
- ☐ I am writing relevant clinical notes in the space provided here

Important Safety Information (continued)

Warnings and Precautions (continued)

- **Acute gouty arthritis:** Treatment of acute gouty arthritis should be limited to a few days. Conventional concomitant therapy should be administered during corticotropin treatment and for several days after it is stopped.
- **Drug interactions:** Aspirin should be used cautiously with corticotropin in hypoprothrombinemia.
- **Pregnancy:** Since fetal abnormalities have been observed in animals, Cortrophin Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Adverse Reactions

Adverse reactions for Cortrophin Gel include fluid or sodium retention; muscle weakness; osteoporosis; peptic ulcer with possible perforation and hemorrhage; injection site reactions; impaired wound healing; hypertension; convulsions; headache; development of Cushingoid state; suppression of growth in children; anaphylaxis (anaphylactic shock, urticaria, respiratory compromise, edema); and weight gain. These are not all the adverse reactions reported with Cortrophin Gel.

Indications

Cortrophin Gel is a prescription medicine that is injected subcutaneously or intramuscularly. It is indicated for:

- Short-term administration as an adjunctive therapy during an acute episode or exacerbation in rheumatoid arthritis, including juvenile rheumatoid arthritis; psoriatic arthritis; ankylosing spondylitis; and acute gouty arthritis.
- Exacerbations or as maintenance therapy in select cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).
- Severe erythema multiforme (Stevens-Johnson syndrome) and severe psoriasis.
- Atopic dermatitis and serum sickness.
- Severe acute and chronic allergic and inflammatory conditions affecting the eye and its adnexa, such as allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation.
- Symptomatic sarcoidosis.
- Inducing a diuresis or remission of proteinuria due to nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
- Acute exacerbations of multiple sclerosis.

Please see Indications and Important Safety Information on pages 4-6 and full Prescribing Information or visit cortrophinhcp.com.

ani Pharmaceuticals, Inc.