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-FAX-CIYC (1-844-329-2492) with copies of the front and back of all medical and prescription insurance cards. Questions? Call 1-800-805-5258.

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

First Name | M.I. | Last Name | Date of Birth *(mm/dd/yyyy)* | ☐ M ☐ F Sex | 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

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, see pages 5 and 6 or full list at cortrophinhcp.com/icd10.

Purified Cortrophin Gel NDC# 62559-860-15
5-mL multiple-dose vial containing 80 USP units/mL
For intramuscular or subcutaneous injection

If you need help determining the quantity of 5-mL vials needed, follow these 2 simple steps.

Step 1: Calculate Total Units Needed ____ units per dose **x** ____ doses per week **x** ____ weeks duration = ____ total units needed

Step 2: Calculate Number of Vials Needed ____ total units needed ÷ 400 units per vial = ____ total vials needed (round up to the next whole vial)

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: _____ **Refills:** _____

Quantity of 5-mL multidose vials: _____

Please identify the 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 ☐ 3 mL ☐ Other: _____

Needle size for drawing ☐ 20 G needle, 1" ☐ Other: _____

Needle size for injection ☐ 25 G needle, 5/8" ☐ 25 G needle, 1" ☐ 23 G needle, 1" ☐ 23 G needle, 3/4" ☐ **Sharps container**

OR

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

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

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

Duration: _____

Quantity of prefilled syringes: _____

Refills: _____

☐ **Sharps container**

Taper instructions: Special instructions, titration, or taper dose, if applicable

☐ Duplicate above orders for Patient Assistance Program (PAP) prescription*
*Indicating a prescription for PAP does not guarantee patient will be eligible for PAP. Terms and conditions will apply.

Allergies ☐ NKDA (no known drug allergies)

Patient injection training for administering Cortrophin Gel
☐ By checking here, I request that injection training be arranged for my patient at no cost. I understand that this service is available for multiple in-person or virtual visits and is intended as injection training only.

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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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.

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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 where Cortrophin Gel is available can also be found by scanning this QR code or visiting cortrophinhcp.com/specialtypharmacies

Clinical Documentation

NOTE: Many prior authorization processes require a patient's relevant treatment history. Sections 6, 7, and 8 of the Enrollment Form can be sent to the specialty pharmacy and/or payer as prior authorization.

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

☐ **Please request expedited review because patient is currently experiencing an acute issue and is at risk of losing vision.**

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
- ☐ Other: _____

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

- ☐ Topical corticosteroid eyedrops (dexamethasone, difluprednate, fluorometholone, loteprednol, prednisolone)
- ☐ Oral corticosteroids (dexamethasone, hydrocortisone, methylprednisolone, prednisolone, prednisone)
- ☐ Ocular corticosteroid injection (triamcinolone)
- ☐ Ocular corticosteroid implant (dexamethasone, fluocinolone)
- ☐ Other: _____

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

7 Recent Relevant Treatment History (Include corticosteroid history)

	Treatment History 1	Treatment History 2	Treatment History 3	Treatment History 4
Medication *Potentially relevant medications could include topical corticosteroid eyedrops, topical immunomodulatory eyedrops, oral corticosteroids, ocular corticosteroid injections, and/or ocular corticosteroid implants.*				
Dose				
Duration				
Treatment Details/Outcome				

8 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

✓ Enrollment Checklist

Before submitting your completed Enrollment Form, please double check the form and refer to this checklist to ensure it is ready for processing.

☐ Yes, all patient information in Sections 1 and 2 (including preferred shipping and email addresses) is filled out completely and accurately.

☐ Yes, all prescriber and prescription information in Sections 3 and 4 is filled out completely and accurately.

☐ Yes, the prescribing physician signed in the pink box on Page 1 of the Enrollment Form.

☐ Yes, the patient signed in the pink box on Page 3 of the Enrollment Form.

☐ Yes, I have attached copies of all insurance and pharmacy cards.

☐ Yes, I have attached or written all relevant clinical notes.

Possible Relevant ICD-10 Diagnosis Codes

DIAGNOSIS	Right Eye	Left Eye	Bilateral	Unspecified
Other Inflammation of Eyelid				
Discoid lupus erythematosus of right upper eyelid	H01.121			
Discoid lupus erythematosus of right lower eyelid	H01.122			
Discoid lupus erythematosus of right eye, unspecified eyelid	H01.123			
Discoid lupus erythematosus of left upper eyelid		H01.124		
Discoid lupus erythematosus of left lower eyelid		H01.125		
Discoid lupus erythematosus of left eye, unspecified eyelid		H01.126		
Discoid lupus erythematosus of unspecified eye, unspecified eyelid				H01.129
Other specified inflammations of eyelid				H01.8
Unspecified inflammation of eyelid				H01.9
Disorders of Lacrimal System				
Chronic dacryoadenitis, lacrimal gland	H04.021	H04.022	H04.023	H04.029
Chronic dacryocystitis, lacrimal passage	H04.411	H04.412	H04.413	H04.419
Disorders of Orbit				
Unspecified acute inflammation of orbit				H05.00
Tenonitis	H05.041	H05.042	H05.043	H05.049
Unspecified chronic inflammatory disorders of orbit				H05.10
Granuloma	H05.111	H05.112	H05.113	H05.119
Orbital myositis	H05.121	H05.122	H05.123	H05.129
Conjunctivitis				
Acute atopic conjunctivitis	H10.11	H10.12	H10.13	
Unspecified chronic conjunctivitis	H10.401	H10.402	H10.403	H10.409
Chronic giant papillary conjunctivitis	H10.411	H10.412	H10.413	H10.419
Simple chronic conjunctivitis	H10.421	H10.422	H10.423	H10.429
Chronic follicular conjunctivitis	H10.431	H10.432	H10.433	H10.439
Vernal conjunctivitis				H10.44
Other chronic allergic conjunctivitis				H10.45
Ligneous conjunctivitis	H10.511	H10.512	H10.513	H10.519

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.

Possible Relevant ICD-10 Diagnosis Codes (continued)

DIAGNOSIS	Right Eye	Left Eye	Bilateral	Unspecified
Disorders of Sclera				
Unspecified scleritis	H15.001	H15.002	H15.003	H15.009
Anterior scleritis	H15.011	H15.012	H15.013	H15.019
Posterior scleritis	H15.031	H15.032	H15.033	H15.039
Scleritis with corneal involvement	H15.041	H15.042	H15.043	H15.049
Other scleritis	H15.091	H15.092	H15.093	H15.099
Keratitis				
Unspecified corneal ulcer	H16.001	H16.002	H16.003	H16.009
Central corneal ulcer	H16.011	H16.012	H16.013	H16.019
Ring corneal ulcer	H16.021	H16.022	H16.023	H16.029
Corneal ulcer with hypopyon	H16.031	H16.032	H16.033	H16.039
Marginal corneal ulcer	H16.041	H16.042	H16.043	H16.049
Mooren's corneal ulcer	H16.051	H16.052	H16.053	H16.059
Perforated corneal ulcer	H16.071	H16.072	H16.073	H16.079
Unspecified superficial keratitis	H16.101	H16.102	H16.103	H16.109
Macular keratitis	H16.111	H16.112	H16.113	H16.119
Filamentary keratitis	H16.121	H16.122	H16.123	H16.129
Punctate keratitis	H16.141	H16.142	H16.143	H16.149
Unspecified keratoconjunctivitis	H16.201	H16.202	H16.203	H16.209
Keratoconjunctivitis sicca, not specified as Sjögren's	H16.221	H16.222	H16.223	H16.229
Vernal keratoconjunctivitis, with limbar and corneal involvement	H16.261	H16.262	H16.263	H16.269
Other keratoconjunctivitis	H16.291	H16.292	H16.293	H16.299
Unspecified interstitial keratitis	H16.301	H16.302	H16.303	H16.309
Diffuse interstitial keratitis	H16.321	H16.322	H16.323	H16.329
Sclerosing keratitis	H16.331	H16.332	H16.333	H16.339
Other interstitial and deep keratitis	H16.391	H16.392	H16.393	H16.399
Other keratitis				H16.8
Unspecified keratitis				H16.9

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.

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.

Possible Relevant ICD-10 Diagnosis Codes (continued)

DIAGNOSIS	Right Eye	Left Eye	Bilateral	Unspecified
Iridocyclitis				
Unspecified acute and subacute iridocyclitis				H20.00
Primary iridocyclitis	H20.011	H20.012	H20.013	H20.019
Recurrent acute iridocyclitis	H20.021	H20.022	H20.023	H20.029
Secondary noninfectious iridocyclitis	H20.041	H20.042	H20.043	H20.049
Hypopyon	H20.051	H20.052	H20.053	H20.059
Chronic iridocyclitis	H20.11	H20.12	H20.13	H20.10
Vogt-Koyanagi syndrome	H20.821	H20.822	H20.823	H20.829
Unspecified iridocyclitis				H20.9
Chorioretinal Inflammation				
Unspecified focal chorioretinal inflammation	H30.001	H30.002	H30.003	H30.009
Focal chorioretinal inflammation, juxtapapillary	H30.011	H30.012	H30.013	H30.019
Focal chorioretinal inflammation of posterior pole	H30.021	H30.022	H30.023	H30.029
Focal chorioretinal inflammation, peripheral	H30.031	H30.032	H30.033	H30.039
Focal chorioretinal inflammation, macular or paramacular	H30.041	H30.042	H30.043	H30.049
Unspecified disseminated chorioretinal inflammation	H30.101	H30.102	H30.103	H30.109
Disseminated chorioretinal inflammation of posterior pole	H30.111	H30.112	H30.113	H30.119
Disseminated chorioretinal inflammation, peripheral	H30.121	H30.122	H30.123	H30.129
Disseminated chorioretinal inflammation, generalized	H30.131	H30.132	H30.133	H30.139
Acute posterior multifocal placoid pigment epitheliopathy	H30.141	H30.142	H30.143	H30.149
Posterior cyclitis	H30.21	H30.22	H30.23	H30.20
Harada's disease	H30.811	H30.812	H30.813	H30.819
Other chorioretinal inflammations	H30.891	H30.892	H30.893	H30.899
Unspecified chorioretinal inflammation	H30.91	H30.92	H30.93	H30.90

Important Safety Information (continued)

Warnings and Precautions (continued)

- **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.

Possible Relevant ICD-10 Diagnosis Codes (continued)

DIAGNOSIS	Right Eye	Left Eye	Bilateral	Unspecified
Other Retinal Disorders				
Retinal vasculitis	H35.061	H35.062	H35.063	H35.069
Disorders of Globe				
Panuveitis	H44.111	H44.112	H44.113	H44.119
Sympathetic uveitis	H44.131	H44.132	H44.133	H44.139
Optic Neuritis				
Optic papillitis	H46.01	H46.02	H46.03	H46.00
Retrobulbar neuritis	H46.11	H46.12	H46.13	H46.10
Other optic neuritis				H46.8
Unspecified optic neuritis				H46.9
Other Disorders of Optic [2nd] Nerve and Visual Pathways				
Ischemic optic neuropathy	H47.011	H47.012	H47.013	H47.019
Pemphigoid				
Cicatricial pemphigoid				L12.1

Important Safety Information (continued)

Warnings and Precautions (continued)

- **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.
- **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.

Please see Indications and additional Important Safety Information on pages 6-9 and accompanying full Prescribing Information or visit cortrophinhcp.com.