

# An FDA-approved ACTH treatment

Consider Cortrophin Gel for those suffering with specific chronic autoimmune and inflammatory conditions

Both patients and healthcare professionals now have another ACTH therapy for treating appropriate patients, including those with:

- Acute exacerbations of multiple sclerosis
- An acute episode or exacerbation in rheumatoid arthritis, including juvenile rheumatoid arthritis; psoriatic arthritis; ankylosing spondylitis; and acute gouty arthritis, as an adjunctive therapy for short-term administration
- Proteinuria due to nephrotic syndrome, by inducing a diuresis or remission, without uremia of the idiopathic type or that due to lupus erythematosus

## 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 full **Prescribing Information**.



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# Another FDA-approved option in the ACTH treatment class

Cortrophin Gel is a naturally sourced, purified corticotropin (ACTH) that is made up of a complex mixture of ACTH, ACTH-related peptides, and other natural pituitary-derived peptides.



**Cortrophin Gel is a repository corticotropin injection in the ACTH drug class.<sup>1</sup>**

**Cortrophin Gel is compliant with the United States Pharmacopeia (USP) monograph for Repository Corticotropin Injection.<sup>2</sup>**

ACTH=adrenocorticotropic hormone.

## 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 reinstated 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.

Please see full **Prescribing Information**.

## PROPOSED MECHANISM OF ACTION (MOA) FOR ACTH:

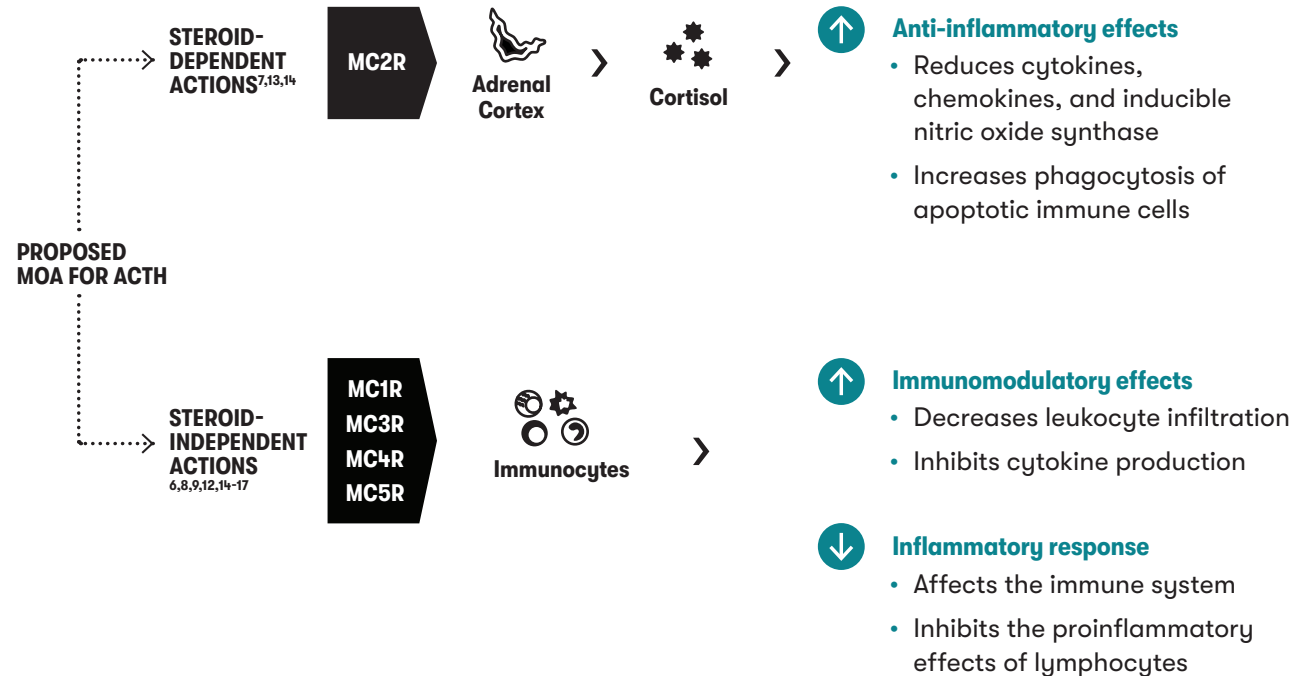
# ACTH may work through the melanocortin pathway, possessing both anti-inflammatory and immunomodulatory properties<sup>3-6</sup>

ACTH is a melanocortin peptide that stimulates one or more melanocortin receptors (MCRs).<sup>5-8</sup>

MCRs are receptors on immune and other cells throughout the body that may play a role in regulating inflammation among other functions.<sup>3,5,6,9</sup>

Preclinical data suggest leveraging the melanocortin signaling pathway may represent an important therapeutic strategy for various chronic autoimmune disorders.<sup>3,5,6,9</sup>

**ACTH binds to all 5 MCRs *in vitro* with varying affinities, and therefore may have both steroid-dependent and steroid-independent activity.**<sup>8,10-12</sup>



## Important Safety Information (continued)

### Warnings and Precautions

- **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. 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.

Please see full **Prescribing Information**.

# Indications and types of patients for ACTH use

Cortrophin Gel is indicated for the following chronic autoimmune and inflammatory conditions.

## Ophthalmic diseases (uveitis, optic neuritis, etc)

Indicated for 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.

## Nephrotic syndrome

Indicated for inducing a diuresis or a remission of proteinuria due to nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

- Per the evidence-based consensus for the treatment of primary focal segmental glomerulosclerosis (FSGS), ACTH has been considered for patients who may require another treatment option after glucocorticoids or calcineurin inhibitors.<sup>18\*</sup>

\*Based on the Kidney Disease Improving Global Outcomes (KDIGO) 2021 Clinical Practice Guideline for the Management of Glomerular Diseases.

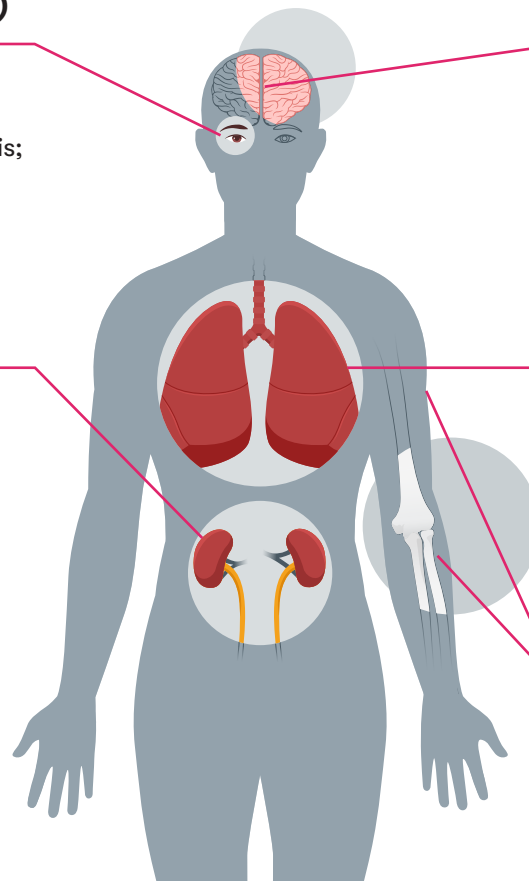
†Based on the European Respiratory Society (ERS) 2021 clinical practice guidelines on the treatment of sarcoidosis.

## Important Safety Information (continued)

### Warnings and Precautions (continued)

- **Use in patients with hypothyroidism and cirrhosis:** There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis.

Please see full **Prescribing Information**.



## Multiple sclerosis exacerbations

Indicated for people with acute exacerbations of multiple sclerosis.

- Per evidence-based drug compendia (Wolters Kluwer Lexi-Drugs<sup>®</sup>), corticotropin may be an alternative therapy for patients if IV corticosteroids cannot be administered or are not tolerated.<sup>1</sup>

## Symptomatic sarcoidosis

Indicated for people with symptoms of sarcoidosis.

- Per the evidence-based consensus for the treatment of sarcoidosis, repository corticotropin injection should be used in patients who may require another treatment option after corticosteroids and/or anti-metabolites.<sup>19†</sup>

## Rheumatic and collagen disorders

Indicated for:

- Short-term administration as an adjunctive therapy during an acute episode or exacerbation in rheumatoid arthritis, including juvenile rheumatoid arthritis
- Exacerbations or as maintenance therapy in select cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis)

# Dose and frequency will vary by condition

Dosing and frequency should be individualized according to medical condition, severity of the disease, and initial response of the patient.<sup>20,21</sup>



## Neurology

In the treatment of acute exacerbations of multiple sclerosis:

- **The recommended daily intramuscular dosage is 80-120 units for 2-3 weeks**



## Rheumatology

In the treatment of rheumatoid arthritis, including juvenile rheumatoid arthritis; psoriatic arthritis; and ankylosing spondylitis as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation)<sup>1,22</sup>:

- **The recommended dosage is 40-80 units every 24-72 hours, per evidence-based drug compendia\***

\*Dosage and schedule per the Wolters Kluwer Lexi-Drugs and the Truven Health Analytics Micromedex<sup>®</sup> DRUGDEX<sup>®</sup>, which are evidence-based drug compendia recommended by Centers for Medicare and Medicaid Services.

Please monitor your patients for side effects if Cortrophin Gel is administered at more than 40 units daily, because chronic administration of more than 40 units daily may be associated with uncontrollable adverse effects.

Standard tests for verification of adrenal responsiveness to corticotropin may utilize as much as 80 units as a single injection or one or more injections of a lesser dosage. Verification tests should be performed prior to treatment with corticotropins. The test should utilize the route(s) of administration proposed for treatment. Following verification, dosage should be individualized according to the disease under treatment and the general medical condition of each patient.

## Important Safety Information (continued)

### Warnings and Precautions (continued)

- **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.

Please see full **Prescribing Information**.



## Nephrology

In the treatment of proteinuria in the nephrotic syndrome, by inducing a diuresis or a remission, without uremia of the idiopathic type or that due to lupus erythematosus<sup>1,22</sup>:

- **The recommended dosage is 40-80 units every 24-72 hours, per evidence-based drug compendia\***



## Ophthalmology & Pulmonology

In the treatment of other conditions, including 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) and symptomatic sarcoidosis<sup>1,22</sup>:

- **The recommended dosage is 40-80 units every 24-72 hours, per evidence-based drug compendia\***

\*Dosage and schedule per the Wolters Kluwer Lexi-Drugs and the Truven Health Analytics Micromedex® DRUGDEX®, which are evidence-based drug compendia recommended by Centers for Medicare and Medicaid Services.

Please monitor your patients for side effects if Cortrophin Gel is administered at more than 40 units daily, because chronic administration of more than 40 units daily may be associated with uncontrollable adverse effects.

Standard tests for verification of adrenal responsiveness to corticotropin may utilize as much as 80 units as a single injection or one or more injections of a lesser dosage. Verification tests should be performed prior to treatment with corticotropins. The test should utilize the route(s) of administration proposed for treatment. Following verification, dosage should be individualized according to the disease under treatment and the general medical condition of each patient.

## Important Safety Information (continued)

### Warnings and Precautions (continued)

- **Growth and development:** Carefully observe growth and development of infants and children on prolonged corticotropin therapy.
- **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.

Please see full **Prescribing Information**.

# A dedicated support program for your patients

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The *Cortrophin In Your Corner* program can provide your patients with support and educational information throughout their treatment. Our team of experts is here to help patients:

- Get information on insurance coverage and financial support
- Coordinate shipments with the specialty pharmacy supplying the medication
- Learn how to administer treatment through in-person or virtual injection training
- Get access to useful resources and answers to questions about treatment or Cortrophin Gel



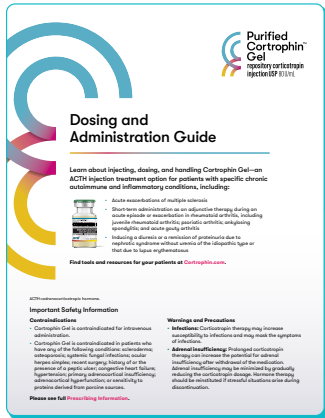
If you have questions about the *Cortrophin In Your Corner* program, call 1-800-805-5258, Monday–Friday, 8 AM–8 PM ET





# Resources for you and your patients

## For you and your office



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

### Dosing and Administration Guide

Learn about injecting, dosing, and handling Cortrophin Gel—an ACTH injection treatment option for patients with specific chronic autoimmune and inflammatory conditions, including:

- Auto-immunobliteration of multiple sclerosis
- Auto-immune Addison's disease as an adjunctive therapy during or after steroid administration in rheumatoid arthritis, including juvenile rheumatoid arthritis, psoriatic arthritis, and psoriasis (psoriasis and psoriatic arthritis)
- Insulin-dependent diabetes or a reduction of prednisone due to refractory lupus without control of the corticosteroid dose or that due to lupus nephritis

Find links and resources for your patients at [Cortrophin.com](http://Cortrophin.com).

**Important Safety Information**

**Contraindications**

- Cortrophin Gel is contraindicated for intravenous administration.
- Cortrophin Gel is contraindicated in patients who have any of the following conditions: active tuberculosis, untreated syphilis, fungal infections, or other infections.

**Warnings and Precautions**

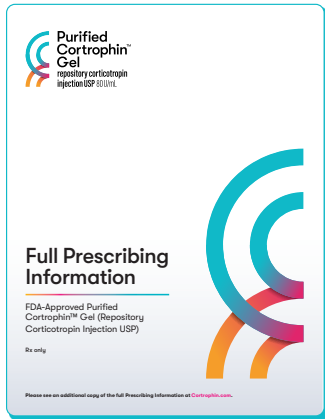
**Warnings:** Cortrophin Gel may vary in potency and may mask the signs and symptoms of infection.

**Adverse Reactions:** Patients using Cortrophin Gel may experience severe allergic reactions, including anaphylaxis, after withdrawal of the medication. Adverse reactions may be minimized by gradually tapering the corticosteroid therapy. Before therapy should be initiated if structural changes are detected during administration.

**Other warnings:** Patients using Cortrophin Gel may experience severe allergic reactions, including anaphylaxis, after withdrawal of the medication. Adverse reactions may be minimized by gradually tapering the corticosteroid therapy. Before therapy should be initiated if structural changes are detected during administration.

Please see full Prescribing Information.

## Dosing and Administration Guide



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

### Full Prescribing Information

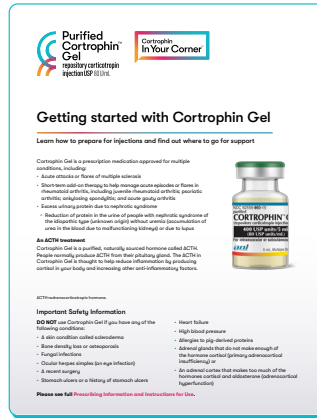
FDA-Approved Purified Cortrophin® Gel (Repository Corticotropin Injection USP)

Rx only

Please see an additional copy of the Full Prescribing Information at [Cortrophin.com](http://Cortrophin.com).

## Prescribing Information

## For your patients



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

**Cortrophin® In Your Corner**

### Getting started with Cortrophin Gel

Learn how to prepare for injections and find out where to go for support

Cortrophin Gel is a prescription medication approved for multiple conditions, including:

- Auto-immunobliteration of multiple sclerosis
- Auto-immune Addison's disease as an adjunctive therapy during or after steroid administration in rheumatoid arthritis, including juvenile rheumatoid arthritis, psoriatic arthritis, and psoriasis (psoriasis and psoriatic arthritis)
- Insulin-dependent diabetes or a reduction of prednisone due to refractory lupus without control of the corticosteroid dose or that due to lupus nephritis

**An ACTH treatment**

Cortrophin Gel is a purified, naturally-occurring hormone called ACTH. People normally produce ACTH from their pituitary gland. The ACTH in Cortrophin Gel is thought to help reduce inflammation by producing cortisol in your body and decreasing other anti-inflammatory factors.

**Important Safety Information**

**DO NOT** use Cortrophin Gel if you have any of the following conditions:

- A late condition called osteoporosis
- Bone density loss or osteoporosis
- Fungal infections
- Ocular herpes (simplex [eye infection])
- A heart surgery
- Severe ulcers or a history of stomach ulcers

**Warnings and Precautions**

**Warnings:** Cortrophin Gel may vary in potency and may mask the signs and symptoms of infection.

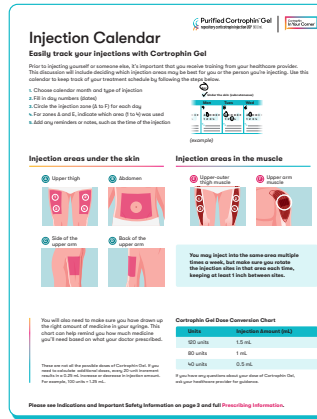
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**Other warnings:** Patients using Cortrophin Gel may experience severe allergic reactions, including anaphylaxis, after withdrawal of the medication. Adverse reactions may be minimized by gradually tapering the corticosteroid therapy. Before therapy should be initiated if structural changes are detected during administration.

Please see full Prescribing Information and Instructions for Use.

## Informational Brochure

Find more resources at [Cortrophin.com](http://Cortrophin.com) or contact your ANI Pharmaceuticals Representative



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

### Injection Calendar

Easily track your injections with Cortrophin Gel

When the calendar shows an orange dot, it's important that you receive another injection from your healthcare provider. This calendar will include identifying which injection areas may be best for you or the person you're injecting. Use this calendar to keep track of your treatment schedule by following the easy steps:

1. Choose calendar month and age of injection
2. 80 U (mg) number (orange)
3. Circle the injection area 80 U for each day
4. For areas 80 U, include white area 10 U (week end)
5. Add any allergies or notes, such as the time of the injection

**Injection areas under the skin**

- Upper thigh
- Abdomen
- Side of the upper arm
- Back of the upper arm

**Injection areas in the muscle**

- Upper thigh muscle
- Upper arm muscle

You may inject into the same area multiple times a week, but make sure you rotate the injection sites to that area each time, keeping at least 1 inch between sites.

You will often need to make sure you have drawn up the right amount of medication in your syringe. This sheet can help remind you how much medicine you need based on what your doctor prescribed.

There are not all the possible doses of Cortrophin Gel. If you have any questions about your dose of Cortrophin Gel, ask your healthcare provider for guidance.

**Cortrophin Gel Dose Conversion Chart**

Units	Injection Amount (mL)
80 units	1.0 mL
40 units	0.5 mL
10 units	0.125 mL

Please see Indications and Important Safety Information on page 2 and Full Prescribing Information.

## Injection Calendar

# Indications & Important Safety Information

## 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.

## 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 reinstated 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. 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.
- **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; impaired wound healing; hypertension; convulsions; headache; development of Cushingoid state; and suppression of growth in children. These are not all the adverse reactions reported with Cortrophin Gel.

Please see full **Prescribing Information**.

# References

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