

Purified Cortrophin[®] Gel

repository corticotropin injection USP 80 U/mL

For your appropriate difficult-to-treat patients, consider Purified Cortrophin Gel as a potential next step in their treatment journey

Single-Dose Prefilled Syringes

40 USP units/0.5 mL and

80 USP units/mL¹

For subcutaneous use only.

Providing the option for patients to receive Purified Cortrophin Gel, with less steps to administer.



To learn more about the prefilled syringe, visit Cortrophinhcp.com/howtouse or scan this code.



Prefilled syringes are not to scale.

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).
- Symptomatic sarcoidosis.
- Acute exacerbations of multiple sclerosis.
- 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.

See additional Indications on the next page.

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 additional Important Safety Information on the next page and [full Prescribing Information](#).

Purified Cortrophin Gel is available in multiple-dose vials for intramuscular or subcutaneous use and single-dose prefilled syringes for subcutaneous use only¹

Storage¹

- Store Purified Cortrophin Gel vials and prefilled syringes refrigerated at 2° to 8°C (36° to 46°F)
- Purified Cortrophin Gel vials and prefilled syringes **may** be stored at room temperature between 20° to 25°C (68° to 77°F) **for up to 24 hours**

Additional Indications

- Severe erythema multiforme (Stevens-Johnson syndrome) and severe psoriasis.
- Inducing a diuresis or remission of proteinuria due to nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
- Atopic dermatitis and serum sickness.

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.

Package Size

Volume Size

NDC

1-mL multiple-dose vial	80 USP units/mL	62559-860-11
5-mL multiple-dose vial	400 USP units/5 mL	62559-860-15
0.5-mL single-dose prefilled syringe	40 USP units/0.5 mL	62559-861-35
1-mL single-dose prefilled syringe	80 USP units/mL	62559-861-11

Important Safety Information (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.
- **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.

Please see [full Prescribing Information](#).

Reference: 1. Purified Cortrophin Gel. Prescribing information.