



Dear Healthcare Professional,

Thank you for your unsolicited request for information. Accompanying this letter is the following information you requested on Purified Cortrophin® Gel. If we can be of any further assistance, please contact our Medical Information department at (844) CORT-GEL (844-267-8435) between the hours of 9:00 AM to 7:00 PM ET (6:00 AM to 4:00 PM PT), Monday through Friday or via email at cortrophinmedinfo@anipharmaceuticals.com.

Purified Cortrophin Gel is indicated in the following disorders:

1. Rheumatic disorders:

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

Psoriatic arthritis.

Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy).

Ankylosing spondylitis.

Acute gouty arthritis.

2. Collagen diseases:

During an exacerbation or as maintenance therapy in selected cases of:

Systemic lupus erythematosus.

Systemic dermatomyositis (polymyositis).

3. Dermatologic diseases:

Severe erythema multiforme (Stevens-Johnson syndrome).

Severe psoriasis.

4. Allergic states:

Atopic dermatitis

Serum sickness.

5. Ophthalmic diseases:

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:

Allergic conjunctivitis.

Keratitis.

Iritis and iridocyclitis.

Diffuse posterior uveitis and choroiditis.

Optic neuritis.

Chorioretinitis.

Anterior segment inflammation.

6. Respiratory diseases:
Symptomatic sarcoidosis.

7. Edematous states:
To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

8. Nervous system:
Acute exacerbations of multiple sclerosis.

Purified Cortrophin Gel is contraindicated for intravenous administration.

Purified Cortrophin Gel is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, hypertension, or sensitivity to proteins derived from porcine sources.

Purified Cortrophin Gel is contraindicated in patients with primary adrenocortical insufficiency or adrenocortical hyperfunction.

Please see the enclosed Purified Cortrophin Gel Prescribing Information (PI) for detailed information including Warnings and Precautions and Adverse Reactions as well as the appropriate use of Purified Cortrophin Gel.

This communication may contain confidential, proprietary, and/or privileged information. It is intended solely for the use of the addressee. If you are not the intended recipient, you are strictly prohibited from disclosing, copying, distributing or using any of this information. If you received this communication in error, please contact the sender immediately and destroy the material in its entirety, whether electronic or hard copy.

Thank you for your inquiry.

Sincerely,



Steve Wu, PharmD
ANI Pharmaceuticals Medical Information

Purified Cortrophin[®] Gel (Repository Corticotropin Injection USP) 80 U/mL is Not Indicated for Infantile Spasms

Abstract

- Purified Cortrophin Gel (repository corticotropin injection USP) is currently not approved by the FDA for use in patients with infantile spasms.
- To date, no trials using Cortrophin Gel for the treatment of infantile spasms have been conducted.

Note that this document is for information purposes only. Please refer to the Purified Cortrophin Gel (repository corticotropin injection USP) USPI for [full prescribing information](#). ANI Pharmaceuticals does not recommend the use of its products in any manner inconsistent with the FDA-approved labeling.

To report an adverse event for any ANI Pharmaceuticals product, please call 1-800-308-6755 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Email: drugsafety@anipharmaceuticals.com.

Clinical Information: Infantile Spasms

Purified Cortrophin Gel (repository corticotropin injection USP) is currently not approved by the FDA for use in patients with infantile spasms.¹

To date, no clinical trials using Purified Cortrophin Gel for the treatment of infantile spasms have been conducted.

Overview of Purified Cortrophin Gel

Composition of Cortrophin Gel¹

Purified Cortrophin Gel is a porcine-derived purified corticotropin, adrenocorticotrophic hormone (ACTH), in a sterile solution of gelatin. It is made up of a complex mixture of ACTH, ACTH-related peptides, and other porcine pituitary-derived peptides.

The drug product is a sterile preparation containing 80 USP units per mL and it contains 0.5% phenol (as preservative), 15.0% gelatin (for prolonged activity), water for injection, and the pH is adjusted with hydrochloric acid and sodium hydroxide.

Purified Cortrophin Gel contains the porcine-derived ACTH (1-39) with the following amino acid sequence:



Purified Cortrophin Gel Clinical Pharmacology

ACTH, the active agent in Purified Cortrophin Gel, is the anterior pituitary hormone which stimulates the functioning adrenal cortex to produce and secrete adrenocortical hormones.¹

Following administration of a single intramuscular (IM) injection of 80 units of Purified Cortrophin Gel to healthy volunteers (n=20) in an open label pharmacodynamic study, the median time (range) to reach

peak plasma cortisol concentration was 8 (3 to 12) hours. The baseline corrected geometric mean maximum (CV%) cortisol levels were 34.52 µg/dL (28.2%).¹

The porcine-derived ACTH (1-39) found in Purified Cortrophin Gel is biologically similar to endogenous human ACTH² and of the same class as synthetic and FDA-approved natural-product formulations of ACTH.^{3,4}

ANI conducted a study on the pharmacodynamic effect of Purified Cortrophin Gel, including E_{max} , $AUEC_{0-24}$, and TE_{max} , and compared it with the response of the same or similar depot structures from published literature.⁵

Citations

1. *Purified Cortrophin™ Gel (Repository Corticotropin Injection USP) 80U/MI*. ANI Pharmaceuticals, Inc.; 2023. <https://cortrophin.com/pdfs/purified-cortrophin-gel-prescribing-information.pdf>
2. Upton GV, Hollingsworth DR, Lande S, Lerner AB, Amatruda TT. Comparison of purified human and porcine ACTH in man. *J Clin Endocrinol Metab*. 1970;30(2):190-195. doi:10.1210/jcem-30-2-190
3. *Acthar Gel (Repository Corticotropin Injection), for Intramuscular or Subcutaneous Use. Prescribing Information*. Mallinkrodt ARD LLC; 2021. Accessed November 12, 2023. <https://acthar.com/Static/pdf/Acthar-PI.pdf>
4. *Synacthen Depot Ampoules 1 Mg/MI. Summary of Product Characteristics (SmPC)*. Atnahs Pharma UK Ltd; 2021. Accessed November 12, 2023. <https://www.medicines.org.uk/emc/product/10823/smpc/>
5. ANI Pharmaceuticals, Inc. Clinical monograph. Data on file.