

## **ACTHAR H.P. (repository corticotropin gel)**

Effective Date: 1/28/14

Date Developed: 1/28/14 by Robert Sterling, MD

Date Approved by P&T Committee: 1/26/16, 1/24/17, 1/23/18, 1/22/19

**(Archived 1/22/19)**

**H.P. Acthar Gel** is a highly purified sterile preparation of adrenocorticotrophic hormone (ACTH) in 16% gelatin to provide a prolonged release after intramuscular or subcutaneous injection. ACTH stimulates the adrenal cortex to secrete cortisol, corticosterone, aldosterone and some weak androgens.

**Pre-Authorization Criteria:** infantile spasms (West syndrome); multiple sclerosis; short-term adjunctive therapy for rheumatic disorders during an acute episode or exacerbation in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis; During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis); severe erythema multiforme or Stevens-Johnson syndrome; serum sickness; severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation; symptomatic pulmonary sarcoidosis; nephrotic syndrome (to induce diuresis or remission of proteinuria)

### **Please note the following:**

Repository corticotropin injection in adults is considered **medically necessary** when all of the following criteria are met:

- A. The individual is an adult with a corticosteroid-responsive condition, including but not limited to acute exacerbations of multiple sclerosis; AND
- B. There is no contraindication to or intolerance of corticosteroids; AND
- C. There is clear documentation that a corticosteroid can't be used and that a repository corticotropin injection can be used effectively.

**Dosing:** Depends on the condition being treated (ranges from 40 to 120 units every 24 hours to 3 weeks); consult the product information

**PRECAUTIONS:** Cushing's syndrome during therapy; adrenal insufficiency during withdrawal; bp elevation, salt and water retention and hypokalemia; GI bleeding; mood disturbances; growth delay in children; decreased bone density; suppression of symptoms of other diseases (e.g. infections); glaucoma or cataracts; avoid live attenuated vaccines

**Note:** consult product information for a complete listing of precautions and adverse reactions.

**DRUG INTERACTIONS:** numerous medications may interact with this product (e.g. CYP3A4 Inducers, androgens, warfarin, loop diuretics); consult the product information

## REFERENCES

Pellock JM, Hrachovy R, Shinnar S, et al, "Infantile Spasms: A U.S. Consensus Report," *Epilepsia*, 2010, 51(10):2175-89.

Haines ST, Casto DT. Treatment of infantile spasms. *Ann Pharmacother*. 1994;28:779–791.

Schapiro RT. Medications used in the treatment of multiple sclerosis. *Rehab Pharmacother*. 1999;10(2):437–446.

Rose AS, Kuzma JW, Kurtzke JF, et al. Cooperative study in the evaluation of therapy in multiple sclerosis. ACTH vs. placebo--final report. *Neurology*. 1970; 20(5):1-59.

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