

Acthar® (repository corticotropin injection)



When requesting Acthar® (repository corticotropin injection), the individual requiring treatment must be diagnosed with infantile spasms and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indications¹

Acthar® (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms (West syndrome) in infants and children under 2 years of age.

(Note: All the other FDA-Approved indications will be reviewed by medical directors)

Approved Off-label Compendial use²

No off-label uses meet evidence standards

Coverage Guidelines

Infantile spasms

The individual must meet **all** of the following criteria for approval:

- Has a diagnosis of infantile spasms (West syndrome) confirmed by appropriate diagnostic testing
- Is less than 2 years of age
- Does **not** have any of the following contraindications:
 - o Suspected congenital infection
 - o Scleroderma
 - o Osteoporosis
 - o Systemic fungal infections
 - o Ocular herpes simplex
 - o Recent surgery
 - o History of or the presence of a peptic ulcer
 - o Congestive heart failure
 - o Uncontrolled hypertension
 - o Sensitivity to proteins of porcine origin
 - o Primary adrenocortical insufficiency
 - o Adrenocortical hyperfunction

Approval duration: 12 months

Additional Information for Prescribers¹

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Acthar® (repository corticotropin injection) should not be given intravenously
- Live or live attenuated vaccines (e.g., FluMist®, oral polio vaccine [OPV], rotavirus, typhoid, yellow fever, measles, varicella, herpes zoster) should not be administered to patients on immunosuppressive doses.
- Acthar® (repository corticotropin injection) may increase the risks related to infections with any pathogen, including viral, bacterial, fungal, protozoan or helminthic infections.
- Monitor for hypothalamic-pituitary-axis (HPA) suppression and Cushing's syndrome, especially with chronic use; adrenal insufficiency may occur after withdrawal of the medication.
- Acthar® (repository corticotropin injection) can cause GI bleeding and gastric ulcer. Use caution in individuals where there is the possibility of impending perforation, abscess or other pyogenic infections, diverticulitis, fresh intestinal anastomoses, and active or latent peptic ulcer.
- Individuals may develop antibodies to Acthar® (repository corticotropin injection) after chronic administration due to its immunogenicity potential. Prolonged administration may increase the risk of hypersensitivity reactions.
- Negative effects on growth and physical development in children may develop after long-term use of Acthar® (repository corticotropin injection), and should be carefully monitored.

References

1. Acthar® prescribing information. Hazelwood, MO: Mallinckrodt ARD Inc.: January 2015. <http://www.acthar.com/pdf/Acthar-PI.pdf>. Accessed February 27, 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 27, 2017. <https://www.micromedexsolutions.com>
3. Nelson GR. Management of infantile spasms. *Transl Pediatr*. 2015;4:260-270. Accessed February 27, 2017. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4728997/pdf/tp-04-04-260.pdf>