



Mallinckrodt Presents Data on Real-World Outcomes with Acthar® Gel (repository corticotropin injection) at the International Congress on Systemic Lupus Erythematosus (LUPUS 2025)

May 14, 2025

– Late-breaking poster abstract highlights physician-reported treatment patterns and characteristics of patients with systemic lupus erythematosus treated with Acthar Gel¹ –

DUBLIN, May 14, 2025 /PRNewswire/ -- [Mallinckrodt plc](#), a global specialty pharmaceutical company, today announced a late-breaking poster abstract on Acthar® Gel (repository corticotropin injection) in patients with systemic lupus erythematosus (SLE) at the [International Congress on Systemic Lupus Erythematosus \(LUPUS 2025\)](#), taking place in Toronto, Canada from May 21-24, 2025.



Acthar Gel is a naturally sourced complex mixture of adrenocorticotrophic hormone (ACTH) analogs and other pituitary peptides.¹ Acthar Gel is approved by the FDA for the treatment of several autoimmune disorders and medical conditions known to cause inflammation, including during an exacerbation or as maintenance therapy in selected cases of SLE.¹

Please see Important Safety Information and additional indications for Acthar Gel below.

The poster abstract details a chart review from April 1, 2022, and November 2024 of 56 patients who had been treated with Acthar Gel for SLE within the prior 24 months.² Data collected included demographics, comorbidities, symptoms, prior treatments, and health outcomes following Acthar Gel treatment.²

Results reported from this chart review included:

- 84% (47/56) of patients were female and 50% (28/56) were African-American²
- Common comorbidities included chronic joint disease (34%, 19/56), hyperlipidemia (34%, 19/56), hypertension (34%, 19/56), and arthritis/osteoarthritis (30%, 17/56)²
- Physicians reported 63% (35/56) of patients were in fair-to-poor health status prior to treatment with Acthar Gel²
- The average duration of Acthar Gel treatment was 8 months, and 91% (51/56) of patients were dosed at 40-80 units twice per week²
- Physicians reported that 89% (50/56) of patients experienced improved health status after Acthar Gel treatment²
 - This included physician-reported improvements in overall symptoms (82%, 41/50), pain (54%, 27/50), fatigue (44%, 22/50), physical function (38%, 19/50), and strength (28%, 14/50).² A reduction in corticosteroid use (44%, 22/50) was also reported.²

"Mallinckrodt is committed to evaluating real-world treatment outcomes among those living with SLE, particularly among patient subpopulations who are disproportionately affected such as African Americans and women," said **George Wan, Ph.D., M.P.H., Vice President, Evidence Generation and Data Sciences, Mallinckrodt**. "This chart review provides additional data to consider when treating appropriate patients with this often difficult-to-manage disease."

"This study is an example of how real-world evidence can improve our understanding of the impact of treatment for individuals affected by lupus, particularly in populations with the greatest disease burden. The Lupus Foundation of America (LFA) is grateful for the research conducted by companies like Mallinckrodt, who remain committed to advancing treatments and improving outcomes for those impacted by this disease," said **Louise Vetter, President and Chief Executive Officer, Lupus Foundation of America**.

The limitations of this physician-reported chart review include, but are not limited to, small sample sizes, variables in methodology, and possible errors.² Safety outcomes were not reported.² Most patients were previously treated with other therapies and may have been using other therapies in tandem with Acthar Gel; clinical outcomes may not be solely attributable to Acthar Gel.²

This study was sponsored by Mallinckrodt Pharmaceuticals. Presentation details can be found below:

[Abstract #799: TREATMENT PATTERNS AND OUTCOMES OF ACTHAR GEL IN SYSTEMIC LUPUS ERYTHEMATOSUS: A PHYSICIAN-REPORTED CHART REVIEW²](#)

- **Presenter:** Johanna Purcell, PhD
- **Presentation Date:** Friday May 23, 2025 through Saturday May 24, 2025
- **Location:** Exhibition Room

INDICATIONS

Acthar Gel is indicated for:

- Inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
- Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- Treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease
- 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 sarcoidosis
- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus
- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic dermatomyositis (polymyositis)
- 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

IMPORTANT SAFETY INFORMATION

Contraindications

Acthar is contraindicated:

- For intravenous administration
- In infants under 2 years of age who have suspected congenital infections
- With concomitant administration of live or live attenuated vaccines in patients receiving immunosuppressive doses of Acthar
- In patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins of porcine origin

Warnings and Precautions

- The adverse effects of Acthar are related primarily to its steroidogenic effects
- Acthar may increase susceptibility to new infection or reactivation of latent infections
- Suppression of the hypothalamic-pituitary-adrenal (HPA) axis may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by tapering of the dose when discontinuing treatment. During recovery of the adrenal gland patients should be protected from the stress (e.g., trauma or surgery) by the use of corticosteroids. Monitor patients for effects of HPA axis suppression after stopping treatment
- Cushing's syndrome may occur during therapy but generally resolves after therapy is stopped. Monitor patients for signs and symptoms
- Acthar can cause elevation of blood pressure, salt and water retention, and hypokalemia. Monitor blood pressure and sodium and potassium levels
- Acthar often acts by masking symptoms of other diseases/disorders. Monitor patients carefully during and for a period following discontinuation of therapy
- Acthar can cause gastrointestinal (GI) bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain GI disorders. Monitor for signs of perforation and bleeding
- Acthar may be associated with central nervous system effects ranging from euphoria, insomnia, irritability, mood swings, personality changes, and severe depression to psychosis. Existing conditions may be aggravated
- Patients with comorbid disease may have that disease worsened. Caution should be used when prescribing Acthar in patients with diabetes and myasthenia gravis
- Prolonged use of Acthar may produce cataracts, glaucoma, and secondary ocular infections. Monitor for signs and symptoms
- Acthar is immunogenic and prolonged administration of Acthar 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 Acthar activity

- There may be an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver
- Long-term use may have negative effects on growth and physical development in children. Monitor pediatric patients
- Decrease in bone density may occur. Bone density should be monitored in patients on long-term therapy

Adverse Reactions

- Commonly reported postmarketing adverse reactions for Acthar include injection site reaction, asthenic conditions (including fatigue, malaise, asthenia, and lethargy), fluid retention (including peripheral swelling), insomnia, headache, and blood glucose increased
- The most common adverse reactions for the treatment of infantile spasms (IS) are increased risk of infections, convulsions, hypertension, irritability, and pyrexia. Some patients with IS progress to other forms of seizures; IS sometimes masks these seizures, which may become visible once the clinical spasms from IS resolve

Pregnancy

- Acthar may cause fetal harm when administered to a pregnant woman

Please see full [Prescribing Information](#) for additional Important Safety Information.

About Systemic Lupus Erythematosus (SLE)

Systemic lupus erythematosus (SLE) is the most common type of lupus.³ In the United States, approximately 160,902–261,725 adults are affected by SLE.⁴ It is a chronic inflammatory condition that may affect joints, skin, and kidneys.⁵ No two cases of SLE are the same and SLE can affect people differently. Signs and symptoms can also change over time.⁶ There is no cure for SLE, but certain treatments may reduce symptoms and may prevent permanent damage to the body.³

About Mallinckrodt

Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. The Company's Specialty Brands reportable segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, hepatology, nephrology, pulmonology and ophthalmology; and neonatal respiratory critical care therapies; and gastrointestinal products. Its Specialty Generics reportable segment includes specialty generic drugs and active pharmaceutical ingredients. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS

This release contains forward-looking statements, including with regard to Acthar® Gel, its potential to improve health and treatment outcomes, its potential impact on patients. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: the effects of Mallinckrodt's recent emergence from bankruptcy; satisfaction of, and compliance with, regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; issues with product quality, manufacturing or supply, or patient safety issues or adverse side effects or adverse reactions associated with Acthar Gel; and other risks identified and described in more detail in the "Risk Factors" section of Mallinckrodt's most recent Annual Report on Form 10-K and other filings with the SEC, all of which are available on its website. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.

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References

¹ Acthar® Gel (repository corticotropin injection) [prescribing information]. Bridgewater, NJ: Mallinckrodt ARD LLC.

² Shanbhag P., Evans D., Patel. et al. Treatment Patterns and Outcomes of Acthar Gel in Systemic Lupus Erythematosus: A Physician-Reported Chart Review. *Abstract: International Congress on Systemic Lupus Erythematosus (LUPUS 2025)*

meeting. March 2025.

³ About Lupus. Lupus Research Alliance website. <https://www.lupusresearch.org/understanding-lupus/what-is-lupus/about-lupus/>. Accessed March 2025.

⁴ Izmirly P.M., Parton H., Wang L., et al. Prevalence of Systemic Lupus Erythematosus in the United States: Estimates From a Meta-Analysis of the Centers for Disease Control and Prevention National Lupus Registries. American College of Rheumatology. 2021 Jun;73(6):991-996. doi:10.1002/art.41632.

⁵ Symptoms. Lupus Research Alliance website. <https://www.lupusresearch.org/understanding-lupus/what-is-lupus/symptoms/>. Accessed March 2025.

⁶ Squance M.L., Reeves G.E., Bridgman H. The lived experience of lupus flares: features, triggers, and management in an Australian female cohort. International Journal of Chronic Diseases. 2014:1-12.

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