



## Mallinckrodt Announces Publication of Findings on Treatment Patterns and Outcomes in Patients with Two Types of Arthritis Treated with Acthar® Gel (repository corticotropin injection)

September 18, 2025

– Cross-sectional physician survey and medical chart review showed some patients evaluated with AS or PsA who were treated with Acthar Gel experienced a reported reduction in overall symptoms, decreased pain, improved physical function, reduced corticosteroid use, improved strength, and improved fatigue using prespecified assessments<sup>1</sup> –

DUBLIN, Sept. 18, 2025 /PRNewswire/ -- [Mallinckrodt plc](#), a global specialty pharmaceutical company, today announced the publication of findings from a cross-sectional physician-reported medical chart review and survey assessing patient characteristics, medication utilization patterns, and the effects of treatment on health status in patients with ankylosing spondylitis (AS) or psoriatic arthritis (PsA) who underwent treatment with Acthar® Gel (repository corticotropin injection).<sup>1</sup> The manuscript was recently published online in [Open Access Rheumatology: Research and Reviews](#).



Acthar Gel is a naturally sourced complex mixture of adrenocorticotrophic hormone (ACTH) analogs and other pituitary peptides.<sup>2</sup> Acthar Gel is approved by the FDA for the treatment or adjunct treatment of several autoimmune disorders and medical conditions known to cause inflammation.<sup>2</sup>

**Please see Indications and Important Safety Information for Acthar Gel below.**

"Until recently, there was limited real-world data to help us understand how Acthar Gel is used in clinical practice for patients with ankylosing spondylitis or psoriatic arthritis," said **George Wan, Ph.D., M.P.H., Vice President, Evidence Generation and Data Sciences, Mallinckrodt**. "These physician insights provide further data regarding Acthar Gel as a treatment option for appropriate patients with these complex conditions."

"It is imperative that individuals living with chronic inflammatory conditions, like ankylosing spondylitis or psoriatic arthritis, have access to treatments that can help manage a variety of symptoms that affect their daily lives," said **Cassie Shafer, Chief Executive Officer, Spondylitis Association of America**. "We value our collaboration with organizations like Mallinckrodt, whose commitment to research in these areas continues to make a meaningful difference for patients and their families."

### About the Chart Review

"Treatment Patterns and Outcomes of Acthar Gel in Ankylosing Spondylitis and Psoriatic Arthritis: A Physician-Reported Chart Review" was conducted among a group of physician participants who were blinded to the sponsor, and vice versa.<sup>1</sup> Data received from participating physicians were validated for accuracy and completeness.<sup>1</sup> Patients in the sample were aged ≥18 years, had a diagnosis of AS or PsA, had received treatment with Acthar Gel in the previous 24 months, and had completely accessible medical records. Patients with contraindications, comprising adrenocortical hyperfunction, congestive heart failure, ocular herpes simplex, osteoporosis, peptic ulcers, primary adrenocortical insufficiency, scleroderma, systemic fungal infections, and uncontrolled hypertension, were excluded.<sup>1</sup>

The chart review collected data abstracted from the records of 63 patients with AS and 77 patients with PsA between April 2022 and November 2024.<sup>1</sup> The mean age of patients with AS was 44 years, and the mean age of patients with PsA was 51 years.<sup>1</sup> The majority of patients with AS were male (67%, n=42/63) while patients with PsA had a similar gender distribution (49%, n=38/77).<sup>1</sup> More than half of patients with AS (57%, n=36/63) and PsA (60%, n=46/77) were identified as Caucasian/non-Hispanic.<sup>1</sup> Additionally, physicians reported that before receiving treatment with Acthar Gel<sup>1</sup>:

- 41% (n=26/63) of patients with AS and 44% (n=34/77) with PsA had fair-to-poor health status
- 89% (n=56/63) of patients with AS had back pain, 76% (n=48/63) had lower back/hip stiffness, and 62% (n=39/63) had fatigue
- 81% (n=62/77) of patients with PsA had joint swelling and pain, 70% (n=54/77) had reduced range of motion, and 66%

(n=51/77) had fatigue

Based on physician assessment, 95% (n=60/63) of patients with AS and 88% (n=68/77) with PsA experienced improved health status after treatment with Acthar Gel.<sup>1</sup>

Among the patients with improved health status, further findings reported included<sup>1</sup>:

- 70% (n=42/60) of patients with AS and 63% (n=43/68) of patients with PsA had a reduction in overall symptoms
- 68% (n=41/60) of patients with AS and 62% (n=42/68) of patients with PsA had decreased pain
- 53% (n=32/60) of patients with AS and 54% (n=37/68) of patients with PsA had improved physical function
- 37% (n=22/60) of patients with AS and 38% (n=26/68) of patients with PsA had improved strength
- 35% (n=21/60) of patients with AS and 32% (n=22/68) of patients with PsA had improved fatigue
- 30% (n=18/60) of patients with AS and 31% (n=21/68) of patients with PsA had reduced corticosteroid use

Summary of limitations of the research include<sup>1</sup>:

- Survey data was derived from patient medical records, which may contain inaccuracies or omissions.
- This chart review population is limited to patients receiving Acthar Gel and those included in the reviewed records, potentially limiting generalizability to broader AS and PsA populations, particularly those in different healthcare settings or with varying disease severity.
- As a real-world chart review, a uniform disease-activity instrument was not used. Instead, disease status was abstracted as documented in the record (physician assessments and routinely recorded clinical signs/symptoms).
- Collecting standardized disease activity measures from observational data presents substantial challenges. In previously published studies using electronic medical records from two separate rheumatology care management organizations, such measures were available in only up to 20% of patient records.
- Variability in physician documentation and subjective assessments of patient improvement could introduce bias, especially without standardized objective measures of disease activity.
- Absence of a control group limits the ability to determine the true effectiveness of Acthar Gel.
- These results should not be interpreted as comparative effectiveness.
- This chart review does not quantify diagnostic or safety outcomes and primarily captures short-term effects, limiting understanding of the impact of long-term treatment.
- While some patients may receive Acthar Gel alongside short-term glucocorticoids, this descriptive chart review did not collect standardized safety endpoints or detailed concomitant dosing and therefore cannot compare adverse events between concomitant-use and non-concomitant-use groups; prospective studies with predefined safety outcomes are needed.

This research was sponsored by Mallinckrodt Pharmaceuticals.

## INDICATIONS

Acthar Gel is indicated for:

- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic dermatomyositis (polymyositis) and systemic lupus erythematosus
- 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
- Symptomatic sarcoidosis
- 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
- Inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
- 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
- Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age

## 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 Ankylosing Spondylitis (AS)

Ankylosing spondylitis (AS) is a form of arthritis that is characterized by systemic inflammation leading to fusion of the axial skeleton.<sup>3</sup> Most commonly appearing in people in their mid-20s and more commonly in men, AS can significantly impact a person's physical and mental health.<sup>3</sup> It affects an estimated one in every 200 people.<sup>4</sup>

### About Psoriatic Arthritis (PsA)

Psoriatic arthritis (PsA) is characterized by chronic arthritis in the presence of psoriasis, and is found in up to 30% of people with psoriasis.<sup>5</sup> Up to 80% of patients with PsA present with psoriasis before developing musculoskeletal symptoms.<sup>6</sup> Delayed diagnosis and consequent inability to obtain appropriate treatment may lead to progressive joint destruction and often long-term disability.<sup>6</sup>

### About Mallinckrodt

Mallinckrodt is dedicated to enhancing lives by providing therapeutics that strive to address unmet patient needs, and is a world-class manufacturer of high-quality generics, sterile injectables, and active pharmaceutical ingredients.

Our company consists of multiple wholly owned subsidiaries that operate in two businesses. Our Brands business is focused on autoimmune and rare diseases in areas including endocrinology, gastroenterology, hepatology, neonatal respiratory critical care, nephrology, neurology, pulmonology, ophthalmology, orthopedics, rheumatology, and urology. Our Par Health business includes generic drugs, sterile injectables, and active pharmaceutical ingredients. To learn more, visit [www.MNK-Endo.com](http://www.MNK-Endo.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, and 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 each of Mallinckrodt's and Endo's recent emergences from bankruptcy; satisfaction of, and compliance with, regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; changes in market demand; 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" and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Mallinckrodt's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission (SEC), all of which are available from the SEC's website ([www.sec.gov](http://www.sec.gov)) and Mallinckrodt's website ([www.mallinckrodt.com](http://www.mallinckrodt.com)). 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

<sup>1</sup> Patel A., Shanbhag P., Evans D., et al. Treatment Patterns and Outcomes of Acthar Gel in Ankylosing Spondylitis and Psoriatic Arthritis: A Physician-Reported Chart Review. *Open Access Rheumatology: Research and Reviews*. 2025;17:193-202.

<https://doi.org/10.2147/OARRR.S538839>


<sup>2</sup> Acthar<sup>®</sup> Gel (repository corticotropin injection) [Prescribing Information]. Bridgewater, NJ: Mallinckrodt ARD LLC.

<sup>3</sup> Crossfield S.S.R., Marzo-Ortega H., Kingsbury S.R., et al. Changes in ankylosing spondylitis incidence, prevalence and time to diagnosis over two decades. *RMD Open*. 2021;7:e001888. <https://rmdopen.bmj.com/content/7/3/e001888>

<sup>4</sup> Hwang M.C., Ridley L., Reveille J.D., Ankylosing spondylitis risk factors: a systematic literature review. *Clinical Rheumatol*. 2021;40:3079-3093. <https://doi.org/10.1007/s10067-021-05679-7>

<sup>5</sup> Ibrahim G., Waxman R., Helliwell P.S. The Prevalence of Psoriatic Arthritis in People With Psoriasis. *Arthritis & Rheumatism*. 2009;61:1373-1378. <https://doi.org/10.1002/art.24608>

<sup>6</sup> Kishimoto M., Deshpande G.A., Fukuoka K., et al. Clinical features of psoriatic arthritis. *Best Practice & Research Clinical Rheumatology*. 2021;35(2). <https://doi.org/10.1016/j.berh.2021.101670>

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