

Glenmark Receives U.S. FDA Approval to Expand the Use of RYALTRIS® Nasal Spray for Children Aged 6 to Less Than 12 Years

Approval extends the use of RYALTRIS® to a younger pediatric population for the treatment of symptoms of Seasonal Allergic Rhinitis

Milestone strengthens Glenmark's innovative respiratory portfolio following its transition to direct commercialization of RYALTRIS® in the United States

Elmwood Park, New Jersey, July 21, 2026: Glenmark Specialty S.A. (Glenmark) today announced that U.S. FDA has approved the expanded use of RYALTRIS® (olopatadine hydrochloride and mometasone furoate) Nasal Spray, 665 mcg/25 mcg per spray, for the treatment of symptoms of Seasonal Allergic Rhinitis (SAR) in pediatric patients aged 6 to less than 12 years.

With this approval, RYALTRIS® is now approved in the United States for adults and pediatric patients aged 6 years and older, extending this treatment option to a younger pediatric population.

The approval was supported by a Phase 3, randomized, double-blind, placebo-controlled study involving 446 children aged 6 to 11 years with Seasonal Allergic Rhinitis. The study demonstrated that RYALTRIS® improved nasal symptoms compared with placebo and was well tolerated over the 14-day treatment period¹.

Seasonal allergies are common among school-age children in the United States. According to the U.S. Centers for Disease Control and Prevention, 25% of children aged 6 to 11 years had a diagnosed seasonal allergy in 2024². Seasonal Allergic Rhinitis (SAR) affects far more than nasal symptoms, significantly impacting children's overall health, emotional well-being, sleep, and participation in physical activity, with potential long-term consequences for healthy development and obesity risk^{3,4,5}.

Commenting on the development, Marc Kikuchi, President & Business Head, North America said, "This approval marks an important step in expanding access to RYALTRIS® in the United States by extending its use to children aged 6 to less than 12 years with Seasonal Allergic Rhinitis. It also strengthens the role of RYALTRIS® as a key innovative brand within Glenmark's growing US respiratory portfolio."

"Our transition to direct commercialization gives us greater ownership of the brand and enables closer engagement with healthcare professionals and patients. We intend to use this platform to expand access, build the RYALTRIS® franchise and further strengthen Glenmark's innovation-led presence in the U.S. specialty market," **he added.**

Effective April 1, 2026, Glenmark Pharmaceuticals Inc., USA assumed responsibility for the end-to-end commercialization and distribution of RYALTRIS® in the United States. Glenmark now directly leads the product's brand strategy, market access, distribution and customer engagement, enabling more focused execution and closer alignment with the needs of healthcare professionals and patients.

RYALTRIS® is a fixed-dose combination nasal spray that combines olopatadine hydrochloride (an antihistamine) and mometasone furoate (a corticosteroid) in a single formulation. It was initially approved by the U.S. FDA in 2022 for the treatment of symptoms of Seasonal Allergic Rhinitis (SAR) in adults and pediatric patients 12 years of age and older.

RYALTRIS® has established a broad international footprint, with approvals across key markets including the European Union, United Kingdom, Australia, South Korea, Russia, and China. In FY26, RYALTRIS® was launched in 11 additional markets, further expanding its global presence to 56 countries.

Important Safety Information

CONTRAINDICATIONS

Patients with known hypersensitivity to any ingredients of RYALTRIS®, including mometasone furoate.

WARNINGS AND PRECAUTIONS

Epistaxis, nasal ulcerations, nasal septal perforations, impaired wound healing, and Candida albicans infection: Monitor patients periodically for signs of adverse reactions on the nasal mucosa.

Somnolence: Avoid engaging in hazardous occupations requiring complete mental alertness and motor coordination such as driving or operating machinery when taking RYALTRIS®.

Avoid concurrent use of alcohol or other central nervous system (CNS) depressants with RYALTRIS® because additional reductions in alertness and additional impairment of CNS performance may occur.

Glaucoma and cataracts: Monitor patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

Hypersensitivity Reactions: Hypersensitivity reactions can occur with RYALTRIS®. Hypersensitivity reactions including wheezing, have occurred after the nasal administration of mometasone furoate. Discontinue RYALTRIS® if such reactions occur.

Immunosuppression and Risk of Infections: Potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. More serious or even fatal course of chickenpox or measles in susceptible patients: Use caution in patients with the above because of the potential for worsening of these infections.

Hypercorticism and adrenal suppression with misuse or use of higher-than-recommended dosages or at the regular dosage in susceptible patients at risk for such effects.

Potential reduction in growth velocity in children: Routinely monitor the growth in pediatric patients receiving RYALTRIS®.

ADVERSE REACTIONS

The most common adverse reactions (≥1% incidence) are dysgeusia, epistaxis, and nasal discomfort.

INDICATIONS

RYALTRIS® is a combination of olopatadine, a histamine-1 (H1)-receptor inhibitor, and mometasone furoate, a corticosteroid, indicated for the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients of age 6 years and older.

Please click [here](#) to view full prescribing information, including Important Safety Information.

For additional information about RYALTRIS® and how to access, please visit us.ryaltris.com

RYALTRIS® is a registered trademark of Glenmark Specialty SA.

¹ Prenner BM, et al. Efficacy and safety of GSP301 nasal spray in children aged 6–11 years with Seasonal Allergic Rhinitis. *Annals of Allergy, Asthma & Immunology*. 2022;129(5):618–626.e2.

² National Center for Health Statistics. Diagnosed Allergic Conditions in Children Ages 0–17: United States, 2024. NCHS Data Brief No. 546. January 2026.

³ Meltzer, E.O., Blaiss, M.S., Derebery, M.J., Mahr, T.A., Gordon, B.R., Sheth, K.K., Simmons, A.L., Wingertzahn, M.A., & Boyle, J.M. (2009). Burden of allergic rhinitis: results from the Pediatric Allergies in America survey. *J Allergy Clin Immunol*, 124(3Suppl), S43–S70.

⁴Fereidouni, M., Rezapour, H., Saharkhiz, M., Mahmoudzadeh, S., Ayadilord, M., Askari, M., Karbasi, S., Abbaszadeh, A., Hoseini, Z. S., Ferns, G. A., & Bahrami, A. (2021). A study of the association of cognitive abilities and emotional function with allergic disorders in young women. *BMC Womens Health*, 21(1), 205.

⁵Strom, M. A., & Silverberg, J. I. (2016). Associations of physical activity and sedentary behavior with atopic disease in United States children. *J Pediatr*, 174, 247–253.e243.

About Glenmark Pharmaceuticals Limited

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is a global, research-led pharmaceutical company with a unique focus on innovation and accessibility. We pioneer transformative breakthrough therapies that aim to redefine treatment while expanding access to high quality and affordable medicines for patients around the world. With 11 world-class manufacturing facilities across four continents, supported by six cutting-edge R&D centres, and a commercial footprint in 80+ countries, we deliver a diversified portfolio across branded, innovative, generics, and consumer health products, with a focus on respiratory, dermatology, and oncology. Scrip 100 positions Glenmark among the Top 100 biopharmaceutical companies globally by pharmaceutical sales for 2024. For more information, visit www.glenmarkpharma.com

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