

Ryaltris™ (olopatadine/mometasone furoate monohydrate) – New drug approval

- On January 14, 2022, [Glenmark Pharmaceuticals announced the FDA approval of Ryaltris \(olopatadine/mometasone furoate monohydrate\)](#), for the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older.
- The efficacy of Ryaltris was established in two randomized, double-blind, placebo-and active-controlled clinical studies in 2,352 patients 12 years of age and older with seasonal allergic rhinitis. In both studies, patients were randomized to 1 of 4 treatment groups: Ryaltris, olopatadine, mometasone furoate, and vehicle placebo for 2 weeks. The primary endpoint for both studies was the change from baseline in average morning and evening subject reported 12-hour reflective total nasal symptom score (rTNSS) over the 14-day treatment period.
 - In both studies, treatment with Ryaltris resulted in a statistically significant improvement in rTNSS vs. olopatadine and to mometasone furoate as well as to placebo (except for study 1 comparison to mometasone furoate).

	Study 1			Study 2		
	Baseline mean	Change from baseline LS mean	Treatment effect Difference LS mean (95% CI)	Baseline mean	Change from baseline LS mean	Treatment effect Difference LS mean (95% CI)
Ryaltris	10.1	-3.5	--	10.1	-3.5	--
Olopatadine	10.3	-2.9	-0.6 (-1.0, -0.2)	10.2	-3.1	-0.4 (-0.8, -0.1)
Mometasone	10.2	-3.1	-0.4 (-0.8, 0.0)	10.2	-3.1	-0.5 (-0.9, -0.1)
Placebo	10.2	-2.5	-1.0 (-1.3, -0.6)	10.3	-2.4	-1.1 (-1.5, -0.7)

- Warnings and precautions for Ryaltris include local nasal adverse reactions; somnolence and impaired mental alertness; glaucoma and cataracts; hypersensitivity reactions; immunosuppression and risk of infections; hypercorticism and adrenal suppression; and effect of growth.
- The most common adverse reactions ($\geq 1\%$) with Ryaltris use were dysgeusia, epistaxis, and nasal discomfort.
- The recommended dosage of Ryaltris is 2 sprays (2 sprays deliver a total of 1,330 mcg of olopatadine and 50 mcg of mometasone furoate) in each nostril twice daily.
- Ryaltris will be marketed and distributed through Hikma Specialty and launch plans are pending. Ryaltris will be available as a nasal spray delivering 665 mcg of olopatadine and 25 mcg of mometasone furoate in each spray.