Optum Rx®

Xhance® (fluticasone propionate) – New indication

- On March 15, 2024, OptiNose announced the FDA approval of Xhance (fluticasone propionate), for the treatment of chronic rhinosinusitis **without nasal polyps** (CRSsNP) in adults.
- Xhance is also approved for the treatment of chronic rhinosinusitis **with nasal polyps** (CRSwNP) in adults.
- The approval of Xhance for the new indication was based on two randomized, double-blind, placebo-controlled studies in 555 adults 18 years and older (Trial 3 and Trial 4). Trial 3 included 223 patients with CRSsNP, and Trial 4 included 332 patients with either CRSsNP or CRSwNP. While Trial 4 included CRSwNP patients, efficacy results from Trials 3 and 4 are presented for CRSsNP patients only. In both studies, patients were randomized to receive Xhance 186 mcg twice daily, Xhance 372 mcg twice daily, or placebo, all administered nasally for 24 weeks. In both studies, the coprimary efficacy endpoints were 1) change from baseline at week 4 in the composite symptom score (CSS) as determined by patients using a daily diary and 2) change from baseline at week 24 in percent opacified sinus volume.
    - Efficacy was demonstrated for both coprimary endpoints (CSS and percent opacified sinus volume) for Xhance 186 mcg twice daily and Xhance 372 mcg twice daily.

	Placebo	Xhance 186 mcg	Xhance 372 mcg	Difference (95% CI) 186 mcg vs. placebo	Difference (95% CI) 372 mcg vs. placebo
Trial 1					
Baseline Mean CSS	6.2	5.9	6.0	--	--
LS mean change from baseline in CSS at week 4	-0.8	-1.5	-1.7	-0.7 (-1.3, -0.2)	-0.9 (-1.5, -0.4)
Baseline percent of opacified sinus volume	64.1	60.5	61.5	--	--
LS mean change from baseline in percent of opacified sinus volume at week 24	0.4	-7.0	-5.5	-7.5 (-12.1, -2.8)	-5.9 (-10.6, -1.3)
Trial 2					
Baseline Mean CSS	5.7	5.5	5.8	--	--
LS mean change from baseline in CSS at week 4	-0.7	-1.6	-1.6	-0.9 (-1.6, -0.2)	-0.9 (-1.6, -0.2)
Baseline percent of opacified sinus volume	61.9	63.0	60.7	--	--

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LS mean change from baseline in percent of opacified sinus volume at week 24	-5.3	-5.7	-8.4	-0.5 (-6.8, 5.9)	-3.2 (-9.5, 3.2)

- The most common adverse reactions (≥ 3%) with Xhance use for CRSsNP were epistaxis, headache, and nasopharyngitis.

- The recommended dosage of Xhance is 186 mcg (1 spray per nostril) or 372 mcg (2 sprays per nostril) twice daily (total daily dose of 372 mcg or 744 mcg). The maximum total daily dosage should not exceed 2 sprays in each nostril twice daily (total daily dose of 744 mcg).

    — Patients should use Xhance at regular intervals since its effectiveness depends on regular use. Individual patients will experience a variable time to onset and different degrees of symptom relief.
    — The safety and efficacy of Xhance when administered in excess of recommended doses have not been established.