



Xhance™ (fluticasone propionate) – New drug approval

- On September 18, 2017, [Optinose announced](#) the FDA approval of [Xhance \(fluticasone propionate\)](#) for the treatment of nasal polyps in patients 18 years of age or older.
- An estimated 10 million Americans suffer from nasal polyps and the symptoms that accompany them.
- Xhance contains fluticasone propionate, a synthetic trifluorinated corticosteroid with anti-inflammatory activity.
 - Xhance is designed to deliver medicine to targeted areas deep in the nose by using a new approach, called an Exhalation Delivery System.
 - Xhance is delivered into the nose by actuating the pump spray into one nostril while simultaneously blowing (exhaling) into the mouthpiece of the device.
- The approval of Xhance was based on two placebo-controlled trials involving 646 adult patients with nasal polyps and associated moderate-to-severe nasal congestion. Most patients reported previous use of a topical steroid nasal spray, previous nasal surgery or polypectomy.
 - With Xhance treatment, patients experienced statistically significant reductions of both nasal congestion/obstruction at week 4 and total polyp grade at week 16, which were the co-primary endpoints.
- Warning and precautions of Xhance include local nasal effects, glaucoma and cataracts, hypersensitivity reactions including anaphylaxis, immunosuppression, hypothalamic-pituitary-adrenal axis suppression, drug interactions with strong cytochrome P450 3A4 inhibitors, reduction in bone mineral density, and effect on growth.
- The most common adverse reactions ($\geq 3\%$) with Xhance use were epistaxis, nasal septal ulceration, nasopharyngitis, nasal mucosal erythema, nasal mucosal ulcerations, nasal congestion, acute sinusitis, nasal septal erythema, headache, and pharyngitis.
- The recommended dose of Xhance is 1 spray (93 mcg) in each nostril twice daily.
 - A dose of 2 sprays in each nostril twice daily may also be effective in some patients; however, the maximum total daily dosage should not exceed 2 sprays in each nostril twice daily.
 - Patients should use Xhance at regular intervals since its effectiveness depends on regular use.
 - The safety and efficacy of Xhance when administered in excess of recommended doses have not been established.
- Optinose plans to launch Xhance in the 2nd quarter of 2018. Xhance will be available as a metered-dose nasal spray, which delivers 93 mcg of fluticasone propionate in each spray.



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