XYLITOL NASAL SPRAY

Ketotifen · Xylitol Base · ± Budesonide

Prescriber Reference Guide · The Medicine Shoppe, York PA

Allergic Rhinitis · Mast Cell Stabilization · Multi-Mechanism · Compounded · Rx Required

Program Overview

This compounded nasal spray combines a xylitol base with ketotifen -- a mast cell stabilizer and H1 antihistamine -- and optionally budesonide, a corticosteroid, into a single daily spray. It is designed for patients with allergic rhinitis, perennial nasal allergies, or mast cell-mediated nasal symptoms where standard OTC options provide incomplete relief or cause tolerability issues. The three-component formula addresses nasal allergy through complementary mechanisms: upstream mast cell stabilization, H1 receptor blockade, mucosal support, and (optionally) corticosteroid anti-inflammatory control.

Key Clinical Advantages

- Three-mechanism approach in one spray -- mast cell stabilization + H1 blockade (ketotifen) + sinus support (xylitol) + optional corticosteroid (budesonide)
- Nasal ketotifen is not commercially available in the US -- compounding is required; provides both mast cell stabilization and antihistamine action that no OTC nasal spray offers
- Xylitol base provides active benefit beyond vehicle -- antimicrobial, biofilm-disrupting, and mucosal moisturizing properties address the nasal environment, not just symptoms
- Modular formula -- prescribe ketotifen alone or add budesonide based on clinical picture; concentrations customizable
- Non-controlled -- no scheduling, no prior authorization; straightforward compounding prescription
- Suitable for patients who cannot tolerate or have insufficient response to fluticasone, azelastine, or olopatadine nasal sprays

Ingredient 1: Xylitol Base -- More Than a Vehicle

Xylitol is not merely a carrier in this formulation -- it is an active contributor to nasal health through mechanisms that complement the prescription active ingredients.

What Is Xylitol	A five-carbon sugar alcohol naturally found in many fruits and vegetables. Widely used in dental products for its anti-cariogenic properties; in nasal applications, it leverages the same antimicrobial and osmotic mechanisms in the sinonasal environment.
Antimicrobial Properties	Xylitol interferes with bacterial adhesion and biofilm formation in the nasal passages. Bacteria that colonize the upper respiratory tract (Streptococcus pneumoniae, H. influenzae, Staphylococcus aureus) are less able to adhere to mucosal surfaces in the presence of xylitol, reducing infectious burden and secondary inflammatory triggers.

Biofilm Disruption	Many patients with chronic sinusitis and perennial rhinitis harbor established bacterial biofilms that perpetuate inflammation and reduce antibiotic efficacy. Xylitol disrupts biofilm structure, supporting a healthier nasal microenvironment.
Mucosal Hydration	Xylitol is osmotically active and hygroscopic -- it draws moisture to nasal tissue, counteracting the dryness and crusting associated with inflammation, dry climates, and some corticosteroid nasal sprays. Reduces the burning and irritation that some patients experience with commercial sprays.
Mucociliary Support	Evidence suggests xylitol supports ciliary function by maintaining appropriate nasal surface liquid tonicity -- important for normal mucociliary clearance of allergens, pathogens, and debris.
Clinical Evidence	RCTs of xylitol nasal irrigation demonstrate reductions in bacterial colonization and symptom burden in chronic rhinosinusitis. Xylitol nasal sprays are widely used in pediatric and adult upper respiratory care internationally.

Ingredient 2: Ketotifen (Nasal)

Ketotifen is the pharmacologically active cornerstone of this formula. Unlike commercially available nasal antihistamines (azelastine, olopatadine) that only block H1 receptors after histamine release, ketotifen provides mast cell stabilization upstream -- preventing mediator release in the first place -- while simultaneously blocking H1 receptors downstream.

Mechanism of Action

Mast Cell Stabilization	Inhibits mast cell degranulation by blocking calcium influx, preventing release of preformed mediators (histamine, tryptase) and newly synthesized mediators (prostaglandins, leukotrienes) in response to allergen challenge. Acts upstream of the allergic cascade.
H1 Antihistamine	Second-generation H1 inverse agonist -- blocks histamine binding at nasal mucosal H1 receptors, reducing itching, sneezing, rhinorrhea, and congestion caused by already-released histamine. Provides immediate symptomatic relief concurrent with long-term stabilization.
Eosinophil Inhibition	Inhibits eosinophil chemotaxis and activation -- addresses the eosinophilic component of allergic rhinitis that drives late-phase allergic responses and chronic nasal inflammation beyond the acute histamine reaction.
Buildup Effect	Mast cell stabilization requires consistent use -- maximal benefit develops over 2-4 weeks of daily application. Prescribers and patients should understand this is not a PRN spray; consistent daily use is required for full effect.
Nasal vs. Oral Ketotifen	Topical nasal delivery concentrates ketotifen at the site of action (nasal mucosa and mast cells) with minimal systemic absorption -- substantially reducing the sedation associated with oral ketotifen at equivalent therapeutic effect in the nasal compartment.

Available Concentrations

0.025% Ketotifen	Starting concentration -- appropriate for patients new to ketotifen, pediatric patients, or those with sensitivity concerns. Provides meaningful mast cell stabilization and H1 blockade with the lowest systemic exposure.
0.05% Ketotifen	Standard therapeutic concentration -- appropriate for most adult patients with moderate-to-severe allergic rhinitis or those with inadequate response to 0.025%. Comparable to international ketotifen nasal spray formulations.
Titration Approach	Some prescribers initiate at 0.025% for 2-4 weeks then advance to 0.05% if needed; others start at 0.05% in adults with established allergic disease. Concentration selection per prescriber judgment.

Ingredient 3: Budesonide (Optional)

Budesonide is an optional add-on for patients in whom corticosteroid anti-inflammatory control is clinically indicated. It addresses inflammatory pathways beyond mast cell and histamine mechanisms -- particularly chronic mucosal inflammation, eosinophilic infiltration, and nasal polyp-associated disease.

Mechanism	Intranasal corticosteroid -- binds glucocorticoid receptors in nasal mucosal cells, reducing transcription of pro-inflammatory cytokines, chemokines, and adhesion molecules. Reduces mucosal edema, eosinophilic infiltration, goblet cell hyperplasia, and sub-mucosal inflammation.
Why Add to Ketotifen	Ketotifen addresses mast cell and histamine pathways; budesonide addresses the broader inflammatory milieu. Together they cover a wider range of allergic and inflammatory mechanisms than either alone -- particularly useful in moderate-to-severe perennial rhinitis or patients with significant mucosal hypertrophy.
Compounded vs. Commercial	Budesonide nasal spray (Rhinocort) is commercially available. The compounded combination formulation is used when the prescriber wants budesonide co-delivered with ketotifen in a single spray, improving adherence and adding xylitol's mucosal support.
Systemic Absorption	Intranasal budesonide has low systemic bioavailability (~34% absorbed, with significant first-pass hepatic metabolism) -- substantially less systemic corticosteroid exposure than oral steroids. HPA axis suppression is not a concern at standard nasal doses.
When to Include	Consider adding budesonide for patients with: moderate-to-severe perennial allergic rhinitis, significant nasal congestion/mucosal swelling, nasal polyp history, inadequate response to antihistamine-only nasal therapy, or concurrent asthma requiring steroid-level nasal control.
When to Omit	Ketotifen-only formulation (without budesonide) is appropriate for: milder seasonal allergic rhinitis, patients preferring a steroid-free option, pediatric patients where corticosteroid minimization is preferred, or patients already on a separate intranasal steroid.

Comparison to Commercial Nasal Sprays

	Fluticasone (Flonase)	Azelastine (Astelin)	Olopatadine (Patanase)	Cromolyn (Nasalcrom)	This Formula
Mast Cell Stabilizer	--	--	--	Yes	Yes
H1 Antihistamine	--	Yes	Yes	--	Yes
Corticosteroid	Yes	--	--	--	Optional
Mucosal Moisturizing	--	--	--	--	Yes (xylitol)
Antimicrobial Base	--	--	--	--	Yes (xylitol)
Sedation Risk	Low	Moderate	Low	Low	Low (nasal)
US Availability	OTC/Rx	Rx	Rx	OTC	Compounded Rx

Indications & Patient Selection

Appropriate Candidates

- Seasonal or perennial allergic rhinitis with incomplete response to OTC antihistamines or fluticasone alone
- Patients who want mast cell stabilization in addition to antihistamine coverage -- no commercial US nasal spray provides both
- MCAS or histamine intolerance with prominent nasal/sinus involvement -- complements oral ketotifen or standalone nasal therapy
- Patients experiencing dryness, burning, or irritation from commercial nasal sprays -- xylitol base is soothing and moisturizing
- Perennial allergic rhinitis with significant mucosal congestion or swelling -- add budesonide for corticosteroid coverage
- Patients on oral antihistamines seeking to reduce systemic antihistamine burden -- nasal delivery minimizes systemic exposure
- Pediatric allergic rhinitis (at prescriber discretion) -- xylitol-based sprays have an established pediatric safety record; ketotifen concentration adjusted accordingly

When to Use Ketotifen Only vs. Adding Budesonide

Ketotifen + Xylitol (No Budesonide)	Add Budesonide When...
Mild-to-moderate seasonal allergic rhinitis	Moderate-to-severe perennial allergic rhinitis
Steroid-free preference	Significant nasal congestion or mucosal swelling
Pediatric patients (corticosteroid minimization)	Nasal polyp history or eosinophilic rhinitis
Already on separate intranasal steroid	Inadequate response to ketotifen alone after 4+ weeks
Primary MCAS/histamine intolerance symptom target	Concurrent asthma requiring steroid-level nasal control

Dosing & Administration

Standard Dosing	1-2 sprays per nostril once or twice daily -- per prescriber specification; most patients use once daily for maintenance
Ketotifen Concentration	0.025% (initiation / pediatric / sensitive patients) or 0.05% (standard adult dose); prescriber specifies on the prescription
Budesonide (if included)	Typically 32-64 mcg per nostril per day; prescriber specifies concentration and volume per actuation
Administration Technique	Blow nose gently before use; tilt head slightly forward; insert nozzle into nostril aiming away from septum; spray while breathing in gently through nose; repeat for other nostril. Do not sniff forcefully -- allows medication to contact mucosal surface rather than pass to throat.
Priming	Prime pump before first use (4-6 actuations into air) and after prolonged storage (2-3 actuations). Wipe nozzle clean after each use.
Onset of Effect	H1 antihistamine relief: within 30-60 minutes of first use. Mast cell stabilization benefit: builds over 2-4 weeks of consistent daily use. Budesonide anti-inflammatory effect: 1-2 weeks for full benefit.
Duration of Use	Intended for daily maintenance during allergy season or year-round for perennial disease; not a PRN spray for mast cell stabilization benefit

Drug Interactions & Safety

Ketotifen -- Systemic Sedation	Nasal delivery minimizes systemic absorption substantially vs. oral ketotifen. Clinically significant sedation from nasal ketotifen is rare; concurrent use of CNS depressants (alcohol, benzodiazepines, sedating antihistamines) should still be noted.
Budesonide -- Systemic Steroids	Patients already on systemic or inhaled corticosteroids: consider cumulative steroid burden, particularly with concurrent oral prednisone, high-dose inhaled ICS, or other intranasal steroids.
Budesonide -- CYP3A4	Budesonide is metabolized by CYP3A4. Strong CYP3A4 inhibitors (ketoconazole, itraconazole, ritonavir) can increase systemic budesonide exposure -- use with caution. At standard intranasal doses the interaction is clinically minor but worth noting.
Nasal Septum Integrity	Instruct patients to direct spray away from the nasal septum toward the lateral nasal wall. Prolonged corticosteroid nasal spray use directed at the septum carries a small risk of septal perforation.
Pregnancy	Limited data on nasal ketotifen in pregnancy; budesonide is Pregnancy Category B and is among the preferred intranasal steroids in pregnancy when clinically indicated. Discuss risk-benefit.
Contraindications	Hypersensitivity to any component; active nasal infection or nasal surgery/trauma until healed (avoid introducing spray into disrupted tissue)

Monitoring & Follow-Up

Baseline	Document allergic rhinitis severity, current medications (antihistamines, nasal sprays, ICS), and symptom distribution; note any prior adverse reactions to nasal sprays
2 Weeks	Assess tolerability -- nasal irritation, taste/smell complaints (metallic taste can occur with some nasal sprays; xylitol base minimizes this), early symptom response
4 Weeks	Assess mast cell stabilization benefit beginning -- reduction in reactive episodes, decreased need for rescue antihistamines, improved nasal symptom scores
3 Months	Full assessment of formula efficacy; consider concentration adjustment (0.025% to 0.05% ketotifen) or budesonide addition if partial response; review technique
If Budesonide Included	Annual assessment of nasal mucosa (epistaxis, crusting, or septal changes); consider brief steroid holiday if well-controlled; note cumulative steroid burden if on concurrent ICS or systemic steroids
Ongoing	Reassess seasonally or annually; consider step-down to ketotifen-only if budesonide component is no longer needed in well-controlled patients

Formulation & Dispensing

Dosage Form	Nasal spray solution in xylitol base -- compounded at The Medicine Shoppe; supplied in metered-dose nasal pump bottle
Ketotifen Strengths	0.025% or 0.05% -- prescriber specifies; both available
Budesonide	Optional; concentration per prescriber specification; not included unless specifically prescribed
Xylitol Base	Pharmaceutical-grade xylitol in buffered isotonic nasal solution; pH-adjusted for mucosal compatibility; preservative selection per prescriber preference
Quantity	30-day supply standard (typically 15-30 mL depending on dosing frequency)
Pricing	Cash pay -- contact pharmacy for current pricing by formula
BUD / Storage	Per USP compounding standards; store at room temperature; do not refrigerate; discard per labeled BUD; labeled on each preparation

Ordering & Contact Information

All preparations require a valid prescription specifying ketotifen concentration, whether budesonide is included (and at what concentration), and dosing instructions. Patients fill directly at our pharmacy. No prior authorization required.

How to Order

- By phone -- call (717) 846-0500; ask for the compounding pharmacist; have patient name, DOB, ketotifen concentration (0.025% or 0.05%), whether budesonide is included, and quantity ready
- By fax -- send prescription to (717) 845-8767; specify ketotifen % and budesonide concentration if applicable; note any preservative preference
- E-prescribe -- select 'Compound' as medication type; enter formula in Sig/Comments (e.g., 'Ketotifen 0.05% / Xylitol nasal spray -- 1-2 sprays each nostril daily' or add 'Budesonide 64 mcg/mL' if indicated)

The Medicine Shoppe 1698 S Queen St · York, PA 17403	Phone: (717) 846-0500 Fax: (717) 845-8767

For educational purposes only -- not medical advice. Prescription required. Individual results may vary.