

Effect of SINUVA™ (mometasone furoate) sinus implant in the ethmoid sinus cavity



SINUVA sinus implant is indicated for the treatment of chronic rhinosinusitis with nasal polyps in adult patients ≥ 18 years of age who have had ethmoid sinus surgery.












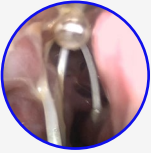

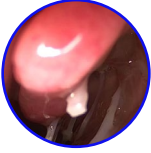









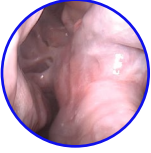
IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Patients with known hypersensitivity to mometasone furoate and any of the ingredients of the SINUVA sinus implant.

Please see additional important safety information on the following pages.

Examples from the RESOLVE II study† individual results may vary

	Patient 1 <ul style="list-style-type: none"> • 72 year old male • Polyp grade: 3.5 • ESO: 100% 	Patient 2 <ul style="list-style-type: none"> • 54 year old male • Polyp grade: 2.5 • ESO: 80% 	Patient 3 <ul style="list-style-type: none"> • 49 year old male • Polyp grade: 2.5 • ESO: 51% 	Patient 4 <ul style="list-style-type: none"> • 59 year old male • Polyp grade: 2.0 • ESO: 75% • No middle turbinate present
Baseline				
Day 1: SINUVA™ (mometasone furoate) sinus implant™ placement				
Day 14				
Day 30				
Day 60: Per the RESOLVE II study protocol, implants were removed at day 60 to allow for an independent panel review of patient videos at day 90				
Day 90				
ESO = Ethmoid Sinus Obstruction	<ul style="list-style-type: none"> • Polyp grade: 1.5 • ESO: 25% 	<ul style="list-style-type: none"> • Polyp grade: 1.0 • ESO: 24% 	<ul style="list-style-type: none"> • Polyp grade: 0 • ESO: 0% 	<ul style="list-style-type: none"> • Polyp grade: 1.0 • ESO: 10%

† The mean reduction in nasal obstruction / congestion score from baseline to day 30 was -0.80 (scale 0 to 3) and the mean reduction in bilateral polyp grade from baseline to day 90 was -0.56 (scale 0 to 8) for the treatment arm of the RESOLVE II study. Kern RC, Stolovitzky JP, Silvers SL, et al. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. *Int Forum Allergy Rhinol.* 2018;8(4):471-481.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Local Nasal Adverse Reactions: Monitor nasal mucosa adjacent to the SINUVA Sinus Implant for any signs of bleeding (epistaxis), irritation, infection, or perforation. Avoid use in patients with nasal ulcers or trauma.

Please see additional important safety information on the following pages.

The safety of SINUVA™ (mometasone furoate) sinus implants have been studied in 400 patients in 2 randomized controlled trials¹

Adverse reactions with >1% incidence and more common than control in 90-Day controlled clinical trials with SINUVA™ sinus implant¹

Adverse reactions	SINUVA™ implant (N=254) N (%)	Control (N=146) N (%)
Asthma	12 (4.7)	6 (4.1)
Headache	9 (3.5)	5 (3.4)
Epistaxis	6 (2.4)	2 (1.4)
Presyncope	6 (2.4)	3 (2.1)
Bronchitis	5 (2.0)	2 (1.4)
Otitis media	5 (2.0)	2 (1.4)
Nasopharyngitis	3 (1.2)	1 (0.7)

One study, RESOLVE^{2,4}, monitored patients from Day 90 through 6 months. Hypersensitivity (4% (n=2) vs 0), chronic rhinosinusitis (11% (n=6) vs 9% (n=4)), and upper respiratory tract infections (8% (n=4) vs 2% (n=1)) were reported in more than 2 patients in the treatment group, and more commonly than the control group during this time period.

Encore¹ study safety data in PI: Acute sinusitis (29%, n=12), upper respiratory infection (17%, n=7) epistaxis (12%, n=5), nasal discomfort or rhinalgia (12%, n=5), headache (7%, n=3), were the common adverse reactions that occurred in at least 3 subjects who underwent repeat placement during the study period.

IMPORTANT SAFETY INFORMATION (continued)

Glaucoma and Cataracts: Nasal steroids may result in development of glaucoma and/or cataracts. Glaucoma, cataracts, and clinically significant elevation of intraocular pressure were not observed in patients from the treatment group of one randomized controlled clinical study (N = 53) who underwent bilateral placement of SINUVA Sinus Implants. Close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, pruritus, and angioedema have been reported with the use of corticosteroids.

Please see additional important safety information on the following page.

References:

1. SINUVA™ [Prescribing Information] Menlo Park, CA, January 2023.
2. Han J, et al. RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis. *Intl Forum Allergy Rhinol.* 2014;4(11):861-70. Forwith, et al.
3. Kern, RC, Stolowitzky JP, Silvers SL, et al A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. *Int Forum Allergy Rhinol.* 2018. 471-481.
4. Forwith KD, Han JK, Stolovitzky JP, Yen DM, Chandra RK, Karanfilov B, Matheny KE, Stambaugh JW, Gawlicka AK. RESOLVE: bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis after sinus surgery: 6-month outcomes. *Intl Form Allergy Rhino*, 2016;6:573-581.

INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION

SINUVA Sinus Implant is a corticosteroid-eluting implant indicated for the treatment of chronic rhinosinusitis with nasal polyps in adult patients ≥ 18 years of age who have had ethmoid sinus surgery.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Patients with known hypersensitivity to mometasone furoate and any of the ingredients of the SINUVA Sinus Implant.

WARNINGS AND PRECAUTIONS

Local Nasal Adverse Reactions: Monitor nasal mucosa adjacent to the SINUVA Sinus Implant for any signs of bleeding (epistaxis), irritation, infection, or perforation. Avoid use in patients with nasal ulcers or trauma.

Glaucoma and Cataracts: Nasal steroids may result in development of glaucoma and/or cataracts. Glaucoma, cataracts, and clinically significant elevation of intraocular pressure were not observed in patients from the treatment group of one randomized controlled clinical study (N = 53) who underwent bilateral placement of SINUVA Sinus Implants. Close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, pruritus, and angioedema have been reported with the use of corticosteroids.

Immunosuppression and Risk of Infections: Persons who are using drugs that suppress the immune system, such as corticosteroids, including SINUVA Sinus Implant are more susceptible to infections than healthy individuals. The safety and effectiveness of SINUVA Sinus Implant have not been established in pediatric patients less than 18 years of age and SINUVA is not indicated for use in this population. Corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract; untreated systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

Hypercorticism and Adrenal Suppression: If corticosteroid effects such as hypercorticism and adrenal suppression appear in patients, consider sinus implant removal.

ADVERSE REACTIONS

The most common adverse reactions observed ($> 1\%$ of subjects) in clinical studies were asthma, headache, epistaxis, presyncope, bronchitis, otitis media, and nasopharyngitis.

POSTMARKETING EXPERIENCE

The following adverse reactions have been identified during post-approval use of the SINUVA sinus implant. These events include implant migration, lack of efficacy, nasal pain, headache, epistaxis.

Rx only. Please see Full Prescribing Information for SINUVA attached to this document and available at [SINUVA.com/hcp](https://www.sinuva.com/hcp).

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