Sinuva (mometasone furoate)

SINUVA™
(mometasone furoate) sinus implant

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Sinuva
- **Generic name:** Mometasone furoate
- **Pharmacological class:** Steroid
- **Strength and Formulation:** 1350mcg; per sinus implant
- **Manufacturer:** Intersect ENT, Inc.
- **How supplied:** Kit—1 (implant + delivery system)
- **Legal Classification:** Rx

Indications

- Nasal polyps in patients ≥18yrs who have had ethmoid sinus surgery

Sinuva

Dosage & Administration

- To be used by physicians trained in otolaryngology for placement in ethmoid sinus under endoscopic visualization
- Insert 1 implant for **90 days**
- Implant can be removed at Day 90 or earlier based on physician's discretion
- Do not reprocess or reuse

Considerations for Special Populations

- **Pregnancy:** No randomized studies conducted in pregnant women
- **Nursing mothers:** Consider clinical need and potential adverse effects
- **Pediatric:** <18yrs: not established
- **Elderly:** Insufficient number of subjects studied

Warnings/Precautions

- Respiratory tract tuberculosis
- Systemic infections
- Ocular herpes simplex
- Immunosuppression
- If exposed to measles or chickenpox, consider anti-infective prophylactic therapy
- Nasal ulcers or trauma: **avoid**

Warnings/Precautions

- Monitor nasal mucosa for epistaxis, irritation, infection, perforation
- Change in vision, history of increased intraocular pressure, glaucoma, and/or cataracts: monitor closely
- **Monitor** post-operatively and during periods of stress for adrenal response
- Consider implant removal if **hypercorticism** and adrenal suppression occurs

Interactions

- May be potentiated by strong CYP3A4 inhibitors (eg, ketoconazole)

Adverse Reactions

- Bronchitis
- Nasopharyngitis
- Otitis media
- Headache
- Presyncope
- Asthma
- Epistaxis
- Hypersensitivity reactions
- Immunosuppression
- HPA axis effects

Mechanism of Action

- **Mometasone furoate** is a corticosteroid with potent anti-inflammatory activity
- Corticosteroids have been shown to exert effects on multiple cell types (eg, mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (eg, histamine, eicosanoids, leukotrienes, cytokines) involved in inflammation

Clinical Studies

- The Sinuva sinus implant was evaluated in 400 patients aged ≥18yrs with nasal polyps and history of ethmoid sinus surgery
  - **Study 1** was 6 months duration
  - **Study 2** was 3 months duration (efficacy based primarily on Study 2)

Clinical Studies

- **Study 2** was a randomized, controlled, single-blind, multicenter study (N=300) that assigned patients to either bilateral placement of Sinuva or placebo (sham) procedure
  - Implants were removed at Day 60 to allow blinded grading at Day 90
  - All patients were required to use mometasone furoate nasal spray once daily through Day 90

Clinical Studies

- **Co-primary efficacy endpoints** were:
  - Change from baseline to Day 30 in nasal obstruction/congestion score as determined by daily diary
  - Change from baseline to Day 90 in bilateral polyp grade as determined by video endoscopies reviewed by an independent panel

Clinical Studies

- The Sinuva group showed a statistically significant difference from baseline to Day 30 in **nasal obstruction/congestion score** vs the control group (-0.80 vs -0.56)
  - Treatment difference -0.23 (95% CI: -0.39, -0.06)

Clinical Studies

- The Sinuva group showed a statistically significant difference from baseline to Day 90 in **bilateral polyp grade** vs the control group (-0.56 vs -0.15)
  - Treatment difference -0.35 (95% CI: -0.60, -0.09)

Clinical Studies

- Change from baseline to Day 90 in the mean Percent Ethmoid Sinus Obstruction score also met statistical significance and supported the co-primary endpoints

- For more clinical data info, see full labeling

New Product Monograph

- For more information view the product monograph available at:

https://www.empr.com/sinuva/drug/34811/