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