## FREQUENTLY ASKED QUESTIONS

# General information about SINUVA (mometasone furoate) sinus implant

## What is SINUVA?



SINUVA is an FDA-approved stent for the treatment of nasal polyps that can be placed in office. SINUVA has a 2-in-1 design that expands in the sinus and delivers anti-inflammatory medicine directly to where it's needed.

## Is the placement of SINUVA a surgical procedure?



No. SINUVA is not a surgery. Your doctor will place SINUVA during an in-office visit, using local anesthesia.

### How big is SINUVA?



SINUVA is slightly larger than the head of a cotton swab (7.5 mm) when compressed in preparation for the procedure.

### Who can use SINUVA?

SINUVA is used in adults with nasal polyps who have had ethmoid sinus surgery.

# Does SINUVA provide relief from nasal polyp symptoms?

In a clinical trial, SINUVA was proven to shrink nasal polyps and reduce symptoms of nasal obstruction and congestion for up to 90 days. Patients treated with SINUVA had reduced sinus obstruction and reported an improved impaired sense of smell compared to patients treated with daily steroid nasal spray.

### How does SINUVA work to reduce nasal polyps?

SINUVA is placed in your ethmoid sinus cavity next to the nasal polyps, delivering a steroid directly where it is needed. This enables effective anti-inflammatory action and low distribution throughout the body. SINUVA has been shown to be effective in reducing nasal obstruction and congestion and shrinking polyps.

## What happens to the stent while it's in my body?

SINUVA is designed to release medicine over the course of 90 days. It will gradually soften over time while it's in your sinus.

# SINUVA placement and removal

## How is SINUVA placed in my sinus cavity?



Your doctor will place SINUVA during an in-office visit, using local anesthesia. After numbing your nose, your doctor will introduce SINUVA into your nostril on the end of a Delivery System, and place it within your sinus.

## How do I prepare for SINUVA placement?

You don't need to do anything to prepare for SINUVA placement, but your doctor may provide you with specific instructions prior to the procedure. Talk to your doctor if you have questions.

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## How long does the SINUVA procedure take?



The whole procedure typically takes less than an hour, usually 30 to 40 minutes. This includes 10 to 30 minutes to numb the nose and about 5 to 10 minutes to place SINUVA.

## Will placement of SINUVA hurt?

Your doctor will use topical and/or local anesthetic medication to numb your sinuses during placement of SINUVA. Following placement, most patients (over 85%) felt no pain to mild pain/pressure in clinical trials.

## Will I feel SINUVA in my sinus?

In clinical trials, most patients (over 85%) felt no pain to mild pain/pressure following placement.

## What risks are associated with the placement of SINUVA?

Insertion of SINUVA has risks similar to other endoscopic sinus procedures. It may also cause local side effects such as nosebleed and injury to nerves or blood vessels in the nose/sinus, serious allergic reactions, weakened immune system, and adrenal insufficiency. The most common side effects of SINUVA in clinical studies were bronchitis, cold symptoms, middle ear infections, headache, lightheadedness or dizziness, asthma, and nosebleeds. During post-approval use of SINUVA, implant migration, lack of efficacy, nasal pain, headache, and nosebleeds, were also identified as side effects.

## Can SINUVA be ejected from my nose on its own?

One of the benefits of treatment with SINUVA is that SINUVA may shrink your nasal polyps. As your polyps decrease in size, SINUVA may be ejected out of your nose on its own or when you sneeze or blow your nose.

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### Will SINUVA be removed by a doctor?



Yes. SINUVA is designed to deliver the drug over the course of 90 days. It will be removed at that time unless your doctor decides to remove it earlier.

# Dosing and administration

### How long will the medicine in SINUVA work?



SINUVA is designed to deliver anti-inflammatory medicine over the course of 90 days. Based on preclinical animal studies, about 80% of the anti-inflammatory medicine will be supplied in the first 60 days after placement.

### Does SINUVA require routine administration?



No. SINUVA will be placed in your ethmoid sinus and does not have to be administered routinely. After placement of SINUVA, your doctor will let you know how often he/she will check your progress. Your doctor will remove SINUVA 90 days after placement or sooner.

### How long will SINUVA stay in my sinus?



SINUVA is designed to deliver medicine over the course of 90 days. At that time, your doctor will remove it unless he or she has decided to remove it earlier. As the stent softens and polyps decrease, it may be ejected from the nose on its own or when you sneeze or blow your nose.

## Do I need to take other medications with SINUVA?



You should talk with your doctor to determine what treatments you may need following the SINUVA procedure.

# obtaining SINUVA and insurance coverage

## How do I get SINUVA?



Depending upon your insurance, you may get SINUVA either from a specialty pharmacy or from your doctor. In either case, SINUVA will be delivered directly to your doctor.

If you get SINUVA from a specialty pharmacy, you will receive phone calls from either Gentry Health Services, AllianceRx Walgreens Prime, or Orsini Specialty Pharmacy to collect your co-pay directly. It's very important that you answer all calls or messages from a specialty pharmacy or your doctor can't proceed.

If you get SINUVA from your doctor, your doctor will collect your payment at the time of the procedure.

## Is SINUVA covered by insurance?

Many insurance policies cover SINUVA, including certain types of Medicare. Be sure to check with your insurance provider to ensure that your treatment plan is covered under their policy.

# contact information

## Who should I contact if I still have questions?

Please speak with your doctor regarding questions about SINUVA.



#### **INDICATION**

SINUVA Sinus Implant is a prescription steroid-releasing (mometasone furoate) implant indicated for the treatment of nasal polyps in patients 18 years or older who have had ethmoid sinus surgery.

### **IMPORTANT SAFETY INFORMATION**

#### Who should not use SINUVA?

Do not use SINUVA if you are allergic to mometasone furoate or any ingredients of the implant.

#### What should I tell my doctor before receiving SINUVA?

Before you receive SINUVA, tell your doctor about all medical conditions you have including nasal/ sinus problems (such as nasal ulcers or trauma), eye problems (such as glaucoma or cataracts), or any untreated fungal, bacterial, or viral infections.

#### What are the possible side effects of SINUVA?

#### Serious side effects of SINUVA can include:

- Local reactions including nosebleed and injury to nerves or blood vessels in the nose/sinus.
- Serious allergic reactions have happened in patients using mometasone furoate including rash, itching or swelling of the lips, face, tongue, and throat, and breathing problems. Call your doctor right away if you have any of these reactions.
- Weakened immune system that may increase your risk of infections. Avoid contact with people who have contagious diseases such as chickenpox or measles. Call your doctor right away if you have been near someone with chickenpox or measles.
- Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones and can cause tiredness, weakness, nausea and vomiting and low blood pressure. Talk to your doctor if steroid effects such as Cushing Syndrome and adrenal suppression appear.

**The most common side effects** of SINUVA in clinical studies were bronchitis, cold symptoms, middle ear infections, headache, lightheadedness or dizziness, asthma, and nosebleeds. 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, and nosebleeds.

Tell your doctor if you have any side effects that bother you or don't go away.

Risks related with the insertion and removal of SINUVA are similar to other endoscopic sinus procedures.

SINUVA is made from materials designed to soften over time and may fall out of the nose on its own as polyps decrease or if you sneeze or blow your nose forcefully. The implant will be removed 90 days after placement or earlier at your doctor's discretion.

**Contact your doctor immediately** if you have any changes in vision, excessive nasal bleeding, symptoms of infection or symptoms suggesting that the implant has moved, such as irritation or a choking sensation in the back of the throat.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For important risk and use information, please see Full Prescribing Information for SINUVA at www.SINUVA.com/PI.



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