

SINUVA™ (mometasone furoate) sinus implant



SINUVA delivers anti-inflammatory medication directly to the sinuses to treat chronic rhinosinusitis with nasal polyps for adults who have had previous ethmoid sinus surgery.

FOLLOW YOUR DOCTOR'S INSTRUCTIONS AND TAKE NOTE OF THE FOLLOWING:



Regular daily saline irrigations can be helpful after placement of SINUVA.



SINUVA softens over time and may come out of your nose on its own or be removed at the physician's discretion.



Contact a physician immediately if you experience excessive bleeding, pain, or a choking sensation in the throat.



Visit www.SINUVA.com for more information and to sign up for updates.

Do not use SINUVA if you have a hypersensitivity to mometasone furoate or other ingredients in SINUVA. Your doctor should monitor the area around SINUVA for bleeding, irritation, infection, or perforation.

SEE BACK COVER FOR IMPORTANT SAFETY INFO

INDICATION

SINUVA™ Sinus Implant is a steroid-releasing 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

If you have a known hypersensitivity to the mometasone furoate drug or any of the ingredients in SINUVA, do not use SINUVA. Hypersensitivity reactions, including rash, itch, and swelling, have been reported with use of steroids. If steroid effects such as Cushing Syndrome and adrenal suppression appear, consult your healthcare professional.

SINUVA is made from bioabsorbable polymers designed to soften over time. As the implant softens and polyps decrease, the implant may be expelled out of the nose on its own or with actions such as sneezing or forceful nose blowing. The implant can be removed 90 days after placement or earlier at the physician's discretion. Repeat administration of SINUVA has not been studied.

As with other endoscopic sinus procedures, there are risks associated with the insertion or removal of SINUVA. SINUVA should be inserted by physicians trained in otolaryngology. Discuss risks related to insertion or removal of SINUVA with your healthcare professional.

Your healthcare professional will monitor the nasal tissue adjacent to the SINUVA Sinus Implant for any signs of bleeding, irritation, infection, or perforation. SINUVA should not be used in patients with nasal ulcers or trauma.

The most common adverse reactions observed in clinical studies were bronchitis, upper respiratory or middle ear infection, headache, lightheadedness, asthma, and nose bleed.

If you experience 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, immediately contact a healthcare professional.

Close monitoring is recommended if you have a change of vision or a history of increased intraocular pressure, glaucoma and/or cataracts.

You may report side effects to your physician or to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Intersect ENT at 1-866-531-6004.

RX Only. For important risk and use information about SINUVA, please see full Prescribing Information available at www.SINUVA.com.

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