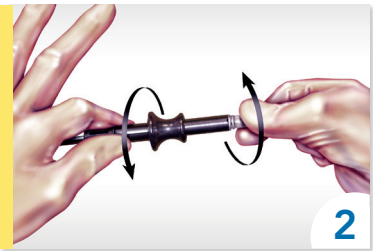
Arestin®
minocycline HCl 1mg
MICROSPHERES

Tips for Use

Before inserting the barrel cartridge into the handle, hold the handle mechanism slightly upwards (To prevent losing powder in case the cap is removed accidentally).

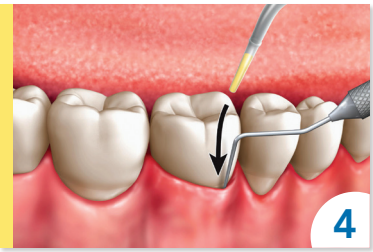


Insert the cartridge into the handle while exerting slight pressure. Twist until you align the notch on the cartridge with the groove on the handle and you feel and hear the cartridge "lock" into place.

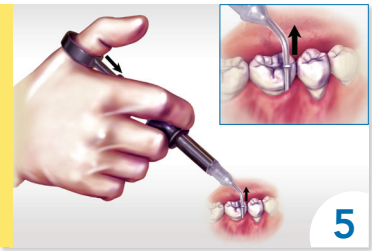
Clear the area to be treated of plaque and tartar buildup.

Remove the cap of the tip.

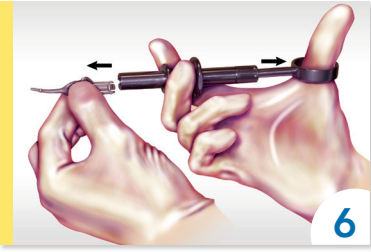
Place the cartridge tip into the periodontal pocket, **parallel to the long axis of the tooth. Be sure not to force the tip into the base of the pocket.**



In a "tight" pocket, a probe or plastic instrument may be gently inserted to retract the tissue before inserting the tip of the cartridge. Sometimes the cartridge tip can be more easily inserted subgingivally on an adjacent tooth surface and "walked" around the tooth.



Gently press the thumb ring to express the ARESTIN powder **while withdrawing the cartridge tip away from the base of the pocket.** If you feel any resistance during delivery, withdraw the device further.



Once delivery is complete, retract the thumb ring and remove the ARESTIN cartridge with your free hand. Appropriately discard the cartridge and sterilize the handle prior to reuse.

The cartridge tip was designed to be flexible to help reach anatomically challenging areas in the mouth. However, bending or flattening the tip may cause the cartridge to malfunction.

INDICATION

ARESTIN® (minocycline HCl) Microspheres, 1mg is indicated as an adjunct to scaling and root planing (SRP) procedures for reduction of pocket depth in patients with adult periodontitis. ARESTIN® may be used as part of a periodontal maintenance program, which includes good oral hygiene and SRP.

IMPORTANT SAFETY INFORMATION

- ARESTIN is contraindicated in any patient who has a known sensitivity to minocycline or tetracyclines. Hypersensitivity reactions and hypersensitivity syndrome that included, but were not limited to anaphylaxis, anaphylactoid reaction, angioneurotic edema, urticaria, rash, eosinophilia, and one or more of the following: hepatitis, pneumonitis, nephritis, myocarditis, and pericarditis may be present. Swelling of the face, pruritus, fever and lymphadenopathy have been reported with the use of ARESTIN. Some of these reactions were serious. Post-marketing cases of anaphylaxis and serious skin reactions such as Stevens Johnson syndrome and erythema multiforme have been reported with oral minocycline, as well as acute photosensitivity reactions.
- THE USE OF DRUGS OF THE TETRACYCLINE CLASS DURING TOOTH DEVELOPMENT MAY CAUSE PERMANENT DISCOLORATION OF THE TEETH, AND THEREFORE SHOULD NOT BE USED IN CHILDREN OR IN PREGNANT OR NURSING WOMEN.
- Tetracyclines, including oral minocycline, have been associated with development of autoimmune syndromes including a lupus-like syndrome manifested by arthralgia, myalgia, rash, and swelling. Sporadic cases of serum sickness-like reaction have presented shortly after oral minocycline use, manifested by fever, rash, arthralgia, lymphadenopathy and malaise. In symptomatic patients, diagnostic tests should be performed and ARESTIN treatment discontinued.
- The use of ARESTIN in an acutely abscessed periodontal pocket or for use in the regeneration of alveolar bone has not been studied.
- The safety and effectiveness of ARESTIN has not been established in immunocompromised patients or in those with coexistent oral candidiasis. Use with caution if there is a predisposition to oral candidiasis.
- In clinical trials, the most frequently reported nondental treatment-emergent adverse events were headache, infection, flu syndrome, and pain.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch Health US, LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the Important Safety Information above and Click Here for Full Prescribing Information.