

FOR PERIODONTAL USE IN DOGS ONLY.

Restoris™ piezoelectric dental gel is a veterinary medical device for use in dogs. The patented Restoris formulation has been shown to reduce periodontal pocket depth and decrease tooth mobility by stimulating alveolar bone formation. Restoris has also been shown to disrupt biofilm formation, thereby aiding in the reduction of plaque and calculus in the periodontal pockets where it is applied.

MECHANISM OF ACTION

In response to mechanical stimulation (e.g., walking, chewing, barking, etc.), piezoelectric particles in the patented Restoris formulation produce electrical microcurrents that stimulate bone-forming osteoblast cells. The same electrical microcurrents also aid in the disruption of biofilm cells.

EFFECTIVENESS

The mechanism of action of Restoris is supported by data generated in clinical studies.*

SAFETY & HANDLING

Avoid direct contact with the skin, eyes, and clothing. As with any dental procedure, surgical gloves should be worn for the application. Skin that has contacted Restoris should be washed with soap and water. If Restoris comes in contact with the eye, hold eye open and rinse eye slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes and continue rinsing eye thoroughly.

STORAGE

Restoris should be stored under refrigeration, 2°C-8°C (36°F-46°F) in its original unopened packaging protected from exposure to ambient light.

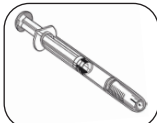
HOW SUPPLIED

Restoris is supplied in 3 individual light-proof packages, each containing one (1) pre-filled syringe and two (2) blunt, sterile 20-gauge cannulas.

INGREDIENTS

Methacrylated gelatin, barium titanate nanopowder, lithium phenyl-2,4,6-trimethylbenzoyl phosphonate, and phosphate buffered saline.

MATERIALS REQUIRED



Pre-filled syringe containing 0.5 mL of Restoris



Two (2) 20-gauge cannulas



Curing light (405 nm wavelength)



Surgical adhesive (Vetbond® or equivalent N-butyl cyanoacrylate product)



Protective glasses for use with 405 nm light

IMPORTANT

Restoris will begin to cure with prolonged exposure to ambient light. To avoid curing prior to application, keep Restoris in its light-proof packaging until you are ready to use the product.

INSTRUCTIONS FOR USE



Figure 1

PREPARATION

1. Ensure curing light has been plugged in and is fully charged.
2. Clean plaque and calculus from tooth, including the pocket. If open root planing is used, then close the flap prior to administering.
3. Before applying Restoris, warm by submerging capped syringe in lukewarm water (approximately 84°F-90°F). Warming should take approximately 1-2 minutes. Remove syringe cap and attach either bent or straight 20-gauge cannula to tip of syringe. Carefully press syringe plunger to confirm Restoris gel can move through cannula. If gel cannot move through cannula, continue warming until gel is able to pass through the cannula.
4. Dry the pocket to be treated, including stopping all bleeding through direct pressure, cautery, and/or use of compressed air.

APPLICATION

5. Gently insert the cannula 1-2 mm below the gingival margin of an affected tooth into pocket, taking care to keep it parallel to the tooth root. (See above, Figure 1)
6. Press the syringe slowly to fill the pocket to the top of the gingival margin with Restoris.
7. Withdraw the cannula and wipe away any excess gel prior to curing step.

DIRECTIONS TO PET OWNER POST PROCEDURE

- Pets should avoid physical exertion for the first few hours after application.
- Pet owners may reintroduce water and food to pet during the first 12 hours after procedure in compliance with usual directions from their veterinarian for post-anesthesia feeding.

ADVERSE REACTIONS

To report suspected adverse events, call 1-833-735-3672.

CUSTOMER SERVICE

For product support, call 1-833-735-3672.



Figure 2

CURING

8. Before curing, wear appropriate protective glasses and cover the patient's eyes.
9. Place curing light as close as possible to the gingival margin, angling the light parallel to the tooth root so that the light travels from the top to the bottom of the pocket to illuminate Restoris. Cure Restoris for one (1) minute. (See above, Figure 2)

SEALING

10. Cover the pocket with 1-2 drops of surgical adhesive.

FOR REPEAT APPLICATION

11. If syringe will be used to fill multiple pockets for a single patient, repeat step 2 if necessary, then repeat steps 3-10.

If a reduction in pocket depth and tooth mobility is not achieved with initial application, a second application of Restoris may be made 30 days after first application, repeating the application steps above.

- Only soft food should be given for the first 14 days after application.
- Don't allow treated dogs to chew bones, rawhide, doggy chews, or teeth cleaning products for 14 days or until your veterinarian says such chewing activities may resume.

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