



parkell S625 Predicta Bioactive Desensitizer Instructions

[Home](#) » [parkell](#) » parkell S625 Predicta Bioactive Desensitizer Instructions 

Contents


















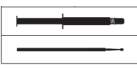

- 1 [parkell S625 Predicta Bioactive Desensitizer](#)
- 2 EXPLANATION OF SYMBOLS USED
- 3 PRODUCT DESCRIPTION
- 4 INDICATIONS
- 5 BASIC SAFETY INSTRUCTIONS
- 6 WARRANTY
- 7 Documents / Resources
 - 7.1 References
- 8 Related Posts

parkell®

parkell S625 Predicta Bioactive Desensitizer



EXPLANATION OF SYMBOLS USED

	• Professional use only
	• Follow instructions for use
	• Temperature limit
	• Keep away from sunlight
	• Use-by date (expiration)
	• Batch code
	• Catalog/stock number
	• Unique Device Identifier
	• Medical Device
	• Package contents
	• Do not use if the package is damaged
	• Manufacturer
	• Single use only
	• Dispensing Tips
	• Mixing Dish
	• Translation
	 • 3 ml Syringe / Gel  • Applicator Brushes

PRODUCT DESCRIPTION

Predicta® Bioactive Desensitizer Gel is used for the treatment of dental hypersensitivity. Predicta features next-generation chemistry, which renders the product highly biocompatible as well as bioactive. Predicta Bioactive Desensitizer releases calcium and phosphate ions and thereby stimulates rapid hydroxyapatite crystal formation on the surface of treated dentin and in dentinal tubules. This results in the formation of a solid mineral layer atop treated dentin, as well as solid mineral plugs which extend from the mineral layer and which occlude dentinal tubules. The end result for patients is robust pain relief. This product is intended for use by a professional Dental clinician. Predicta Desensitizer is in the form of an easy-to-use gel. Therefore, no mixing or other steps are required before use (unlike other conventional desensitizers). It is packaged in hand-dispensable syringes and is applied to treatment areas using simple applicator brushes. It will not provide permanent tooth desensitization; may need re-application.

INDICATIONS

Predicta Bioactive Desensitizer Gel is indicated for the reduction of tooth hypersensitivity by the following treatments:

- treatment of dentin exposed by toothbrush abrasion, gingival recession, periodontal disease and/or acid erosion.
- treatment of dentin after mechanical tooth cleaning, scaling, and/or root planing.
- treatment of tooth hypersensitivity associated with bleaching; and
- treatment of prepared dentin for fillings, and/or prosthetic restorations.

CONTRAINDICATIONS

- Patients with a history of sensitivity to this product or nano-hydroxyapatite-based products.

BASIC SAFETY INSTRUCTIONS

- Keep out of reach of children.
- For dental use only.
- Contact between Predicta Bioactive Desensitizer Gel and sensitive or inflamed soft tissues (mucosa, eyes, nose, and the like) may cause irritation, dermatitis, and/or inflammatory reactions. If this occurs, discontinue use, flush area with copious amounts of water, and consult a physician.
- Use a rubber dam or other suitable isolation method to prevent contamination of surfaces.
- Prior application of some medicaments (desensitizers, varnishes, liners, etc.) or products with eugenol is not recommended, as they may reduce the efficacy of this product.
- Avoid contamination of product. Do not return dispensed components to their original container. Dispose of leftover material properly. Do not reuse applicator brushes to avoid cross-contamination.
- Please review the Safety Data Sheet (SDS) at www.parkell.com before use.

CLINICAL PROCEDURE FOR TOOTH DESENSITIZATION

1. Using appropriate diagnostic tests and professional clinical judgment, confirm that the patient's cold sensitivity is related to exposed dentin from cervical root exposure. Rule out dental caries, tooth fractures, occlusal trauma, endodontic pathology, and any other possible dental or medical problems.
2. Explain to the patient what you're proposing to do to treat their problem and obtain informed consent.
3. To reduce the plaque load, have the patient rinse out their mouth with mouthwash diluted with warm water. Remove any plaque or debris from the tooth surface with gentle hand instrumentation. Avoid excessive force or rotary polishing, which may make the pain worse. Rinse the root surface with warm water and gently dry with absorbent cotton to avoid cold sensitivity from compressed air or vacuum suction. Use local anesthesia only if necessary, as it will make post-op testing impossible at this visit.
4. Isolate the sensitive tooth to be treated with appropriate lip and tongue retraction devices.
5. Remove the cap from the Predicta Bioactive Desensitizer gel syringe and set it aside. Affix a tip to the syringe and extrude a small amount into the plastic mixing well.
6. Saturate a cotton pledget or precision applicator with the material and massage it into the tooth for 30-40 secs. The patient may feel a slight "rush", but it shouldn't hurt. Using a rubbing motion will liquefy the gel and allow it to penetrate the surface. If the applicator dries out, re-wet it with more gel.
7. Wipe most of the gel off with a cotton roll and gently test the tooth by having the patient rinse with cool tap water. Repeat the procedure (if necessary), until the cold sensitivity is gone.
8. If the patient has not been anesthetized, and the tooth is still sensitive, repeat the application of Predicta Bioactive Desensitizer gel. If sensitivity persists after a second application, consider other possible sources for the pain (e.g. high occlusion, pulpal pathology, extreme root erosion, etc.). If the patient has been anesthetized, test at the next visit.
9. Issue appropriate post-op instructions and dismiss the patient.
10. Discard the applicator tip and seal the syringe with the original product cap.
11. Disinfect the syringe as per the disinfection instructions below.

TIPS FOR DENTAL PRACTITIONERS:

The following information should help dental practitioners reduce the risk of cross-contamination between patients when using multiple-use dental dispensers: apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient; use new, uncontaminated gloves when handling multiple-use dental dispensers; utilize dental assistants to dispense material for the dentist; avoid contact of the reusable parts (e.g., the body of the multiple-use dental dispenser) with the patient's mouth; do not reuse the multiple-use dental dispenser if it becomes contaminated; do not reprocess a contaminated multiple-use dental dispenser by using chemical wipes or disinfectants; do not immerse multiple-use dental dispensers in a high level chemical disinfectant, as this may damage the dispenser and the material contained in the device; do not sterilize multiple-use dental dispensers, as this may damage the material contained in the device.

STORAGE AND SHELF LIFE

Store in a dry place at 2 – 25° C (36 – 77° F). Store tightly sealed, away from direct light. Do not freeze, it may affect the clinical performance of the product. Use at room temperature. Do not store near eugenol-containing materials. Do not use after the expiration date.

DISPOSAL OF MATERIAL

The material can be disposed of in general refuse. All cartridges and needle tips may be disposed of in normal refuse.

EVENTS

Reportable incidences should be reported to Parkell and the competent authority in which the user and or patient is established.


WARRANTY

For full Warranty and Terms of Use information, please visit our website at www.parkell.com. Parkell's Quality System is certified to ISO 13485.

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Documents / Resources

	parkell S625 Predicta Bioactive Desensitizer [pdf] Instructions S625, Predicta Bioactive Desensitizer, Bioactive Desensitizer, Predicta Desensitizer, Desensitizer
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References

- [P Dental Tools, Devices and Materials](#)
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