



# BRIX3000®

La Nueva Tecnología Enzimática para Remoción  
Atraumática de Caries

## **BRIX 3000® PAPAINE 30000 U / mg 10% EXCIPIENT C.S.**

**1- DIRECTIONS FOR USE** Brix3000® is a gel suitable for the atraumatic removal of carious lesions and should be used by a professional dentist.

**2- COMPONENTS** Brix3000® is a gel composed of papain 30,000 U / mg 10%. Papain is an endoprotein similar to human pepsin, (present in gastric juices) which has bactericidal, bacteriostatic and anti-inflammatory activity.

### **3. INFORMATION FOR PROFESSIONALS INVOLVED**

3.1 **STERILIZATION** Non-sterile product. It does not need to be sterilized.

3.2 **CHEMICAL COMPOSITION** Each 100 ml topical gel contains: Papain 30,000 U / mg 10 g, Excipients (Propylene Glycol, Citric Pectin, Triethanolamine, Sorbitan Monolaurate, Disodium Phosphate, Monopotasic Phosphate, Toluidine Blue, Distilled Water q.s. 100 ml).

3.3 **PRESENTATION OF Brix3000®** Tubes of 3.0 ml multidose. Non-reusable doses. Its secondary packaging is made in tamper-evident cartons. They are packed in cartons containing 100 units.

3.4 **INDICACION** Brix3000® is used to perform the atraumatic removal of carious lesions.

3.5 **MECHANISM OF ACTION** It acts exclusively on necrotic dental tissue, since it does not possess the  $\alpha$ 1-antitrypsin plasma antiprotease, which would prevent proteolytic action in healthy tissues. For this reason, a softening of the necrotic tissue occurs, resulting in debriding the partially degraded collagen fibers, preserving the healthy tissue because it is not demineralized nor has collagen fibers exposed.

3.6 **CONTRAINDICATIONS** Parts presenting painful symptomatology of any kind. Fistulas. Known hypersensitivity to any of the components.

3.7 **PRECAUTIONS** Do not expose the product directly to the sun or store inside the container. Do not use if the packaging is damaged or the safety seal has been tampered with. If present in multidose container, cover well after each use. Do not use after its expiration date. Keep out of the reach of children. Use non-edged reamer. Eye protection is recommended for professionals, assistants and patients.

3.8 **WARNINGS** Only to be handled by dental professionals. The empty knob is not reusable.

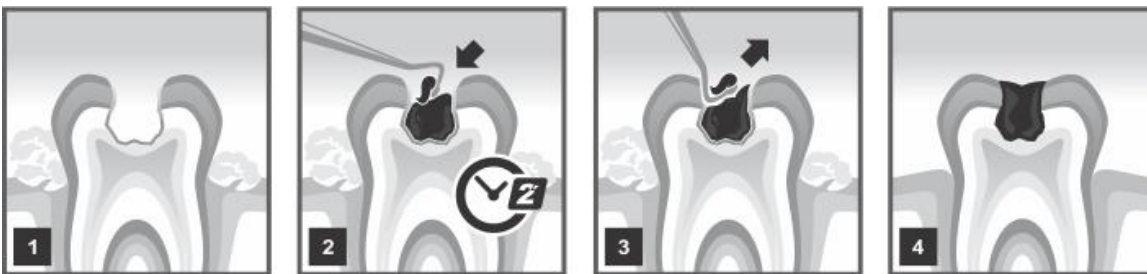
3.9 **POSSIBLE SIDE EFFECTS** There are no known side effects.

**4. SPECIAL CARE (INFORMATION FOR THE PATIENT)** It is advised not to eat or drink for 30 minutes after the end of treatment, not for the medical product, but for the drying time of the sealing material. Treatment with Brix3000® replaces the use of rotary instruments (turbine), so you will not feel pain or stress and will not need the use of anesthetics or analgesics. The carious tissue is separated by a technique of manual removal so that Brix3000® is presented as an alternative of greater comfort for the patient of all the ages.

**5. PACKAGING** Brix3000® is packed in multi-dose tubes. Each tube yields 15/20 doses per ml. The tubes are identified and labeled with data required by the ANMAT. Its secondary packaging is made in inviolable polypropylene carton boxes. These containers are packed in cartons containing and 100 units.

## 6. TECHNICAL FOR THE PROFESSIONAL

Pre-preparation: If necessary, extend the cavity with hand or rotary instruments if available until cavity is expelled. In wide lesions, place directly. Relative insulation with cotton rolls. Apply Brix3000® to the cavity allowing 2 minutes to act. Remove the material with non-sharp spoons, with pendulum movements and without pressure. Repeat the operation until the presence of healthy dentin. Corroborate the presence of healthy dentin with the scanner and caries detector. If necessary, make a pulp coating and immediately place a sealing material.



## INSTRUCTIONS FOR USE

- 1- Relative insulation with cotton rolls.
- 2- Apply Brix3000® with spoon without edge on the cavity allowing to act 2 minutes.
- 3- Remove the material with spoonless dies, with pendulum movements and without pressure. · If necessary, repeat the procedure until obtaining healthy dentin. · Corroborate the presence of healthy dentine with the scanner or/ and caries detector.
- 4- If necessary, make a pulp coating. Immediately apply sealant. An antiseptic mouthwash (such as chlorhexidine) is recommended at the end of treatment with Brix3000®.

Brix 3000 Enzyme Gel Validity: **48 Months**

CONDITIONS OF STORAGE Store between 4 and 36 ° C - Avoid exposure to light. - Avoid blows.

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