



# C-Root EDTA Gel

C-Root Dental Medical Devices Co., LTD.

WARNING: US Federal Law

restricts this device to sale by or

on the order of a dentist professional

For Dental Use Only

**PRODUCT TRADE NAME**

- C-Root EDTA Gel

**SPECIFICATIONS**

- Preloaded Syringe: 0.2g; 0.5g; 2.0g; 3.0g; 6.0g; 10g

**PRODUCT DESCRIPTION**

- C-Root EDTA Gel softens the root canal wall by decalcifying the dentin, which facilitates the expansion of root canal files and preparation for root canals, shortens the time of mechanical preparation, and prevents the breakage and loss of instruments. Meanwhile, the Gel has a slight foaming effect, which would rinse the debris off the root canal during the preparation of instruments, avoiding the deposition of debris and the blockage of the root canal.

**INDICATIONS**

- To assist with instrumentation and debridement during endodontic treatment  
EDTA-2Na (w/w) : 17%-22%  
CARBAMIDE PEROXIDE (w/w) 5%-12%

**CONTRAINDICATIONS**

- Do not use EDTA in patients suffering systemic disease with no medical controls or in pathogenic status;
- Do not use EDTA in impacted teeth with apical tressis shown by X-Ray film;
- Do not use EDTA in patients with a known allergy to any of the product's ingredients. An allergic reaction may require re-treatment.

**DIRECTIONS FOR USE:**

For Root Canal Cleaning and Shaping

1. A dental dam is placed upon the area of the procedure to isolate the C-Root EDTA Gel away from oral mucosa, and other similar tissues;
2. Install the applicator tip on syringe, screw it tightly;
3. Apply EDTA at the entrance of canal with syringe, and smear proper amount of EDTA on root canal file, then fill the canal slightly. Afterwards, start preparation for Root Canal Treatment instantly;

4. Reapply EDTA as necessary till canal is enlarged to the desired size;
5. Rinse canal thoroughly with Sodium Hypochlorite Solution with concentration not more than 1%;
6. EDTA can be repeatedly used, no single use. After use, remove the applicator tip, and re-cap syringe promptly and tightly to keep it sealed. Reuse of Applicator tip is prohibited.
7. In clinical use, EDTA can be co-used with dental douche as necessary.

**STORAGE AND HANDLING**

- Store below 26°C.
- Shelf life of unopened product: 2 years from date of manufacture.

**WARNING:**

1. For use by dental professionals only;
2. Reuse of Applicator tip is prohibited;
3. If contact with eyes, skin, mucous membranes, etc, rinse with plenty of water;
4. EDTA wastes shall be disposed as Chemicals acc. to Chemical Waste Disposal Requirements;
5. A dental dam is placed upon the area of the procedure to isolate the C-Root EDTA Gel away from oral mucosa, and other similar tissues;
6. Do not cross through the root apical.

**REPORTING OF SERIOUS INCIDENTS**

- Any serious incidents involving the device should be reported to the manufacturer and the Competent Authority of the Member State in which the incident occurred, or other appropriate regulatory body. Reports of serious incidents should be sent to: info@crootmed.com

**KEY TO SYMBOLS**

	Manufacturer
	Date of manufacturer
	Use-by date
	Batch code
	Catalogue number
	Do not use if package is damaged
	<26°C
	Medical device
	UDI
	Consult instructions for use
	Caution
	Rx only
	Keep away from sunlight



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