

# Fluor Protector

## Instructions for Use

Version: 01  
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U.S. Federal Law restricts this device to sale by or on the order of a dental professional. Prior to use the product, please read the instruction carefully.

### 1. Indications for Use

For the prevention of recurrent caries, caries development, decalcification around orthodontic appliances, pit and fissure (occlusal) caries.

### 2. Main Ingredient

This product mainly consists sodium fluoride, ethanol, resin, beeswax, shellac, sweetener and food flavor.

### 3. Content

The content of sodium fluoride is 5% equivalent to 2.26% fluoride.

### 4. Specification

10g, 5g, 0.5g, 0.4g, 0.3g, 0.2g.

### 5. Method of operation

- (1) Teeth cleaning: The teeth should be cleaned before using the product, especially at the sites most susceptible to carries.
- (2) Teeth Drying: Dry the teeth surface by air syringe or cotton balls.
- (3) Product applying: Squeeze out appropriate amount of product (for a single-use pack, just remove the sealing film), applied a thin layer on teeth surface by a miniature dental brush, probe or cotton swab.
- (4) After treatment: Do not brush teeth, chew food, and do not drink hot drinks or use alcoholic products (drinks, mouthwash, etc.) for 4 hours. The product can be removed by brushing and rinsing after 4 hours.

### 6. Dosage and Frequency

- (1) Dosage for single treatment: Deciduous dentition  $\leq 0.25\text{g}$  (5.65 mg fluoride)  
Mixed dentition  $\leq 0.4\text{g}$  (9.04 mg fluoride)  
Permanent dentition  $\leq 0.75\text{g}$  (16.95 mg fluoride)
- (2) Frequency: According to the dentist's recommendation, the treatment can be repeated every 3-6 months.

### 7. Precautions

- (1) This product should be used by a dentist within a safe dosage range.
- (2) This product contains ethanol.
- (3) After using, cleaning up excess products around the aluminum tube outlet and tighten the cap in time.
- (4) Do not use other fluoride preparations while using this product.
- (5) Avoid use during pregnancy and lactation.
- (6) Keep out of the reach of children.
- (7) Irritation, avoid contact with Eyes.

(8) Notification of any serious incident any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in your country.

### 8. Side effects

- (1) In sensitive patients, oral mucosa swelling, ulcerative gingivitis or stomatitis may occur;
- (2) In rare cases, asthma attacks may occur in patients who have bronchial asthma;
- (3) In patients with gastric sensitivity, retching or emesis may occur after a high-dose use;
- (4) In case of overdose, fluoride can cause an acute toxic reaction resulting in the hypocalcaemia.

### 9. Contraindications

- (1) Ulcerative gingivitis, stomatitis, bronchial asthma.
- (2) Hypersensitivity to colophony and/or any other constituents.

### 10. Shelf life

3 years for unopened product.

For 10g and 5g aluminum tube: after opening, use within 3 months.

For 0.5g, 0.4g, 0.3g, and 0.2g plastic package: single-use.














### 11. Storage condition


5- 25 °C dry environment.

### 12. Accessories

Brush, container, measuring card, extruder.

### 13. Symbols for use in the labeling

-  —Use-by date       —Batch code       — Date of manufacture
-  —Keep away from sunlight
-  —Do not re-use       —Temperature limit       —Caution       — Manufacturer
-  —Consult instructions for use       —Country of manufacture       —Medical Device
-  —Unique device identifier
-  —Caution: U.S.Federal Law restricts this device to sale by or on the order of a dentist or professionals.

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