

# FLUOROTOP APF

## Topical Fluoride Acidulated Phosphate

### Fluoride 1.23% Fluoride ion



**Product description :** A topical APF anticavity preparation for dental use containing 1.23 % fluoride ion from 2.72% sodium fluoride. Fluorotop APF gel is an economical and quick application fluoride treatment. Optimized PH for a quick complete treatment. The improved thixotropic properties ensure closer adherence to enamel and interproximal areas. It contains xylitol-a proven anti-carries ingredient. The gel is offered in flavours for patient satisfaction and has no bitter taste.

**Available in :** Strawberry, Vanilla.

**Composition :** Sodium Fluoride, Phosphoric Acid, Xylitol, Thickening Agents, Flavouring Agents, Preservatives & Colouring Agents.

**Intended Purpose / Intended Use :** It is intended to be used as a topical gel for fluoride treatment.

**Indications for Use :** For the topical application of fluoride to aid in the protection against dental caries.

**Instructions for Use :**

1. Complete prophylaxis and remove excess fluid from tooth surfaces.
2. Usual dosage is approximately 4-8 grams of Fluorotop APF per dual arch foam tray. Shake well before use.
3. Fill applicator tray with the required amount of gel.
4. Insert the tray into patient's mouth and instruct to bite down gently for 4 minutes.
5. After completion of the treatment time, remove tray and ask patient to expectorate residual gel.
6. For optimal benefits, instruct patient not to rinse, eat or drink for 30 minutes.
7. Repeat treatment at least once or twice a year. For patients with rampant or active caries, repeat treatment once or twice every six months. If the gel becomes frozen, warm to room temperature.
8. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

**Warnings :** Instruct the patient not to swallow. If dosage or less than 100mg is ingested, contact physician. Keep out of reach of children.

**Precautions :**

- ◆ Not intended for systemic use/treatment. Do not swallow.
- ◆ Not intended use on patients with an allergy to fluoride.
- ◆ Fluorotop APF contains artificial colour and flavours which may cause allergies in susceptible individuals. Confirm that no known allergies exist.
- ◆ Special care should be taken to avoid swallowing of the gel, especially in children under 6 years of age.
- ◆ Contact with breached/ulcerated oral tissue may produce discomfort.
- ◆ In case of swallowing of the gel, advise the patient to have calcium (milk) and contact your physician or specialised centre.

**Contraindication :**

1. Avoid usage in children in whom the swallowing reflex is not fully developed.
2. Sensitivity to fluoride.
3. Avoid application on porcelain and composite restoration.
4. In rare cases, the product may cause sensitivity to some persons. If such reactions are experienced, discontinue the use of product and refer to a physician.

**FLUOROTOP APF** is free of gluten, soy, milk, egg, peanut and tree nut products.

**Storage Conditions :** Store at temperature between 10°C(50°F) to 24°C(75°F). Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stored in a cool dry place. Avoid freezing.

**Shelf life :** 2 years from the date of manufacturing.

**Presentation :**

Ref. : 80004

Net content : 200g Plastic Bottle.

Ref. : 80005

Net content : 500g Plastic Bottle.

**Disposal conditions :** To be disposed off based on the prevailing rules of the country in which it is used.

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**UDI** Symbol for "UNIQUE DEVICE IDENTIFIER"

- LOT** Symbol for "BATCH CODE"    Symbol for "USE-BY DATE"    Symbol for "NON STERILE"    Symbol for "KEEP DRY"
- Symbol for "CAUTION"    Symbol for "CONSULT INSTRUCTION FOR USE"    **REF** Symbol for "CATALOGUE NUMBER"
- EC/REP** Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"
- Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"    Symbol for "KEEP OUT OF THE REACH OF CHILDREN"    Symbol for "MANUFACTURER"
- Symbol for "TEMPERATURE LIMIT"    Symbol for "KEEP AWAY FROM SUNLIGHT"    **MD** Symbol for "MEDICAL DEVICE"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.