IFU Size: 161 H x 104 W

SPECTRA PROPHYLAXIS PASTE



Product Description : Spectra Prophylaxis Paste is a cleaning and polishing paste with a unique combination of abrasive materials like zirconium silicate and pumice powder for cleaning and polishing during dental procedures. It contains sodium fluoride at a concentration of 1% fluoride ion for post treatment comfort to the patient. Spectra Prophylaxis paste is produced in a variety of fruit flavors for pleasant feeling during the treatment procedure.

Composition: Zirconium Silicate, Pumice Powder, Glycerine, Fillers, Sodium Fluoride, Pigments and flavoring matter.

Intended Purpose / Intended Use: It is intended to be used as cleaning and polishing paste.

Indications for Use: Prophylaxis Paste, is indicated for use to effectively clean and polish tooth structure with minimal abrasion.

Instructions for Use:

- 1. Dispense Prophylaxis Paste into dappen dish or other suitable container. A saliva ejector may be helpful during the actual prophylaxis.
- 2. Fill rubber prophylaxis cup with paste. Before starting hand piece, carry paste to the field of operation and deposit a small amount on each tooth surface. It is necessary that fresh paste is provided for each surface in order to obtain maximum cleaning effectiveness.
- 3. Run rubber cup at SLOW SPEED over each tooth surface for approximately 10 seconds. Make sure that the edge of the cup goes below the free margin of the gingival into the gingival sulcus. Continue procedure until all exposed surfaces of the teeth have been thoroughly cleaned and polished.
- 4. A rubber cup or soft bristle brush may be used on occlusal surfaces.
- 5. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Warnings: Prophylaxis Paste may cause eye irritation upon contact. If contact with eyes occurs, immediately flush eyes with copious amount of water for 15 minutes. Seek medical attention if irritation or discomfort persists.

Precautions:

- 1. All tooth surfaces should be thoroughly scaled to remove calculus.
- 2. Necessary examination and radiographs should be taken prior to prophylaxis with Prophylaxis Paste.
- 3. During use, wear protective glasses and gloves.

Contraindication: Prophylaxis Paste is contraindicated in patients with a known allergy to any of the components.

Storage Conditions: Store at temperature between $10^{\circ}C(50^{\circ}F)$ to $24^{\circ}C(75^{\circ}F)$. Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stored in a cool dry place.

Shelf Life: 3 years from the date of Manufacturing.

Presentation:

340g Plastic Jar, Fresh Mint (Ref: 50005-1)/200g Plastic Jar, Fresh Mint (Ref: 50005)/75g Plastic Jar, Fresh Mint (Ref: 50006)/Fresh Fruit (Ref: 50007)/Fresh Strawberry (Ref: 50008)/Fresh Orange (Ref: 50009)/Fresh Pineapple (Ref: 50010).

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"

ECREP 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" MDD 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.