

**SPARKLEFRESH FLUORIDE- sodium monofluorophosphate paste, dentifrice**  
**IIMED MEDICAL MEXICANA S DE RL DE CV**

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**IIMED SparkleFresh Fluoride Toothpaste**

**Active ingredient**

Sodium Monofluorophosphate 0.76%

**Purpose**

Anticavity toothpaste

**Use**

Aids in the prevention of dental cavities

**Warnings**

**Keep out of reach of children if**

If you accidentally swallow more than used for brushing, seek medical help or contact a Poison Center immediately.

**Directions**

- adults and children 2 yrs. and older: brush teeth thoroughly after meals or at least twice a day or as directed by a dentist or physician
- instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision
- children under 2 years of age: consult a dentist or physician

**Inactive ingredients**

calcium carbonate, treated water, sorbitol, precipitated silica, sodium lauryl sulfate, flavor, sodium carboxymethyl cellulose, sodium silicate, tetrasodium pyrophosphate, sodium saccharin, methylparaben, titanium dioxide, polyethylene glycol 400, propylparaben

**Label**

**SparkleFresh**  
Fluoride Toothpaste

REF: NONTP275I Net Wt 2.75 oz (78 g)

|                                                                                                                                                                                                                                                                                                                                                                                                                 |                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| <b>Drug Facts</b>                                                                                                                                                                                                                                                                                                                                                                                               |                                         |
| <b>Active Ingredient</b><br>Sodium Monofluorophosphate 0.76%                                                                                                                                                                                                                                                                                                                                                    | <b>Purpose</b><br>Anticavity toothpaste |
| <b>Use</b> Aids in the prevention of dental cavities                                                                                                                                                                                                                                                                                                                                                            |                                         |
| <b>Warnings</b><br>Keep out of the reach of children under 6 yrs. of age. If you accidentally swallow more than used for brushing, seek medical help or contact a Poison Control Center immediately.                                                                                                                                                                                                            |                                         |
| <b>Directions</b> • adults and children 2 yrs. and older: brush teeth thoroughly after meals or at least twice a day or as directed by a dentist or physician. • instruct children under 6 yrs. of age in good brushing and rinsing habits (to minimize swallowing) • supervise children as necessary until capable of using without supervision • children under 2 yrs. of age: Consult a dentist or physician |                                         |
| <b>Inactive Ingredients:</b> calcium carbonate, treated water, sorbitol, precipitated silica, sodium lauryl sulfate, flavor, sodium carboxymethyl cellulose, sodium silicate, tetrasodium pyrophosphate, sodium saccharin, methylparaben, titanium dioxide, polyethylene glycol 400, propylparaben                                                                                                              |                                         |

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# SPARKLEFRESH FLUORIDE

sodium monofluorophosphate paste, dentifrice

## Product Information

|                                |                |                           |                              |
|--------------------------------|----------------|---------------------------|------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:83062-083(NDC:53329-083) |
| <b>Route of Administration</b> | DENTAL         |                           |                              |

## Active Ingredient/Active Moiety

| Ingredient Name                                                                       | Basis of Strength | Strength       |
|---------------------------------------------------------------------------------------|-------------------|----------------|
| <b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION      | 1 mg<br>in 1 g |

## Inactive Ingredients

| Ingredient Name                                         | Strength |
|---------------------------------------------------------|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)                         |          |
| <b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311) |          |
| <b>SORBITOL</b> (UNII: 506T60A25R)                      |          |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)         |          |
| <b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)       |          |
| <b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)          |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)              |          |
| <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)                 |          |
| <b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)             |          |
| <b>SODIUM SILICATE</b> (UNII: IJF18F77L3)               |          |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)                 |          |
| <b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)              |          |

**SILICON DIOXIDE** (UNII: ETJ7Z6XBU4)

### Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | white | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   | MINT  | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

### Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|-----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:83062-083-93 | 24 g in 1 PACKET; Type 0: Not a Combination Product | 10/06/2023           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| OTC Monograph Drug | M022                                     | 10/06/2023           |                    |

**Labeler** - IIMED MEDICAL MEXICANA S DE RL DE CV (812894376)

**Registrant** - Team Technologies (192339703)

### Establishment

| Name                                 | Address | ID/FEI    | Business Operations                    |
|--------------------------------------|---------|-----------|----------------------------------------|
| IIMED MEDICAL MEXICANA S DE RL DE CV |         | 812894376 | relabel(83062-083) , repack(83062-083) |

Revised: 10/2023

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