

**HEB HEBUDDY- sodium fluoride paste, dentifrice**  
**HEB**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Drug Facts**

**Active ingredient**

Sodium Fluoride 0.24% .....Purpose: Anticavity

**Uses**

Helps protect against caviites

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children under 6 years of age.

**Directions**

**Adults and children 2 years of age and older:** brush teeth thoroughly preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

Do not swallow

To minimize swallowing use a pea-sized amount in children under 6

Supervise childrens brushing until good habits are established

**Children under 2 years of age: consult a dentist or doctor.**

**Other Information**

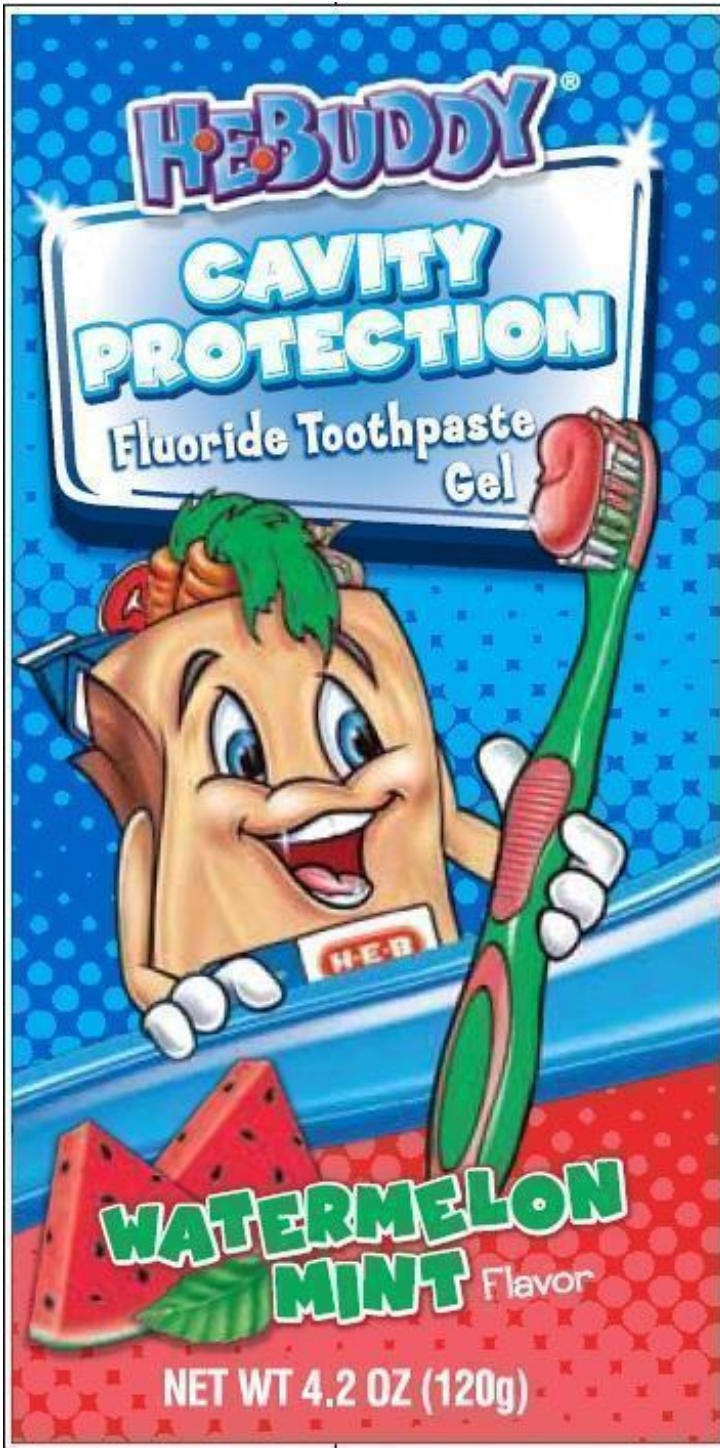
Store in a cool dry place. Keep tube capped when not in use.

**Inactive ingredients**

Sorbitol, Water, Hydrated Silica, Glycerin, Cellulose Gum, PEG-12, Flavor, Sodium Benzoate, Sodium Saccharin, Cocamidopropyl Betaine, Mica, Titanium Dioxide, Red 40

**Adults and children 2 years of age and older:** brush teeth throuoghly, preferably after every meal or at least twice a day, or as directed by a dentist or doctor.

mml.jpg



**Drug Facts**

|                              |                |
|------------------------------|----------------|
| <b>Active ingredient</b>     | <b>Purpose</b> |
| Sodium fluoride 0.243% (w/w) | Anticavity     |

**Use** Helps protect against cavities

**Warning**  
 Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**  
**Adults and children 2 years of age and older:** brush teeth thoroughly, preferably after each meal or at least twice per day, or as directed by a dentist or doctor

- Do not swallow
- To minimize swallowing use a pea-sized amount in children under 6
- Supervise children's brushing until good habits are established

**Children under 2 years of age: consult a dentist or doctor.**

**Inactive ingredients** sorbitol, water, hydrated silica, glycerin, cellulose gum, PEG-12, flavor, sodium benzoate, sodium saccharin, cocamidopropyl betaine, mica, titanium dioxide, red 40

**Other information** Store in a cool, dry place. Keep tube capped when not in use.

**Questions?** Call 1-877-777-2743

MADE WITH PRIDE AND CARE FOR H-E-B,  
 SAN ANTONIO, TX 78204  
 MADE IN USA

**GUARANTEE**  
 We believe the high quality of this H-E-B product makes it an outstanding value. We hope you'll agree. If not, we'll cheerfully refund your money. Thanks for shopping with us.



1821190R1/5820190

**HEB HEBUDDY**  
 fluoride paste, dentifrice

| Product Information             |                      |                    |                |
|---------------------------------|----------------------|--------------------|----------------|
| Product Type                    | HUMAN OTC DRUG LABEL | Item Code (Source) | NDC:378 08-192 |
| Route of Administration         | DENTAL               | DEA Schedule       |                |
| Active Ingredient/Active Moiety |                      |                    |                |
| Ingredient Name                 | Basis of Strength    | Strength           |                |

|                                |              |                  |
|--------------------------------|--------------|------------------|
| SODIUM FLUORIDE (FLUORIDE ION) | FLUORIDE ION | 0.243 g in 100 g |
|--------------------------------|--------------|------------------|

### Inactive Ingredients

| Ingredient Name               | Strength |
|-------------------------------|----------|
| GLYCERIN                      |          |
| WATER                         |          |
| SODIUM BENZOATE               |          |
| SORBITOL                      |          |
| TITANIUM DIOXIDE              |          |
| SACCHARIN SODIUM              |          |
| COCAMIDOPROPYL BETAINE        |          |
| HYDRATED SILICA               |          |
| POLYETHYLENE GLYCOL 600       |          |
| CARBOXYMETHYLCELLULOSE SODIUM |          |
| FD&C RED NO. 40               |          |

### Product Characteristics

|                 |                              |                     |  |
|-----------------|------------------------------|---------------------|--|
| <b>Color</b>    | pink                         | <b>Score</b>        |  |
| <b>Shape</b>    |                              | <b>Size</b>         |  |
| <b>Flavor</b>   | WATERMELON (Watermelon mint) | <b>Imprint Code</b> |  |
| <b>Contains</b> |                              |                     |  |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:37808-192-00 | 12 in 1 CASE        |                      |                    |
| 1 | NDC:37808-192-02 | 120 g in 1 TUBE     |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph final | part355                                  | 12/01/2012           |                    |

**Labeler** - HEB (007924756)

**Registrant** - Lornamead (126440440)

### Establishment

| Name      | Address | ID/FEI    | Business Operations                     |
|-----------|---------|-----------|-----------------------------------------|
| Lornamead |         | 126440440 | manufacture(37808-192), pack(37808-192) |