

**LEVEL ANTICAVITY - sodium monofluorophosphate paste**  
**Level Oral Care, LLC**

*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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**Level Mint Anticavity Toothpaste**

Active Ingredient:

Sodium monofluorophosphate 0.76 percent

Purpose

Anticaries

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Uses:

Aids in the prevention of dental cavities.

Warnings:

Do not swallow. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach children under 6 years of age.

Directions:

Adults and children 2 years of age and older: Apply Level Toothpaste onto a soft bristle toothbrush. Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

Children under 6 years of age: Instruct in good brushing and rinsing habits (to minimize swallowing). Use a pea-sized amount. Supervise children as necessary until capable of using without supervision.

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

Inactive Ingredients: purified water, glycerin, sorbitol, xylitol hydrated silica, calcium carbonate, tetrasodium pyrophosphate, sodium lauryl sulfate, sodium bicarbonate, sodium saccharin, cellulose gum, sodium benzoate, flavor

xylitol

Natural Enamel Protection

True Protection with fluoride

Gentle, yet powerful whitening agents

Ultimate freshness formula

Enamel Guard with pH stabilizers

Distributed by:

Level Oral Care, LLC

Jacksonville, FL 32246

[www.leveloralcare.com](http://www.leveloralcare.com)

Product of MY

Level



**LEVEL™**

**MINT FIVE**  
ANTICAVITY TOOTHPASTE

**perfect your smile™**

NET WT 5.0 OZ (141.7 g)



- True Protection with fluoride
- Gentle, yet powerful whitening agents
- Ultimate freshness formula
- Enamel Guard with pH stabilizers

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*Level*

*Mint One*

*Anticavity Toothpaste*

*perfect your smile*

*NET WT 1.0 oz (28.3 g)*



- True Protection with fluoride
- Gentle, yet powerful whitening agents
- Ultimate freshness formula
- Enamel Guard with pH stabilizers

<b>Drug Facts</b>	
<b>Active ingredient:</b> Sodium monofluorophosphate 0.76%.....	<b>Purpose</b> Anticaries
<b>Uses:</b> Aids in the prevention of dental cavities.	
<b>Warnings:</b> Keep out of reach of children under 6 years of age. Do not swallow. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions:</b>	
Adults and children 2 years of age and older:	Apply Level Toothpaste onto a soft bristle toothbrush. Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.
Children under 6 years of age:	Instruct in good brushing and rinsing habits (to minimize swallowing). Use a pea-sized amount. Supervise children as necessary until capable of using without supervision.
Children under 2 years of age:	Consult a dentist or doctor.
<b>Inactive Ingredients:</b> Calcium Carbonate, Purified Water, Sorbitol Glycerin, Cellulose gum, Hydrated Silica, Sodium Lauryl Sulphate, Flavour, Xylitol, Tetrasodium Pyrophosphate, Sodium Bicarbonate, Sodium Saccharin, Sodium Benzoate	

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## LEVEL ANTICAVITY

sodium monofluorophosphate paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50001-111
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	76 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SACCHARIN</b> (UNII: FST467XS7D)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50001-111-50	141.7 g in 1 TUBE		
2	NDC:50001-111-10	28.3 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part355	12/30/2009	

**Labeler** - Level Oral Care, LLC (832019124)

### Establishment

Name	Address	ID/FEI	Business Operations
AmLion Toothpaste Mfg. Sdn. Bhd.		652244161	manufacture

Revised: 5/2011

Level Oral Care, LLC