

**LEVEL WINTERMINT FIVE WHITENING FORMULA 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 WINTERMINT FIVE WHITENING FORMULA ANTICAVITY TOOTHPASTE  
perfect your smile**

**DRUG FACTS**

Active Ingredient

Purpose

Sodium Monofluorophosphate 0.76%....Anticaries

Purpose

Anticaries

Uses:

Aids in the prevention of dental cavities.

**WARNING**

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 of children under 6 years of age.

**DIRECTIONS**

Adults and children 2 years of age and older:

Apply Level Toothpaste on to a soft bristle toothbrush. Brush 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

Calcium Carbonate, Purified Water, Xylitol, Sorbitol, Glycerin, Sodium Bicarbonate, Cellulose Gum, Hydrated Silica, Sodium Lauryl Sulfate, Flavor, Tetrasodium Pyrophosphate, Sodium Benzoate, Sodium Saccharin

Xylitol

Natural Enamel protection

True protection with fluoride

Ultra concentrated whitening agents

Active stain removal

Invigorating winter mint

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

Wintermint Five

Whitening Formula

Anticavity Toothpaste

perfect your smile

NET WT. 5.0 OZ (141.7G)

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# Product of MY



## LEVEL WINTERMINT FIVE WHITENING FORMULA ANTICAVITY

sodium monofluorophosphate paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50001-121
<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	0.76 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50001-121-50	141.7 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part356	08/16/2010	

**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