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.

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

Product of MY

Level

Wintermint Five

Whitening Formula

Anticavity Toothpaste

perfect your smile

NET WT. 5.0 OZ (141.7G)

Xylitol

natural enamel protection

True protection with fluoride

Ultra concentrated whitening agents Active stain removal

Invigorating winter mint

Enamel Guard with pH stabilizers

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LE♥EI™

WINTERMINT FIVE WHITENING FORMULA ANTICAVITY TOOTHPASTE

perfect your smile"

NET WT 5.0 OZ (141.7g)



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- Ultra concentrated whitening agents
- Active stain removal

- Invigorating winter mint

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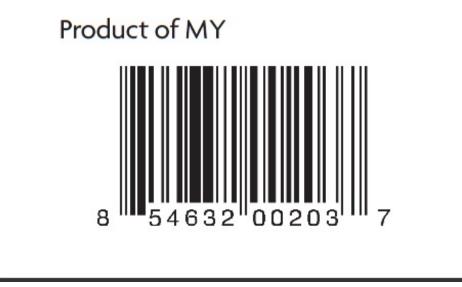
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True Protection with fluoride

Drug Fac	ts			
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Uses: Aids in the preventio	n of dental cavities.			
Warnings: 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.				
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LEVEL WINTERMINT FIVE WHITENING FORMULA ANTICAVITY

sodium monofluorophosphate paste

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (S	Item Code (Source) NDC		DC:50001-121	
Route of Administration	DENTAL					
Active Ingredient/Active	Majety					
U			Basis of Str	angth	Strength	
Ingredient NameBasis of StrengthSODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)SODIUM MONOFLUOROPHOSPHA					0.76 g in 100 g	
Inactive Ingredients						
Ingredient Name					Strength	
CALCIUM CARBONATE (UNII: H	0G9379FGK)					
WATER (UNII: 059QF0KO0R)						
XYLITOL (UNII: VCQ006KQ1E)						
SORBITOL (UNII: 506T60A25R)						
GLYCERIN (UNII: PDC6A3C0OX)						
SODIUM BICARBONATE (UNII: 8	3MDF5V39QO)					
CARBOXYMETHYLCELLULOS	E SODIUM (UNII: K679OBS31	1)				
HYDRATED SILICA (UNII: Y607)	F4G8P9)					
SODIUM LAURYL SULFATE (UI	NII: 368GB5141J)					
SODIUM PYROPHOSPHATE (UN	NII: O352864B8Z)					
SODIUM BENZOATE (UNII: OJ24	45FE5EU)					
SACCHARIN SODIUM (UNII: SB8	ZUX40TY)					
Packaging # Item Code	Package Description	Marketing Sta	_	/Jarketing	- 1-	

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