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.

Level Mint Anticavity Toothpaste

Active Ingredient:	Purpose
Sodium monofluorophoshate 0.76 percent	Anticaries
Purpose Anticaries	
**	

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

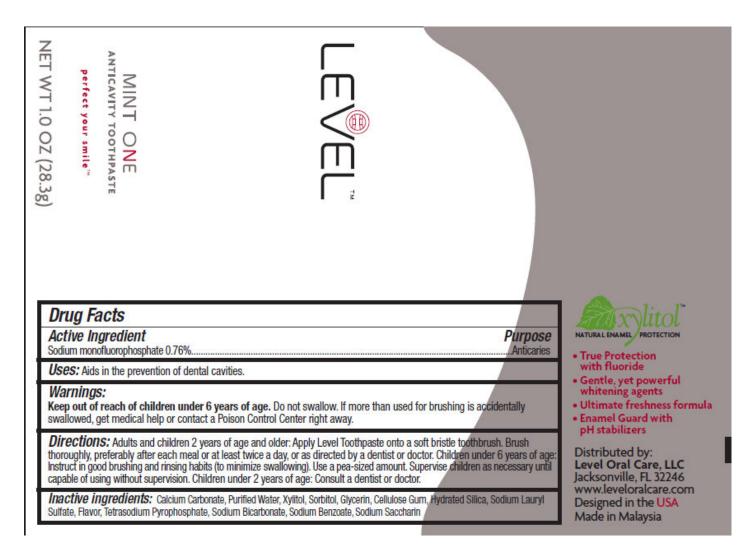
Enamel Guard with pH stabilizers

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Level

Mint Five Anticavity Toothpaste perfect your smile

NET WT 5.0 oz (141.7 g)



LEVEĽ

MINT FIVE ANTICAVITY TOOTHPASTE

perfect your smile™

NET WT 5.0 OZ (141.7 g)

Level

Mint One

Anticavity Toothpaste

perfect your smile



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- Ultimate freshness formula
- Enamel Guard with pH stabilizers

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Drug Facts				
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Water, Sorbitol Glycer Sodium Lauryl Sulpha	nts: Calcium Carbonate, Purified in, Celluiose gum, Hydrated Silica, ite, Flavour, Xyfitol, Tetrasodium um Bicarbonate, Sodium Saccharin,			

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LEVEL ANTICAVITY sodium monofluorophosphate paste **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:50001-111 **Route of Administration** DENTAL **Active Ingredient/Active Moiety** Ingredient Name **Basis of Strength** Strength SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION -SODIUM 76 g UNII:Q80VPU408O) MONOFLUOROPHOSPHATE in 100 g **Inactive Ingredients Ingredient** Name Strength WATER (UNII: 059QF0KO0R) GLYCERIN (UNII: PDC6A3C0OX)

010	C monograph not final	part355		12/30/2009		
	Iarketing Category Comparent part final	Application Number or Monog	raph Citation	Marketing Star 12/30/2009	t Date	Marketing End Date
	arketing Inform				_	
2 N	NDC:50001-111-10	28.3 g in 1 TUBE				
1 N	NDC:50001-111-50	141.7 g in 1 TUBE				
#	Item Code	Package Description	Marketing	Start Date	Ma	rketing End Date
Pa	ckaging					
301	DIOM BENZOATE (ON	n. 03243FE3E0)				
	DIUM BENZOATE (UN					
	CCHARIN (UNII: FST46	DIUM (UNII: M28OL1HH48)				
	DIUM LAURYL SULFA	TE (UNII: 368GB5141J)				
		TE (UNII: O352864B8Z)				
	LCIUM CARBONATE (,				
	ICON DIO XIDE (UNII:	,				
	LITOL (UNII: VCQ006	• /				

Labeler - Level Oral Care, LLC (832019124)

Esta	blis	hm	ent
Loca			CHIC

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

Revised: 5/2011

Level Oral Care, LLC