

**LEVEL HERBAL MINT FIVE SENSITIVE FORMULA ANTICAVITY - potassium nitrate,
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 HERBAL MINT FIVE SENSITIVE FORMULA ANTICAVITY TOOTHPASTE perfect
your smile**

DRUG FACTS

Active Ingredient	Purpose
Potassium Nitrate 5%	Antihypersensitivity
Sodium Monofluorophosphate 0.76%....	Anticaries

Purpose:
Antihypersensitivity and Anticaries

Uses:

Builds increasing protection against painful sensitivity of the teeth due to cold, heat acids, sweets, or contact

Aids in the prevention of dental cavities.

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

Dicalcium Phosphate Dihydrate, Purified Water, Xylitol, Glycerin, Hydrated Silica, Sorbitol, Carboxy Methyl Cellulose, Sodium Lauryl sulfate, Flavor, Tetrasodium Pyrophosphate, Sodium Bicarbonate, Sodium Benzoate, Sodium Saccharin

Xylitol

Natural Enamel protection

True protection with fluoride

Advanced pain-blocking technology

Soothing herbal mint

enamel guard with pH stabilizers

Distributed by

level oral care, LLC

Jacksonville, FL 32246

www.leveloralcare.com

Product of MY

Level

Herbal Mint Five

Sensitive Formula

Anticavity Toothpaste

perfect your smile

NET WT. 5.0 OZ (141.7G)

Xylitol

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Enamel Guard with pH stabilizers

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LEVEL™

HERBAL MINT FIVE
SENSITIVE FORMULA
ANTICAVITY TOOTHPASTE

perfect your smile™

NET WT 5.0 OZ (141.7g)



- True Protection with fluoride
- Advanced pain-blocking technology
- Soothing herbal mint
- Enamel Guard with pH stabilizers

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Inactive ingredients: Dicalcium Phosphate Dihydrate, Purified Water, Xylitol, Glycerin, Hydrated Silica, Sorbitol, Carboxy Methyl Cellulose, Sodium Lauryl Sulfate, Flavor, Tetrasodium Pyrophosphate, Sodium Bicarbonate, Sodium Benzoate, Sodium Saccharin

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Product of MY





LEVEL HERBAL MINT FIVE SENSITIVE FORMULA ANTICAVITY

potassium nitrate, sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50001-131
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM NITRATE	5 g in 100 g
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	0.76 g in 100 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50001-131-50	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	08/12/2010	

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