TEETH DESENSITIZING AND REMINERALIZING GEL- potassium nitrate,sodium fluoride,sodium monofluorophosphate paste
Fuzhou Difeng Bio-tech Co., Ltd.

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.

---

teeth desensitizing and remineralizing gel 49410-200

Active ingredients

Potassium nitrate 5%
Sodium Fluoride 0.15%

Purpose

.antihypersensitivity
.anticavity

Uses

To relieve the discomfort from teeth sensitivity caused by thermal, chemical changes, periodontal conditions...etc. Aids in the prevention of dental cavities.

Warnings

Do not swallow. Avoid contact with eyes. Discontinue use and consultant your dentist if allegric reaction or gum irritation occurs.

Keep out of reach of children.

Directions

Adults and children 18 years of age and older: Directly apply 1ml-1.5ml of the product on sensitive teeth, or use it in a custom mouth tray. Keep your mouth open for 10-15 mins. Then rinse your month to clean the gel. Use it 1-2 times daily or as recommended by a dentist or physician. Children under 18 years of age and pregnant, breast feeding women: consult a dentist or physician prior to use.

INACTIVE INGREDIENT

Carbopol, Deionized Water, Glycerin, Menthol, Sodium Saccharine,SODIUM MONOFLUOROPHOSPHATE

Teeth Desensitizing and Remineralizing Gel

Drug Facts

Active ingredients	Purpose
Potassium nitrate 5%	antihypersensitivity
Sodium Fluoride 0.15%	anticavity

Uses

- To relieve the discomfort from teeth sensitivity caused by thermal, chemical changes, periodontal conditions...etc.
- Aids in the prevention of dental cavities.

Warnings

- Do not swallow. - Avoid contact with eyes. - Discontinue use and consultant your dentist if allegric reaction or gum irritation occurs. - Keep out of reach of children.

Drug Facts(continued)

Directions:

- Adults and children 18 years of age and older: Directly apply 1ml-1.5ml of the product on sensitive teeth, or use it in a custom mouth tray. Keep your mouth open for 10-15 mins. Then rinse your month to clean the gel. Use it 1-2 times daily or as recommended by a dentist or physician.
- Children under 18 years of age and pregnant, breast feeding women: consult a dentist or physician prior to use.

Inactive Ingredients: *Carbopol, Deionized Water, Glycerin, Menthol, sodium monofluorophosphate, Sodium Saccharine*

Storage: Store in cool, dry place. Avoid directly sunlight. For longer shelf life, keep refrigerated.

TEETH DESENSITIZING AND REMINERALIZING GEL

potassium nitrate,sodium fluoride,sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49410-200
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q)	
MENTHOL (UNII: L7T10EIP3A)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CARBOMER HOMOPOLYMER TYPE A (UNII: F68VH75CJC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49410-200-01	5 in 1 CARTON	01/08/2018	

1		200 in 1 CONTAINER		
1		1.5 g in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
2	NDC:49410-200-02	5 in 1 CARTON	01/08/2018	
2		100 in 1 CONTAINER		
2		2 g in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
3	NDC:49410-200-03	5 in 1 CARTON	01/08/2018	
3		100 in 1 CONTAINER		
3		4 g in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
4	NDC:49410-200-04	5 in 1 CARTON	01/08/2018	
4		80 in 1 CONTAINER		
4		6 g in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
5	NDC:49410-200-05	6 in 1 CARTON	01/08/2018	
5		300 in 1 CONTAINER		
5		4.5 g in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
6	NDC:49410-200-06	6 in 1 CARTON	01/08/2018	
6		200 in 1 CONTAINER		
6		10 g in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
7	NDC:49410-200-07	6 in 1 CARTON	01/08/2018	
7		333 in 1 CONTAINER		
7		3 g in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
8	NDC:49410-200-08	300 in 1 CARTON	01/08/2018	
8		3.5 g in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/07/2016	

Labeler - Fuzhou Difeng Bio-tech Co., Ltd. (528195950)

Registrant - Fuzhou Difeng Bio-tech Co., Ltd. (528195950)

Establishment

Name	Address	ID/FEI	Business Operations
Fuzhou Difeng Bio-tech Co., Ltd.		528195950	manufacture(49410-200)