

**DOCTORTIBLETKEREALE- sodium fluoride paste, dentifrice
TRAUM TRADERS**

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.

ACTIVE INGREDIENT

Active ingredients: Sodium Fluoride 0.22%

INACTIVE INGREDIENT

Inactive ingredients: D-Sorbitol, Sodium Lauryl Sulfate, Silicon Dioxide, Xylitol, microcrystalline cellulose, Mint Flavor, Magnesium Sterate, L-Menthol, Hydroxypropylcellulose, Tetrasodium Pyrophosphate, sodium hydrogen carbonate, aspartame, Arabic Gum, Pyridoxine HCl, Ascorbic Acid

PURPOSE

Purpose: Anticaries

WARNINGS

Warnings: Keep out of the reach of children under 6 years of age. Do not use children because they may swallow. If large quantities have been swallowed, consult a physician immediately.

KEEP OUT OF REACH OF CHILDREN

Keep out of the reach of children under 6 years of age.

Uses

Uses: Help better oral hygiene and freshness breath.

Directions

Directions: Take one of Kereale mouth rinse tablet chewing until it melting completely in your mouth and mix with some water then spit it out.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Drug facts

Active ingredients:	Purpose:
Sodium Fluoride 0.22%	Anticaries

Uses:
Help better oral hygiene and freshness breath.

Directions:
Take one of Dr+Tiblet Kereale mouthwash tablet chewing until it melting completely in your mouth and mix with some water then spit it out.

Ingredients:
Silicon Dioxide, Sodium Fluoride, Tetrasodium Pyrophosphate, Pyridoxine HCl, D-Sorbitol, Sodium Lauryl Sulfate, Xylitol, Ascorbic Acid, L-Menthol, Arabic Gum, microcrystalline cellulose, aspartame, Mint flavor, Hydroxypropylcellulose, Magnesium Stearate, sodium hydrogen carbonate

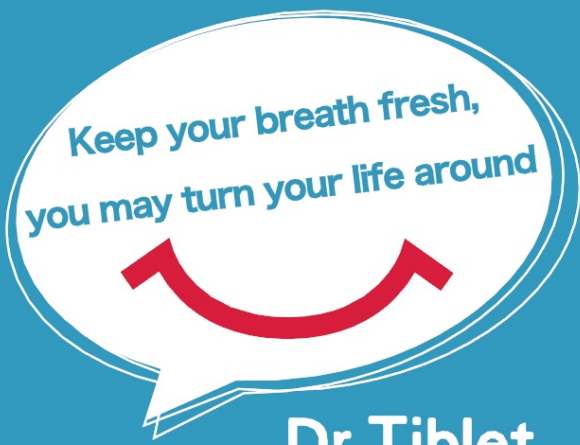
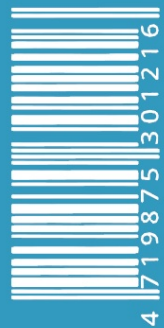
Warnings:
Keep out of the reach of children under 6 years of age.
Do not use children because they swallow. If large quantities have been swallowed, consult a physician immediately.

Questions:
+82 (2) 62079260

Manufactured for TRAUMTRADERS
90Magokjungang 8-ro, Genseo-gu, Seoul, 07803, Republic of Korea

Mouthwash tablet

60pcs
0.7g*60ea
Mint

Dr. Tiblet

Kereale
www.kereale.com
Made in Korea



DOCTORTIBLETKEREALE

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72047-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Sodium Fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.001 g in 0.7 g	

Inactive Ingredients		
Ingredient Name	Strength	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72047-010-02	60 in 1 CARTON	01/02/2018	
1	NDC:72047-010-01	0.7 g in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/02/2018	

Labeler - TRAUM TRADERS (694894613)

Registrant - TRAUM TRADERS (694894613)

Establishment

Name	Address	ID/FEI	Business Operations
Sungwon Pharmaceutical Co., Ltd		689787898	manufacture(72047-010)

Revised: 1/2018

TRAUM TRADERS