

T-SERIES- sodium fluoride tablet
SUNGWON PHARMACEUTICAL 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.

ACTIVE INGREDIENT

sodium fluoride

INACTIVE INGREDIENT

silica, sodium pyrophosphate, pyridoxine hydrochloride, D-sorbitol, microcrystalline cellulose, xylitol, sodium bicarbonate, tea extract, tocopherol acetate, etc

PURPOSE

- Keeps teeth white and strong
- Keep the oral cavity clean
- Prevents tooth decay and bad breath caused by fluoride
- Removing plaque, preventing gingivitis and periodontitis
- Periodontal Disease Prevention
- Gum Disease Prevention
- Prevention of tartar deposition

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

WARNING

For oral use only
When using this product

- This toothpaste has a 1,000 ppm fluoride content
- Do not use other than brushing teeth and be careful not to swallow

Keep out of reach of children

- if swallowed, get medical help or contact a person control center immediately

USES

for oral use only

INDICATION & USAGE SECTION

- Within 3 times a day, chew 1 or 2 tablets sufficiently and then brush your teeth by brushing or brush your teeth by brushing them
- scrub softly as like doing massage

T-SERIES

Drug Facts

Active ingredients (활성성분)

Purpose (용도)

sodium fluoride 0.22% ----- anticaries

Uses

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Directions

- Within 3 times a day, chew 1 or 2 tablets sufficiently and then brush your teeth by brushing or brush your teeth by brushing them
- scrub softly as like doing massage

Other Information

- store between 20-25 °C (68-77 °F)
- avoid freezing and excessive heat above 40 °C (104 °F)

Inactive Ingredients

silica, sodium pyrophosphate, pyridoxine hydrochloride, D-sorbitol, microcrystalline cellulose, xylitol, sodium bicarbonate, tea extract, tocopherol acetate

T-SERIES

sodium fluoride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76058-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.22

Inactive Ingredients

Ingredient Name	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	white	Score	score with uneven pieces
Shape	ROUND	Size	12mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76058-001-01	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/19/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/19/2019	

Labeler - SUNGWON PHARMACEUTICAL CO., LTD. (689787898)

Registrant - SUNGWON PHARMACEUTICAL CO., LTD. (689787898)

Establishment

Name	Address	ID/FEI	Business Operations
SUNGWON PHARMACEUTICAL CO., LTD.		689787898	manufacture(76058-001)

Revised: 10/2019

SUNGWON PHARMACEUTICAL CO., LTD.