# POVI DENTAL CARE- sodium fluoride mouthwash DOCTOR PHARM

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.

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### **DOCTOR PHARM - POVI DENTAL CARE MOUTHWASH**

Sodium Flouride

Keeps it white and makes it strong.

Keep your mouth clean.

Refreshes the oral cavity.

Prevents tooth decay and removes bad breath.

Increases aesthetic effect.

Prevention of gingivitis, periodontitis (alveolar fistula)

Prevention of periodontal disease

Prevention of gum disease

Keep out of reach of children

Adults and children 6 years of age and older: Use twice a day after brushing your teeth with a toothpaste. Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: consult a dentist or doctor.

- 1. Maintain certain usage and capacity.
- 2. When using it for children, use it under the guidance and supervision of the guardian.
- 3.Do not swallow this product.
- 4.Use only for mouthwash. Do not use for any purpose other than use. If you swallow a large amount, consult your doctor immediately.
- 5. Children under 6 years of age should not be used without instructions from pharmacists or doctors.
- 5. Keep out of reach of children.
- 6. Avoid direct sunlight and keep it as cool as possible. 8) Do not insert any other containers for quality preservation.
- 7.Do not administer to the next patient.
- 1). Patients with iodine intolerance
- 2). Patients with thyroid dysfunction
- 3). Pregnant women or breastfeeding women who may be pregnant or pregnant

Water, glycerin, ethyl alcohol, xylitol, sodium bicarbonate, flavor, citric acid hydrate, enzymatically modified stevia, sodium benzoate, sodium chloride, caramel color, povidone iodide topical solution, l-menthol

For dental use only

Active ingredients	Purpose	
Sodium fluoride 0.02%	Anticavity	

#### Uses

Keeps it white and makes it strong. Keep your mouth clean. Refreshes the oral cavity. Prevents tooth dec ay and removes bad breath. Increases aesthetic effect. Prevention of gingivitis, periodontitis (alveolar fist ula) Prevention of periodontal disease Prevention of gum disease

1) Maintain certain usage and capacity. 2) When using it for children, use it under the guidance and supervision of the guardian. 3) Do not swallow this product. 4) Use only for mouthwash. Do not use for any purpose other than use. If you swallow a large amount, consult your doctor immediately. 5) Children under 6 years of age should not be used without instructions from pharmacists or doctors. 6) Keep out of reach of children. 7) Avoid direct sunlight and keep it as cool as possible. 8) Do not insert any other containers for quality preservation. 9) Do not administer to the next patient. ① Patients with iodine intolerance. ② Patients with thyroid dysfunction. ③ Pregnant women or breastfeeding women who may be pregnant or pregnant.

### Directions

Adults and children 6 years of age and older: Use twice a day after brushing your teeth with a toothpaste. Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: consult a dentist or doctor.

#### Other information

Airtight container, room temperature storage (1~30°C)

#### Inactive ingredients

Caramel Colorant, Citric Acid Hydrate, DI-Water, Enzymatically Modified stevia, Ethyl alcohol, Flavor, Glycerin, L-Menthol, Povidone lodide topical solution, Sodium benzoate, Sodium bicarbonate, Sodium

#### Questions

Call +82-32-262-0701 Manufactured for Doctor Pharm / 67 Beun Gil, Gajung-ro Seo-gu Incheon

City, Korea, LOT NO, D20J02 / EXP 2023, 12.10









Povidone Iodine Soiution Included 110ml 3.72 fl.oz.

MADE IN KOREA



### POVI DENTAL CARE

sodium fluoride mouthwash

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81017-0001

ORAL **Route of Administration** 

## **Active Ingredient/Active Moiety**

**Basis of Strength Ingredient Name** Strength SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O) FLUORIDE ION 0.02 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
XYLITOL (UNII: VCQ006KQ1E)		
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)		
CARAMEL (UNII: T9D99G2B1R)		
WATER (UNII: 059QF0KO0R)		
ALCOHOL (UNII: 3K9958V90M)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		
GLYCERIN (UNII: PDC6A3C0OX)		
LEVOMENTHOL (UNII: BZ1R15MTK7)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
PO VIDO NE (UNII: FZ989GH94E)		

Pa	ackaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:81017-0001-1	110 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/05/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	11/05/2020		

## Labeler - DOCTOR PHARM (695222920)

## Registrant - DOCTORPHARM (695222920)

Establishment			
Name	Address	ID/FEI	Business Operations
DOCTOR PHARM		695222920	label(81017-0001), manufacture(81017-0001), pack(81017-0001)

Revised: 11/2020 DOCTOR PHARM