

**DR. ZENNI NATURAL ORTHODONTIC TOOTHPASTE- sodium monofluorophosphate paste, dentifrice  
Zeniton 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.*

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**ACTIVE INGREDIENT**

Sodium Monofluorophosphate 0.75%

**PURPOSE**

Anticavity

**KEEP OUT OF REACH OF CHILDREN**

Keep out of reach of children

**Uses**

- Helps protect against cavities
- Removal of plaque

**WARNINGS**

Keep out of reach of children under 6 yrs. of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**INACTIVE INGREDIENTS**

D-Sorbitol Solution, Water, Silicon Dioxide, Concentrated Glycerin, Hydroxyapatite, Sodium Cocoyl Glutamate, Xanthanum, Red Wine Flavor, Xylitol, L-Menthol, Peppermint Oil, Aminocaproic Acid, Aluminum Chlorohydroxy Allantoinate, Grapefruit Seed Extract, Green Tea Extract, Chamomile Extract, Sage Extract, Aloe Extract, Eucalyptus Extract, Sodium Chloride, Tocopherol Acetate

**Directions**

- Adults and children 2 years of age and older: Brush teeth thoroughly preferably after each meal or at least twice a day or as directed by a dentist or doctor.
- Children under 6 years: To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established.
- Children under 2 years: Consult a dentist or doctor.

## Other Information

■ Do not store this product in an inappropriate place such as high or low temperatures or under direct sun light (1~30°C)

## Questions

■ [www.zeniton.com](http://www.zeniton.com)

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

<p style="text-align: center;">의약품</p> <hr/> <p><b>Drug Facts</b></p> <p><b>Active ingredient</b> ..... <b>Purpose</b> Sodium Monofluorophosphate 0.75% ..... Anticavity</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>Helps protect against cavities</li> <li>Removal of plaque</li> </ul> <p><b>Warnings</b> Contains Keep out or reach of children under 6 yrs. of age, if more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>Adults and children 2 years of age and older: Brush teeth thoroughly preferably after each meal or at least twice a day or as directed by a dentist or doctor</li> <li>Children under 6 years: To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established.</li> <li>Children under 2 years: Consult a dentist or doctor.</li> </ul> <p><b>Other Information</b></p> <ul style="list-style-type: none"> <li>Do not store this product in an inappropriate place such as high or low temperatures or under direct sun light (1~30°C)</li> </ul> <p><b>Questions</b></p> <ul style="list-style-type: none"> <li><a href="http://www.zeniton.com">www.zeniton.com</a></li> </ul> <p><b>Inactive ingredients</b> D-Sorbitol Solution, Water, Silicon Dioxide, Concentrated Glycerin, Hydroxyapatite, Sodium Cocoyl Glutamate, Xanthangum, Red Wine Flavor, Xylitol, L-Menthol, Peppermint Oil, Aminocaproic Acid, Aluminum Chlorohydroxy Allantoinate, Grapefruit Seed Extract, Green Tea Extract, Chamomile Extract, Sage Extract, Aloe Extract, Eucalyptus Extract, Sodium Chloride, Tocopherol Acetate</p> <p><b>Distributor:</b> Zeniton Co., Ltd. 701, 28, Digital-ro 33-gil, Guro-gu, Seoul, Korea</p> <p><b>Manufacturer:</b> DONG IL PHARMS CO., LTD. 26, Rinosandan-gil, Maengdong-Myeon, Eumseong, Korea</p> <p>MADE IN KOREA <b>ZENITON</b> <a href="http://www.zeniton.com">www.zeniton.com</a> WORLD BEST ORAL CARE GROUP</p>	<p style="text-align: center;">의약품</p> <hr/> <p style="text-align: center;">올소돈틱치약</p> <p style="text-align: center;">교정 치아 관리</p> <hr/> <p style="text-align: center;">하이드록시아파타이트 5%</p> <p style="text-align: center;">우리 몸의 뼈·치아와 성분 구조가 동일한 생체 친화성 무기질 성분</p> <hr/> <p style="text-align: center;">ECOCERT 유기농 인증 추출물</p> <p style="text-align: center;">유칼립투스추출물, 세이지추출물, 카모마일추출물, 알로에추출물 함유</p> <hr/> <p style="text-align: center;">합성첨가물 10無</p> <p style="text-align: center;">CMIT / MIT / 합성계면활성제 / 타르색소 트리클로산 / 폼알성오일 / 안공경미로 / PEG 안식향산류 / 합성보존제 無첨가</p> <hr/> <p style="text-align: center;">중금속 및 잔류농약 시험필</p> <p style="text-align: center;">국제공인시험기관에서 중금속(납, 비소) 및 잔류농약(520종) 확인시험 실시</p> <hr/> <p style="text-align: center;">8 809296 113867</p>	<p style="text-align: center;">의약품</p> <hr/> <p>Dr.Zenni</p> <p style="text-align: center;"><b>NATURAL</b> ORTHODONTIC TOOTHPASTE</p> <hr/> <p style="text-align: center;">Protect teeth &amp; stay healthy</p> <hr/> <p style="text-align: center;">3.52 oz (100g)</p> <hr/> <p style="text-align: center;"><b>ZENITON</b> WORLD BEST ORAL CARE GROUP</p>	<p style="text-align: center;">(주)제니튼은 구강전문기업 입니다.</p> <p>'내 가족이 안심하고 사용할 수 있는 제품을 만든다'라는 제품개발 철학에 따라 안전성이 담보되지 않는 성분은 배제하고 가급적 화학성분을 천연유래성분으로 대체하여 내 가족이 안심하고 사용할 수 있는 구강건강 제품을 만들기 위해 제니튼은 책임을 다할 것입니다.</p> <hr/> <p style="text-align: center;">행복을 나누고 사랑을 더하는 (주)제니튼 사회공헌 활동</p> <div style="text-align: center;">  <p>제니튼 해피스마일 치과버스</p> <p>의료 소외계층 아동들을 직접 찾아가는 무료 치과진료 서비스로 제니튼 제품의 판매수입 일부가 운영기금으로 사용되고 있습니다.</p> </div> <hr/> <div style="text-align: center;">  <p>행복한 건강 나눔 음악회</p> <p>영유아를 대상으로 한 어린이 음악회로 이웃과 함께 사랑과 행복을 전합니다.</p> </div> <hr/> <div style="text-align: center;">  <p>제니튼 공식홈페이지 <a href="http://www.zeniton.com">www.zeniton.com</a> 네추럴 올소돈틱치약 상품상세정보</p> </div>
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**DR. ZENNI NATURAL ORTHODONTIC TOOTHPASTE**

sodium monofluorophosphate paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73029-0012
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.7581 g in 100 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:73029-0012-1	100 g in 1 TUBE; Type 0: Not a Combination Product	11/22/2020	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part355	11/22/2020	

**Labeler** - Zeniton Co.,Ltd. (688416831)

**Registrant** - Zeniton Co.,Ltd. (688416831)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
DONG IL PHARMS CO., LTD.		557810721	manufacture(73029-0012)

Revised: 12/2021

Zeniton Co.,Ltd.