

**DR. ZENNI CHILDRENS TOOTH- 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.

ACTIVE INGREDIENT

Sodium Monofluorophosphate 0.37%

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 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.

INACTIVE INGREDIENTS

D-Sorbitol Solution, Concentrated Glycerin, Silicon Dioxide, Water, Sodium Cocoyl Glutamate, Sodium Alginate, Xylitol, Raspberry Flavor, ε-Polylysine, Sodium Pyrophosphate, Eucalyptus Extract, Pyridoxine Hydrochloride, Tocopherol Acetate, Sage Extract, Calendula Extract, Aloe Extract, Chamomile Extract, Green Tea Extract, Beet Red

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

<div style="text-align: right; font-size: small; color: white;">의약품</div> <div style="text-align: center; margin-bottom: 10px;">  </div> <div style="border: 1px solid white; padding: 5px; margin-bottom: 5px;"> Drug Facts </div> <p>Active ingredient Purpose Sodium Monofluorophosphate 0.37% Anticavity</p> <div style="border: 1px solid white; padding: 5px; margin-bottom: 5px;"> Uses <ul style="list-style-type: none"> ▪ Helps protect against cavities ▪ Removal of plaque </div> <div style="border: 1px solid white; padding: 5px; margin-bottom: 5px;"> Warnings Contains Keep out of 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. </div> <div style="border: 1px solid white; padding: 5px; margin-bottom: 5px;"> Directions <ul style="list-style-type: none"> ▪ 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. </div> <div style="border: 1px solid white; padding: 5px; margin-bottom: 5px;"> Other Information <ul style="list-style-type: none"> ▪ Do not store this product in an inappropriate place such as high or low temperatures or under direct sun light (1~30°C) </div> <div style="border: 1px solid white; padding: 5px; margin-bottom: 5px;"> Questions <ul style="list-style-type: none"> ▪ www.zeniton.com </div> <div style="border: 1px solid white; padding: 5px;"> Inactive ingredients D-Sorbitol Solution, Concentrated Glycerin, Silicon Dioxide, Water, Sodium Cocoyl Glutamate, Sodium Alginate, Xylitol, Raspberry Flavor, ε-Polylysine, Sodium Pyrophosphate, Eucalyptus Extract, Pyridoxine Hydrochloride, Tocopherol Acetate, Sage Extract, Calendula Extract, Aloe Extract, Chamomile Extract, Green Tea Extract, Beet Red </div> <div style="margin-top: 10px;"> Distributor: Zeniton Co., Ltd. 701, 28, Digital-ro 33-gil, Guro-gu, Seoul, Korea Manufacturer: DONG IL PHARMS CO., LTD. 26 Rinosandan-gil, Maengdong-Myeon, Eumseong, Korea </div> <div style="text-align: center; margin-top: 10px;"> MADE IN KOREA www.zeniton.com </div> <div style="text-align: center; margin-top: 10px;">  WORLD BEST ORAL CARE GROUP </div>	<div style="text-align: right; font-size: small; color: white;">의약품</div> <div style="text-align: center; margin-bottom: 10px;">  </div> <p style="text-align: center;">위생적이고 안전한 항균캡</p> <p style="text-align: center;">치약 캡(뚜껑)에 세균이나 곰팡이 등에 항균작용을 하는 항균제를 첨가하여 보다 위생적이고 안전</p> <div style="text-align: center; margin-top: 10px;">  </div> <p style="text-align: center;">ECOECERT 유기농 인증 추출물</p> <p style="text-align: center;">유칼립투스추출물, 마트리카리아엑스, 세이지엑스, 알로에엑스 첨가</p> <div style="text-align: center; margin-top: 10px;">  </div> <p style="text-align: center;">합성첨가물 10無</p> <table style="width: 100%; text-align: center; font-size: small;"> <tr> <td>✓ CMIT 無</td> <td>✓ MIT 無</td> </tr> <tr> <td>✓ 합성계면활성제 無</td> <td>✓ 타르색소 無</td> </tr> <tr> <td>✓ 트리클로산 無</td> <td>✓ 합성착향료 無</td> </tr> <tr> <td>✓ 인공감미료 無</td> <td>✓ PEG 無</td> </tr> <tr> <td>✓ 안식향산류 無</td> <td>✓ 합성보존제 無</td> </tr> </table> <div style="text-align: center; margin-top: 10px;">  </div> <p style="text-align: center;">중금속 및 잔류농약 시험필</p> <p style="text-align: center;">국제공인시험기관에서 중금속(납, 카드뮴, 비소, 수은) 및 잔류농약(320종) 확인시험 실시</p> <div style="text-align: center; margin-top: 10px;">  </div> <p style="text-align: center; font-size: small;">8 809306 070067</p>	✓ CMIT 無	✓ MIT 無	✓ 합성계면활성제 無	✓ 타르색소 無	✓ 트리클로산 無	✓ 합성착향료 無	✓ 인공감미료 無	✓ PEG 無	✓ 안식향산류 無	✓ 합성보존제 無	<div style="text-align: right; font-size: small; color: white;">의약품</div> <p style="text-align: center;">Dr. Zenni Childrens Tooth</p> <div style="text-align: center; margin-top: 10px;">  </div> <p style="text-align: center; font-size: small;">에코서트(ECOCERT) 유기농 인증 추출물 첨가</p> <div style="text-align: center; margin-top: 20px;"> <h1 style="margin: 0;">닥터제니 어린이치약</h1> </div> <div style="text-align: center; margin-top: 10px;"> <div style="background-color: #008080; color: white; border-radius: 15px; padding: 5px; display: inline-block;">치약을 뱉는 유아용</div> 저불소 </div> <div style="text-align: center; margin-top: 10px;"> <div style="border: 1px solid white; border-radius: 50%; padding: 5px; display: inline-block;">라즈베리향</div> </div> <div style="text-align: center; margin-top: 20px;">  </div> <p style="text-align: center; margin-top: 10px;">2.11 oz (60g)</p> <div style="text-align: center; margin-top: 10px;">  </div>	<p style="text-align: center; font-size: large;">(주)제니튼은 구강전문기업입니다.</p> <p style="text-align: center;">'내 가족이 안심하고 사용할 수 있는 제품을 만든다'라는 제품개발 철학에 따라 안전성이 담보되지 않는 성분은 배제하고 기급적 화학성분을 자연유래 성분으로 대체하여 내 가족이 안심하고 사용할 수 있는 구강건강 제품을 만들기 위해 제니튼은 책임을 다할 것입니다.</p> <div style="text-align: center; margin-top: 10px;"> <p style="font-weight: bold;">행복을 나누고 사랑을 더하는 (주)제니튼 사회공헌 활동</p>  </div> <p style="text-align: center; font-weight: bold;">제니튼 해피스마일 치과버스</p> <p style="text-align: center; font-size: small;">의료 소외계층 아동들을 직접 찾아가는 무료 치과진료 서비스로 제니튼 제품의 판매수입 일부가 운영기금으로 사용되고 있습니다.</p> <div style="text-align: center; margin-top: 10px;">  </div> <p style="text-align: center; font-weight: bold;">행복한 건강 나눔 음악회</p> <p style="text-align: center; font-size: small;">영유아를 대상으로 한 어린이 음악회로 이웃과 함께 사랑과 행복을 전합니다.</p> <div style="text-align: center; margin-top: 10px;">  </div> <p style="text-align: center; font-size: small;">제니튼 공식홈페이지 www.zeniton.com 닥터제니 어린이치약 상품상세정보</p>
✓ CMIT 無	✓ MIT 無												
✓ 합성계면활성제 無	✓ 타르색소 無												
✓ 트리클로산 無	✓ 합성착향료 無												
✓ 인공감미료 無	✓ PEG 無												
✓ 안식향산류 無	✓ 합성보존제 無												

DR. ZENNI CHILDRENS TOOTH

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:73029-0002

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.379 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73029-0002-1	60 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/01/2019	

Labeler - Zeniton Co.,Ltd. (688416831)

Registrant - Zeniton Co.,Ltd. (688416831)

Establishment

Name	Address	ID/FEI	Business Operations
DONG IL PHARMS CO., LTD.		557810721	manufacture(73029-0002)

Revised: 12/2021

Zeniton Co.,Ltd.