

**DR. ZENNI GGOMA TOOTHPASTE VANILLA FLAVOR- 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 0.37%

**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 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, Concentrated Glycerin, Silicon Dioxide, Xylitol, Hydroxyapatite, Water, Sodium Cocoyl Glutamate, Vanilla Flavor, Sodium Alginate, Enzymatically Modified Stevia, Grapefruit Extract, ε-Polylysine, Sodium Pyrophosphate, Sodium Chloride, Pyridoxine Hydrochloride, Tocopherol Acetate, Chamomile Extract, Sage Extract, Aloe Extract, Eucalyptus Extract, Green Tea Extract

**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: right;">[의약외품]</p> <p>Dr.Zenni GGOMA Toothpaste Vanilla flavor</p> <hr/> <p><b>Drug Facts</b></p> <p><b>Active ingredient</b> ..... <b>Purpose</b> Sodium Monofluorophosphate 0.37%..... Anticavity</p> <hr/> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>Helps protect against cavities</li> <li>Removal of plaque</li> </ul> <hr/> <p><b>Warnings</b></p> <p>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> <hr/> <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> <hr/> <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> <hr/> <p><b>Questions</b></p> <ul style="list-style-type: none"> <li><a href="http://www.zeniton.com">www.zeniton.com</a></li> </ul> <hr/> <p><b>Inactive ingredients</b></p> <p>D-Sorbitol Solution, Concentrated Glycerin, Silicon Dioxide, Xylitol, Hydroxyapatite, Water, Sodium Cocoyl Glutamate, Vanilla Flavor, Sodium Alginate, Enzymatically Modified Stevia, Grapefruit Extract, ε-Polylysine, Sodium Pyrophosphate, Sodium Chloride, Pyridoxine Hydrochloride, Tocopherol Acetate, Chamomile Extract, Sage Extract, Aloe Extract, Eucalyptus Extract, Green Tea Extract</p> <hr/> <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> <hr/> <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: right;">[의약외품]</p> <p>하이드록시아파타이트 3% 우리 몸의 뼈·치아와 성분 구조가 동일한 생체 친화성 무기질 성분</p> <p>위생적이고 안전한 항균캡 치약 캡(뚜껑)에 세균이나 곰팡이 등에 항균작용을 하는 항균제를 첨가하여 보다 위생적이고 안전</p> <p>ECOCERT 유기농 인증 추출물 유칼립투스추출물, 마르리카리아엑스, 세이지엑스, 알로에엑스 첨가</p> <p>중금속 및 잔류농약 시험필 국제공인시험기관에서 중금속(납, 비소) 및 잔류농약(320종) 확인시험 실시</p> <p>합성첨가물 10無</p> <table border="0"> <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> <p style="text-align: center;">8 809296 111450</p>	✓ CMIT無	✓ MIT無	✓ 합성계면활성제無	✓ 타르색소無	✓ 트리클로산無	✓ 합성착향료無	✓ 인공감미료無	✓ PEG無	✓ 안식향산류無	✓ 합성보존제無	<p style="text-align: right;">[의약외품]</p> <p>핀란드산 자일리톨 10% 함유</p> <p>닥터제니 <b>고마 주니어</b> 치약 <small>바닐라향   저불소   5~7세용</small></p> <p>치카 치카</p> <p>2.11 oz (60g) <b>ZENITON</b> WORLD BEST ORAL CARE GROUP</p>	<p>(주)제니튼은 치과의사들이 만든 구강전문기업 입니다.</p> <p>'내 가족이 안심하고 사용할 수 있는 제품을 만든다'라는 제품개발 철학에 따라 안전성이 담보되지 않는 성분은 배제하고 가급적 화학성분을 자연유래 성분으로 대체하여 내 가족이 안심하고 사용할 수 있는 구강건강 제품을 만들기 위해 제니튼은 책임을 다할 것입니다.</p> <p>행복을 나누고 사랑을 더하는 (주)제니튼 사회공헌 활동</p> <p><b>Happy Smile Dental Bus</b></p> <p>제니튼 해피스마일 치과버스 의료 소외계층 아동들을 직접 찾아가는 무료 치과진료 서비스로 제니튼 제품의 판매수입 일부가 운영기금으로 사용되고 있습니다.</p> <p><b>ZENITON</b></p> <p>행복한 건강 나눔 음악회 영·유아를 대상으로 한 어린이 음악회로 이웃과 함께 사랑과 행복을 전합니다.</p> <p> 제니튼 공식홈페이지 <a href="http://www.zeniton.com">www.zeniton.com</a> 닥터제니 고마주니어치약 상품상세정보</p>
✓ CMIT無	✓ MIT無												
✓ 합성계면활성제無	✓ 타르색소無												
✓ 트리클로산無	✓ 합성착향료無												
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✓ 안식향산류無	✓ 합성보존제無												

## DR. ZENNI GGOMA TOOTHPASTE VANILLA FLAVOR

sodium monofluorophosphate paste, dentifrice

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:73029-0009

**Route of Administration** DENTAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.379 g in 100 g

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73029-0009-1	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(73029-0009)

Revised: 12/2021

Zeniton Co.,Ltd.