

**ORABALANCE DENTALCARE- lactobacillus gasseri hhuman, lactobacillus fermentum ok tablet
isamogu Inc.**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

**82690-401
OraBalance Dentalcare**

Active ingredients

Lactobacillus gasseri HHuMin
Lactobacillus fermentum OK

Purpose

Eliminate Bad Breath

use

Improve oral health care

Warnings

do not eat silica gel

Warnings

be careful, as you may get hurt when opening it.

Warnings

Stop use and ask a doctor if irritation or rash appears and lasts.

Warnings

avoid direct sunlight and store it in a dry, ventilated, cool place.

Warnings

Keep out of reach of children

Directions

Melt one tablet slowly in your mouth and eat once

Inactive Ingredients

Oligosaccharide 3(Palatinos, Maltitol Syrup, Galacto-oligosaccharide)
 xylitol
 isomalt
 maltodextrin
 grape flavor powder
 vitamin C
 Magnesium Stearate
 Calcium Pantothenate
 silicon dioxide
 vitamin E
 vitamin K2
 collagen

PACKAGE LABEL

82690-401
 OraBalance Dentalcare



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| <p>Drug Facts</p> <p>Active Ingredients Lactobacillus gasseri HHuMin3% Purpose Lactobacillus fermentum OK9% Eliminate Bad Breath</p> <p>Uses Improve oral health care</p> <p>Warnings When using this product be careful, as you may get hurt when opening it, do not eat silica gel avoid direct sunlight and store it in a dry, ventilated, cool place.</p> <p>Stop use and ask a doctor if irritation or rash appears and lasts.</p> <p>Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p>Directions Melt one tablet slowly in your mouth at once</p> <p>Inactive Ingredients Oligosaccharide 3(Palatinos, Maltitol Syrup, Galacto-oligosaccharide), Xylitol, Isomalt, Maltodextrin, Grape extract, Vitamin C, Magnesium Stearate, Calcium Pantothenate, Silicon Dioxide, Vitamin E, Vitamin K2, Collagen</p> <p>Distributed by Samgdo Inc., 445, 111, Digital-ro 26-gil, Guro-gu, Seoul, Republic of Korea</p> <p>Net wt. 0.85oz (24g)</p> | <p>Supplement Facts</p> <p>Serving Size : 1 Capsule 0.85 oz Serving Per Container : 30 Total Calories 95kcal</p> <table border="1"> <thead> <tr> <th></th> <th>Amount Per Serving</th> <th>% Daily Value</th> </tr> </thead> <tbody> <tr> <td>Carbohydrate</td> <td>22g</td> <td>7%</td> </tr> <tr> <td>Fat</td> <td>0.7g</td> <td>1%</td> </tr> <tr> <td>Sugars</td> <td>1g</td> <td>1%</td> </tr> <tr> <td>Lactobacillus gasseri HHuMin</td> <td>24g</td> <td>**</td> </tr> <tr> <td>Lactobacillus fermentum OK</td> <td>72mg</td> <td>**</td> </tr> </tbody> </table> <p>** Daily Value not established.</p> <p>Made in Korea www.cleanery.co.kr</p> | | Amount Per Serving | % Daily Value | Carbohydrate | 22g | 7% | Fat | 0.7g | 1% | Sugars | 1g | 1% | Lactobacillus gasseri HHuMin | 24g | ** | Lactobacillus fermentum OK | 72mg | ** |
|---|--|---------------|--------------------|---------------|--------------|-----|----|-----|------|----|--------|----|----|------------------------------|-----|----|----------------------------|------|----|
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| <p>Ingredients</p> <p>Oligosaccharide 3(Palatinos, Maltitol Syrup, Galacto-oligosaccharide), Xylitol, Isomalt, Maltodextrin, Grape extract, Vitamin C, Magnesium Stearate, Calcium Pantothenate, Silicon Dioxide, Vitamin E, Vitamin K2, Collagen</p> |
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ORABALANCE DENTALCARE

lactobacillus gasseri hhuman, lactobacillus fermentum ok tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82690-401 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------------|----------------|
| LACTOBACILLUS GASSERI (UNII: Q66E0D2443) (LACTOBACILLUS GASSERI - UNII:Q66E0D2443) | LACTOBACILLUS GASSERI | 24 mg in 100 g |
| LIMOSILACTOBACILLUS FERMENTUM (UNII: 2C1F12C6AP) (LIMOSILACTOBACILLUS FERMENTUM - UNII:2C1F12C6AP) | LIMOSILACTOBACILLUS FERMENTUM | 72 mg in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| MENAQUINONE 6 (UNII: 71ANL51TLA) | |
| COLLAGEN, SOLUBLE, FISH SKIN (UNII: 8JC99XGU4W) | |
| CALCIUM PANTOTHENATE (UNII: 568ET80C3D) | |
| CITRUS PARADISI WHOLE (UNII: 3FNT9K2294) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| ALPHA-TOCOPHEROL (UNII: H4N855PNZ1) | |
| ISOMALTULOSE ANHYDROUS (UNII: V59P50X4UY) | |
| 4'-GALACTOSYLLACTOSE (UNII: B8CW1B3F6R) | |
| MALTITOL (UNII: D65DG142WK) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| ISOMALT (UNII: S870P55O2W) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |

Product Characteristics

| | | | |
|-----------------|-----------|---------------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 13mm |
| Flavor | SPEARMINT | Imprint Code | blank |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:82690-401-01 | 24 g in 1 BOX; Type 0: Not a Combination Product | 07/13/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 07/13/2022 | |

Labeler - isamogu Inc. (695695834)

