

**ORABALANCE BREATHCARE- 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.*

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**82690-402  
OraBalance Breathcare**

**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 at once

## Inactive Ingredients

Isomalt, Oligosaccharide 3(Palatinos, Maltitol Syrup, Galacto-oligosaccharide), Xylitol, Maltodextrin, Spearmint extract, Magnesium Stearate, Bifidobacterium bifidum BGN4, Bifidobacterium animalis ssp. lactis AD011, Bifidobacterium longum BORI, vitamin C, Nicotinamide, Calcium Pantothenate, vitamin B2, Vitamin B1 Hydrochloride, Vitamin B6 Hydrochloride, Gum arabic, Saccharose, Corn Starch, Processed Fat, Silicon Dioxide, Vitamin D3, Vitamin E, Dextrin, Sodium Citrate, Citric Acid, VitaminB12

## label

82690-402

OraBalance Breathcare



**A**

<b>Drug Facts</b> <b>Active Ingredients</b> Lactobacillus gasseri HHuMin .....7% Lactobacillus fermentum OK .....3%		<b>Purpose</b> Eliminate Bad Breath
<b>Uses</b> Improve oral health care		
<b>Warnings</b> 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.		
<b>Stop use and ask a doctor if</b> Irritation or rash appears and lasts.		
<b>Keep out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center immediately.		
<b>Directions</b> Melt one tablet slowly in your mouth at once		
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<b>Distributed by</b> samogu Inc, 403, 111, Digital-ro 26-gil, Guro-gu, Seoul, Republic of Korea		<b>Net wt.</b> 0.85oz (24g)

  

<b>Supplement Facts</b> Serving Size : 1 Capsule 0.85 oz Serving Per Container : 30 Total Calories 95kcal																	
<table border="1"> <thead> <tr> <th>Amount Per Serving</th> <th>% Daily Value</th> </tr> </thead> <tbody> <tr> <td>Carbohydrate</td> <td>22g 7%</td> </tr> <tr> <td>Fat</td> <td>0.7g 1%</td> </tr> <tr> <td>Sugars</td> <td>12g 12%</td> </tr> <tr> <td>Protein</td> <td>1g 2%</td> </tr> <tr> <td>Sodium</td> <td>5mg 0%</td> </tr> <tr> <td>Lactobacillus gasseri HHuMin</td> <td>56g **</td> </tr> <tr> <td>Lactobacillus fermentum OK</td> <td>24mg **</td> </tr> </tbody> </table>		Amount Per Serving	% Daily Value	Carbohydrate	22g 7%	Fat	0.7g 1%	Sugars	12g 12%	Protein	1g 2%	Sodium	5mg 0%	Lactobacillus gasseri HHuMin	56g **	Lactobacillus fermentum OK	24mg **
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**B**

**Ingredients**  
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# ORABALANCE BREATHCARE

lactobacillus gasseri hhuman, lactobacillus fermentum ok tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82690-402
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LACTOBACILLUS GASSERI</b> (UNII: Q66E0D2443) (LACTOBACILLUS GASSERI - UNII:Q66E0D2443)	LACTOBACILLUS GASSERI	56 mg in 100 g
<b>LIMOSILACTOBACILLUS FERMENTUM</b> (UNII: 2C1F12C6AP) (LIMOSILACTOBACILLUS FERMENTUM - UNII:2C1F12C6AP)	LIMOSILACTOBACILLUS FERMENTUM	24 mg in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41)	
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR)	
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV)	
<b>THIAMINE HYDROCHLORIDE</b> (UNII: M572600E5P)	
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>ISOMALTULOSE ANHYDROUS</b> (UNII: V59P50X4UY)	
<b>MALTITOL</b> (UNII: D65DG142WK)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>BIFIDOBACTERIUM BIFIDUM BGN4</b> (UNII: YHK9HJP3KK)	
<b>4'-GALACTOSYLLACTOSE</b> (UNII: B8CW1B3F6R)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>SPEARMINT</b> (UNII: J7I2T6IV1N)	
<b>BIFIDOBACTERIUM LONGUM</b> (UNII: 831AQW699W)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>CALCIUM PANTOTHENATE</b> (UNII: 568ET80C3D)	
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204)	
<b>BIFIDOBACTERIUM ANIMALIS LACTIS</b> (UNII: 5307V7XW8I)	
<b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)	
<b>ISOMALT</b> (UNII: S870P55O2W)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>	SPEARMINT	<b>Imprint Code</b>	blank
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82690-402-01	24 g in 1 BOX; Type 0: Not a Combination Product	08/02/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/02/2022	

**Labeler** - isamogu Inc. (695695834)

**Registrant** - isamogu Inc. (695695834)

### Establishment

Name	Address	ID/FEI	Business Operations
isamogu Inc.		695695834	manufacture(82690-402)

Revised: 8/2022

isamogu Inc.