# BIOVITA- bacillus subtilis, thiamine mononitrate, riboflavin, ascorbic acid, niacinamide, calcium phosphate, dibasic, dihydrate granule OASIS TRADING

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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Active ingredients (1g contains)
Bacillus subtilis 3.0 mg
Thiamine Nitrate 0.3 mg
Riboflavin 0.2 mg
Ascorbic Acid 5.0 mg
Nicotinamide 0.1 mg
Dibasic Calcium Phosphate Hydrate 20.0 mg

Digestion, Vitamins, and Calcium

Probiotic Digestion and Vitamin Supplement for babies.

Administer the following dose 4 times daily in water, milk or weaning baby food.

Infants: 1g / 1-2 years: 2g /3-4 years: 3g / 5-7 years: 4g

Infants: It is recommended to be taken BIOVITA which is dissolved in mild milk or water.

Bottle-fed infants: It is recommended to be taken BIOVITA and powdered milk which are mixed with mild water.

Do not administer this product to patients who are Galactose intolerance, Lapp lactase deficiency, or Glucose-glalactose malabsorption.

BIOVITA should be used carefully with patients under medical conditions.

Follow the dosage recommendations.

If symptoms do not improve after two weeks to one month, it is recommended to consult with physician or pharmacist.

Consult with a doctor or pharmacist for baby who is under 3 months that is administered with this product.

Keep in a dry and cool place without direct sunlight.

Keep out of reach of the children.

Lactose Hydrate, *Lactobacillus sporogenes*, *Clostridium butyricum* Miyairi, Sucrose, Citric Acid Hydrate, Vanillin, Dried Yeast

### **BIOVITA Granules**

Drug Facts	
Active Ingredients (per 1g)	Purpose
Bacillus subtilis 3.0mg	Digestion
Thiamine Nitrate 0.3mg	Vitamin B <sub>1</sub>
Riboflavin 0.2mg	Vitamin B <sub>1</sub>
Ascorbic Acid 5.0mg	Vitamin C
Nicotinamide 0.1mg	Vitamin B <sub>1</sub>
Dibasic Calcium Phosphate Hydrate 20.0mg	Calcium

#### Uses

Probiotic Digestion and Vitamin Supplement for babies.

#### Warnings

- Do not administer this product to patients who are Galactose intolerance, Lapp lactase deficiency, or Glucose-glalactose malabsorption.
- BIOVITA should be used carefully with patients under medical conditions.
- Follow the dosage recommendations.
- If symptoms do not improve after two weeks to one month, it is recommended to consult with physician or pharmacist.
- Consult with a doctor or pharmacist for baby who is under 3 months that is administered with this product.

#### Directions

- Administer the following dose 4 times daily in water, milk or weaning baby food.
- Infants: 1g / 1-2 years: 2g /3-4 years: 3g / 5-7 years: 4g
- Infants: It is recommended to be taken BIOVITA which is dissolved in mild milk or water.
- Bottle-fed infants: It is recommended to be taken BIOVITA and powdered milk which are mixed with mild water.

#### Other Information

Keep in a dry and cool place without direct sunlight.

#### Inactive Ingredient

Lactose Hydrate, Lactobacillus sporogenes, Clostridium butyricum Miyairi, Sucrose, Citric Acid Hydrate, Vanillin, Dried Yeast

#### Questions or comments ?

Call weekdays from 9 a.m to 5 p.m EST at (201) 669-8405

Distributed By: P&K FRONTIER MARKETING CORP.

329 BROAD AVENUE # 2F, PALISADES PARK, NJ 07650, USA

Made in South Korea

#### **BIOVITA**

bacillus subtilis, thiamine mononitrate, riboflavin, ascorbic acid, niacinamide, calcium phosphate, dibasic, dihydrate granule

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72689-0032	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BACILLUS SUBTILIS (UNII: 8CF93KW41W) (BACILLUS SUBTILIS - UNII:8CF93KW41W)	BACILLUS SUBTILIS	3 mg in 1 g	
CALCIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP) (ANHYDROUS DIBASIC CALCIUM PHOSPHATE - UNII:L11K75P92J)	CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE	20 mg in 1 g	

THIAMINE MONONITRATE (UNII: 8K0 I0 49 19 X) (THIAMINE ION - UNII:4ABT0 J9 45 J)	THIAMINE	0.3 mg in 1 g
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	0.2 mg in 1 g
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	5 mg in 1 g
NIACINAMIDE (UNII: 25X5118 RD4) (NIACINAMIDE - UNII:25X5118 RD4)	NIACINAMIDE	0.1 mg in 1 g

Inactive Ingredients				
Ingredient Name	Strength			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
SUCROSE (UNII: C151H8 M554)				
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)				
VANILLIN (UNII: CHI530446 X)				
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)				
BACILLUS COAGULANS (UNII: ISK1LOY57E)				

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:72689-0032-1 120 g in 1 JAR; Type 0: Not a Combination Product		12/25/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		12/25/20 18		

## Labeler - OASIS TRADING (689991468)

## Registrant - OASIS TRADING (689991468)

Establishment			
Name	Address	ID/FEI	Business Operations
ILDONG PHARMACEUTICAL CO., LTD.		689846555	manufacture(72689-0032)

Establishment				
Name	Address	ID/FEI	Business Operations	
OASIS TRADING		689991468	label(72689-0032)	

Revised: 1/2019 OASIS TRADING