

PROBICHEW PROBIOTIC SUPPORT- bacillus coagulans and fiber bar, chewable
Basiem, LLC

Probichew

STATEMENT OF IDENTITY

PROBICHEW Dietary Supplement

Dispensed by Prescription

Amount Per Serving: %DV		
Bacillus Coagulans	21 Billion	*
Dietary Fiber (as Inulin)	1 gram	4%

*Daily Values (DV) not established

Supplement Facts		
Serving Size: 1 Chew Servings per container: 30		
Amount Per Serving		% DV
Calories	15	
Total Fat†	1 g	1%*
Total Carbohydrate	4 g	1%*
Dietary Fiber (as Inulin)	1 g	4%
Total Sugars	0 g	**
Includes 0g Added Sugars		0%*
Sugar Alcohol	3 g	**
Calcium	2 mg	> 1%
Sodium	20 mg	1%
Potassium	2 mg	> 1%
Bacillus Coagulans (21 Billion CFUs)		**

*% Daily Values are based on a 2,000 calorie diet.
**Daily Value not established.
† <0.5 mg Saturated Fat

OTHER INGREDIENTS: Sodium, Potassium, Calcium, Sugar Alcohol, Maltitol Syrup, Inulin, Palm Oil, Gum Arabic, Mono and Diglycerides, Sunflower Lecithin, Sea Salt, Natural Flavor, Stevia Extract, Whey Protein Isolate

PROBICHEW is an orally administered prescription probiotic/prebiotic formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

PROBICHEW should be administered under the supervision of a licensed medical practitioner.

PROBICHEW is manufactured in accordance with Current Good Manufacturing Practice for foods, using ingredients that have been approved by the U.S. Food and Drug

Administration (FDA) as food additives or are Generally Recognized as Safe (GRAS) for their intended use

DOSAGE

Usual adult dose is 1 chew once or twice daily, or as prescribed by a licensed medical practitioner.

If you are pregnant or nursing, ask a healthcare professional.

PROBICHEW should be administered under the supervision of a licensed medical practitioner.

DIRECTIONS FOR USE: REMOVE FOIL BEFORE CONSUMING CHEW. Consume entire chew or as directed by a healthcare professional.

SAFE HANDLING

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

PROBICHEW chews should only be used under the direction and supervision of a licensed medical practitioner. Use with caution in patients that may have a medical condition, are pregnant, lactating, trying to conceive, under the age of 18, or taking medications.

KEEP OUT OF REACH OF CHILDREN

STORAGE

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.]

HOW SUPPLIED HEALTH CLAIM

PROBICHEW, Probiotic/Prebiotic Support

Dietary Supplement

Chews are beige in color and individually wrapped in a bronze and silver foil.

Bottles contain 30 Chews 69597-350-30*

Manufactured in USA for:

Basiem, LLC

Madisonville, LA 70447

Rev. 12/2019

*Basiem does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.

† The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product by prescription. This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product are not to be construed to be drug claims.

PRINCIPAL DISPLAY PANEL - 30 Chew Label

PROBICHEW should be administered under the supervision of a licensed medical practitioner.

Usual Dosage: Usual adult dose is 1 chew once or twice daily or as prescribed by a licensed medical practitioner.


If you are pregnant or nursing, ask a healthcare professional.

KEEP OUT OF REACH OF CHILDREN

Storage: Store in a cool, dry place.

Distributed by: Solubiomix, LLC
Madisonville, LA 70447

MANUFACTURED IN USA
Rev. 12/2019




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69597-352-30

ProbiChew

**PROBIOTIC/
PREBIOTIC SUPPORT
DIETARY SUPPLEMENT**

**BACILLUS COAGULANS
AND FIBER**
21 Billion CFU's
Caramel Flavor



30 Chews

Lift Here

Supplement Facts

Serving Size 1 Chew Servings per container 30

	Amount Per Serving	% Daily Value
Calories	15	
Total Fat	1 g	1%*
Saturated Fat	0 g	0%
Total Carbohydrate	4 g	1%*
Dietary Fiber (as Inulin)	1 g	4%
Total Sugars	0 g	**
Includes 0g Added Sugars		0%*
Sugar Alcohol	3 g	**
Calcium	2 mg	> 1%
Sodium	20 mg	1%
Potassium	2 mg	> 1%
Bacillus Coagulans (21 Billion CFUs)		**

*% Daily Values are based on a 2,000 calorie diet.
**Daily Value not established.

OTHER INGREDIENTS Maltitol Syrup, Inulin, Palm Oil, Gum Arabic, Mono and Diglycerides, Sunflower Lecithin, Sea Salt, Natural Flavor, Stevia Extract, Whey Protein Insolate.

PROBICHEW PROBIOTIC SUPPORT

bacillus coagulans and fiber bar, chewable

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69597-352
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACILLUS COAGULANS (UNII: ISK1LOY57E) (BACILLUS COAGULANS - UNII:ISK1LOY57E)	BACILLUS COAGULANS	21000000000 [CFU]
INULIN (UNII: JOS53KRJ01) (INULIN - UNII:JOS53KRJ01)	INULIN	1000 mg

Inactive Ingredients

Ingredient Name	Strength
MALTITOL (UNII: D65DG142WK)	
PALM OIL (UNII: 5QUO05548Z)	
ACACIA (UNII: 5C5403N26O)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
SEA SALT (UNII: 87GE52P74G)	

STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
WHEY PROTEIN HYDROLYSATE (UNII: 237DZG2JLA)	
SODIUM (UNII: 9NEZ333N27)	
POTASSIUM (UNII: RWP5GA015D)	
CALCIUM (UNII: SY7Q814VUP)	
MANNITOL (UNII: 3OWL53L36A)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69597-352-30	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		12/06/2019	

Supplement Facts		
Serving Size :	Serving per Container :	
	Amount Per Serving	% Daily Value
scoring	1	
shape		
size (solid drugs)	28 mm	
flavor		
color		

Labeler - Basiem, LLC (079686680)