

**XYBIOTIC PROBIOTIC SUPPORT- bacillus coagulans, lactobacillus acidophilus and fiber capsule**  
**Solubiomix, LLC**

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**Xybiotic**

**STATEMENT OF IDENTITY**

**XYBIOTIC Dietary Supplement**

Dispensed by Prescription

**Serving Size: 1 Capsule**

**Servings per container: 30**

<b>Amount Per Serving: %DV</b>		
Folic Acid		
Probiotic Blend	1667 mcg DFE (1 mg)	417%*
( <i>Lactobacillus acidophilus</i> 220 mg, <i>Bacillus Coagulans</i> 220 mg)	15 Billion CFU	
Dietary Fiber (as Inulin)	25 mg	*
*Daily Values (DV) not established		

OTHER INGREDIENTS: whey (milk), capsule (gelatin), magnesium stearate. **CONTAINS: Milk**

**Gluten Free**

XYBIOTIC 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.#

**These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.**

XYBIOTIC 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 capsule once or twice daily, or as prescribed by a licensed medical practitioner.

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

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

## **SAFE HANDLING**

**PRECAUTION**Folic acid in doses above 1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.† XYBIOTIC Capsules should only be used under the direction and supervision of a licensed medical practitioner.‡

**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

Each bottles contains 30 Capsules (white) 69499-352-30#

Manufactured in USA for:

Solubiomix, LLC

Madisonville, LA 70447

Rev. 05/2022

# Solubiomix does not represent these product code 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.

‡ This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels increased risk associated with masking of B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (61 FR 8760).1-3 The most appropriate way to ensure pedigree reporting

consistent with these regulatory guidelines and safety monitoring is to dispense this product only 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.

1. Federal Register Notice of August 2, 1973 (38 FR 20750)
2. Federal Register Notice of October 17, 1980 (45 FR 69043, 69044)
3. Federal Register Notice of March 5, 1996 (61 FR 8760)

PRINCIPAL DISPLAY PANEL

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

**Usual Dosage:** Usual adult dose is 1 capsule 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 at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.

**Distributed by:** Solubiomix, LLC  
Madisonville, LA 70447

MANUFACTURED IN USA Rev. 04/2022

69499-352-30

**Xybiotic**

**Probiotic/Prebiotic Support Dietary Supplement**

**Bacillus Coagulans and Fiber**

**15 Billion CFU's**

Dispensed by Prescription



**SOLUBIOMIX**  
INNOVATING HEALTH SOLUTIONS

**Contents: 30 Capsules**

**Supplement Facts**

Serving Size: 1 Capsule  
Servings per container: 30

Amount Per Serving:	% Daily Value
Folate (from 1000 mcg folic acid)	1667 mcg 417% DFE
Probiotic 15 billion CFU + blend ( <i>Lactobacillus acidophilus</i> 220 mg, <i>Bacillus Coagulans</i> 220 mg)	440 mg *
Organic agave inulin (prebiotic)	25 mg *

\*Daily Value not established. + at the time of manufacture

**OTHER INGREDIENTS:** whey (milk), capsule (gelatin), magnesium stearate

**CONTAINS:** Milk  
Gluten Free

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XYBIOTIC PROBIOTIC SUPPORT			
bacillus coagulans, lactobacillus acidophilus and fiber capsule			
Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69499-352
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BACILLUS COAGULANS (UNII: ISK1LOY57E) (BACILLUS COAGULANS - UNII:ISK1LOY57E)		BACILLUS COAGULANS	220 mg
INULIN (UNII: JOS53KRJ01) (INULIN - UNII:JOS53KRJ01)		INULIN	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)		FOLIC ACID	1 mg
LACTOBACILLUS ACIDOPHILUS (UNII: 1PRR1V42V5) (LACTOBACILLUS ACIDOPHILUS - UNII:1PRR1V42V5)		LACTOBACILLUS ACIDOPHILUS	220 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>WHEY</b> (UNII: 8617Z5FMF6)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69499-352-30	30 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		04/25/2022	

## Supplement Facts

**Serving Size :** **Serving per Container :**

	Amount Per Serving	% Daily Value
scoring	1	
shape		
size (solid drugs)	22 mm	
color		

**Labeler -** Solubiomix, LLC (079640556)

Revised: 10/2024

Solubiomix, LLC