

**PROMELLA- lactobacillus acidophilus, bifidobacterium animalis lactis capsule**  
**Amella Pharma, LLC**

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**Promella in Prebiotic Capsules**  
**Dietary Supplement**

**HEALTH CLAIM:**

Promella in Prebiotic Capsules Dietary Supplement  
Dispensed by Prescription

| <b>Supplement Facts</b>   |                      |
|---|----------------------|
| Serving Size: 2 Capsules  |                      |
| Servings Per Container: 28  |                      |
| <b>Amount Per Serving:</b>  | <b>% Daily Value</b> |
| Probiotic blend<br>(Lactobacillus acidophilus, Bifidobacterium animalis lactis) | 64 billion cfu **    |
| ** Daily values not established   |                      |

Other Ingredients: Hypromellose (capsule) and Inulin.

**DESCRIPTION**

Promella in Prebiotic is an orally administered prescription probiotic 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.

Promella in Prebiotic should be administered under the supervision of a licensed medical practitioner.

**WARNINGS AND PRECAUTIONS**

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

Promella in Prebiotic 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.

**DOSAGE AND ADMINISTRATION**

Usual adult dose is 1 to 2 capsule(s) by mouth daily with or without food.

**INDICATIONS AND USAGE**

Promella in Prebiotic is an orally administered prescription probiotic 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.

## HOW SUPPLIED:

Promella in Prebiotic is supplied as clear capsules dispensed in HDPE plastic bottles of 56ct.  
72287-521-56

Reserved for Professional Recommendation

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision. There are no implied or explicit claims on therapeutic equivalence.

Manufactured for:  
Amella Pharma, LLC  
East Brunswick, NJ 08816  
04/2020 AP7002v1

## STORAGE:

Product is sensitive to moisture and heat. Keep bottle tightly closed in a dry, cool place, not exceeding room temperature 25°C (77°F). Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088.

KEEP THIS OUT OF THE REACH OF CHILDREN.

Probiotic Support

32 Billion CFU Capsules

Do NOT remove the desiccant from the container.

1-844-385-0850

## PACKAGING

**USUAL DOSAGE:** Usual adult dose is 1 to 2 capsule(s) by mouth daily with or without food or as directed by a healthcare professional.

Promella in Prebiotic should be administered under the supervision of a licensed medical practitioner. If you are pregnant or nursing, ask a healthcare professional prior to using.

**KEEP OUT OF THE REACH OF CHILDREN.**

**STORAGE:** Product is sensitive to moisture and heat. Keep bottle tightly closed in a dry, cool place, not exceeding room temperature 25°C (77°F).

Do NOT remove the desiccant from the container.

03/2020 AP7001v1  
  
Manufactured for: Amella Pharma, LLC  
East Brunswick, NJ 08816 1-844-385-0850

72287-0521-56

**Promella** in Prebiotic  
Probiotic Support

32 Billion CFU Capsules

LACTOBACILLUS & BIFIDOBACTERIUM

DIETARY SUPPLEMENT

56 Capsules

## Supplement Facts

Serving Size: 2 Capsules  
Servings Per Container: 28

| Amount Per Serving:  | % Daily Value     |
|--|-------------------|
| Probiotic blend<br>(Lactobacillus acidophilus,<br>Bifidobacterium animalis lactis) | 64 billion cfu ** |

\*\* Daily Value not established

OTHER INGREDIENTS: Hypromellose (capsule) and Inulin.



VARNISH FREE ZONE FOR  
EXPIRATION AND LOT #

## PROMELLA

lactobacillus acidophilus, bifidobacterium animalis lactis capsule

## Product Information

|                                |                    |                           |                 |
|--------------------------------|--------------------|---------------------------|-----------------|
| <b>Product Type</b>            | DIETARY SUPPLEMENT | <b>Item Code (Source)</b> | NHRIC:72287-521 |
| <b>Route of Administration</b> | ORAL               |                           |                 |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength               | Strength          |
|--|---------------------------------|-------------------|
| LACTOBACILLUS ACIDOPHILUS (UNII: 1PRR1V42V5) (LACTOBACILLUS ACIDOPHILUS - UNII:1PRR1V42V5)             | LACTOBACILLUS ACIDOPHILUS       | 16000000000 [CFU] |
| BIFIDOBACTERIUM ANIMALIS LACTIS (UNII: 5307V7XW8I) (BIFIDOBACTERIUM ANIMALIS LACTIS - UNII:5307V7XW8I) | BIFIDOBACTERIUM ANIMALIS LACTIS | 16000000000 [CFU] |

**Inactive Ingredients**

| Ingredient Name                              | Strength |
|--|----------|
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) |          |
| INULIN (UNII: JOS53KRJ01)                    |          |

**Packaging**

| # | Item Code          | Package Description | Marketing Start Date | Marketing End Date |
|---|--------------------|---------------------|----------------------|--------------------|
| 1 | NHRIC:72287-521-56 | 56 in 1 BOTTLE      |                      |                    |

**Marketing Information**

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| dietary supplement |  | 04/21/2020           |                    |

| <b>Supplement Facts</b> |                                |                      |
|-------------------------|--------------------------------|----------------------|
| <b>Serving Size :</b>   | <b>Serving per Container :</b> |                      |
|                         | <b>Amount Per Serving</b>      | <b>% Daily Value</b> |
| color                   |                                |                      |
| shape                   |                                |                      |
| size (solid drugs)      | 20 mm                          |                      |
| scoring                 | 1                              |                      |

**Labeler** - Amella Pharma, LLC (081189492)