

PROBENTRA- probiotic dietary supplement capsules capsule

Oncora Pharma, LLC

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.

Probentra

DESCRIPTION

Probentra™ is a prescription-dispensed oral probiotic dietary supplement formulated to support gastrointestinal health and maintain normal intestinal flora. Each serving (two capsules) delivers 40 billion colony-forming units (CFU) of beneficial probiotic organisms combined with marine polysaccharide and fructooligosaccharide (FOS).

The proprietary probiotic blend includes:

- Lactobacillus acidophilus (La-14®)
- Bifidobacterium lactis (BI-04®)
- Lactobacillus plantarum (Lp-115®)
- Lactobacillus paracasei (Lpc-37®)

The formulation utilizes MAKTreK® Bi-Pass Technology to support probiotic viability during gastrointestinal transit.

Probentra™ is intended for use under the supervision of a licensed healthcare practitioner.

INDICATIONS AND USAGE

Probentra™ is indicated as a probiotic dietary supplement to support digestive health and promote balance of normal intestinal microflora.

It is dispensed by prescription and intended for use under medical supervision as part of a dietary supplementation plan.

(Notice: no disease treatment claims — this keeps you clean in Rx dietary supplement lane.)

DOSAGE AND ADMINISTRATION

Adults: Take two (2) capsules once daily, or as directed by a licensed healthcare practitioner.

CONTRAINDICATIONS

Probentra™ is contraindicated in individuals with known hypersensitivity to any of its ingredients.

WARNINGS AND PRECAUTIONS

- If pregnant, nursing, or attempting to conceive, consult a licensed healthcare professional prior to use.
- Keep out of reach of children.
- Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under six years of age. In case of accidental overdose, call a physician or poison control center immediately.

ADVERSE REACTIONS

Probiotic supplementation may occasionally result in mild gastrointestinal symptoms such as bloating, gas, or abdominal discomfort. If adverse reactions occur, discontinue use and consult a healthcare professional.

HOW SUPPLIED

Probentra™ (NDC 85477-712-30) is supplied in bottles of 30 capsules.

STORAGE

Store at 20°–25°C (68°–77°F); excursions permitted to 15°–30°C (59°–86°F). Protect from excessive heat, moisture, and light.

Principal Display Panel

85477-712-30

Probentra

40 Billion CFU

30 Capsules

Dispensed by Prescription

DOSAGE AND ADMINISTRATION:
Usual adult dose is 2 capsules once daily or as prescribed by a licensed medical practitioner.

If you are pregnant, lactating, or trying to conceive, consult with your licensed healthcare professional.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. In case of accidental overdose, call a doctor or poison control center immediately.

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). Avoid excessive heat, light, moisture, and exceeding 85% humidity.

85477-712-30
Probentra™

40 Billion CFU
30 Capsules
Dispensed by Prescription

Supplement Facts		
Serving Size: 2 Capsules		
Servings Per Container: 15		
	Amount Per Serving	%DV
Proprietary Blend of Probiotic Bacteria: MAKTREX®(Bi-Pass Technology) Lactobacillus Acidophilus (Ls-14) Bifidobacterium Lactis (Bf-04) Lactobacillus Plantarum (Lp-115) Lactobacillus Paracasei (Lpc-37)	800mg (40 Billion CFU)	**
Complex Marine Polysaccharide	60 mg	**
Fructooligosaccharide	24 mg	**

*Percent Daily Values are based on a 2,000 calorie diet
**Daily Value (DV) not established.

Other Ingredients: Hypromellose (capsule), Rice maltodextrin, L-Leucine

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Oncora Pharma
Manufactured for:
Oncora Pharma
Dallas, TX, 75228

PROBENTRA

probiotic dietary supplement capsules capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:85477-712
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LACTOBACILLUS ACIDOPHILUS LA 14 (UNII: D4S8K64J5Z) (LACTOBACILLUS ACIDOPHILUS LA 14 - UNII:D4S8K64J5Z)	LACTOBACILLUS ACIDOPHILUS LA 14	400 mg
BIFIDOBACTERIUM ANIMALIS LACTIS BL04 (UNII: K1YRS2QLN2) (BIFIDOBACTERIUM ANIMALIS LACTIS BL04 - UNII:K1YRS2QLN2)	BIFIDOBACTERIUM ANIMALIS LACTIS BL04	400 mg
LACTIPLANTIBACILLUS PLANTARUM (UNII: QFC21096ON) (LACTIPLANTIBACILLUS PLANTARUM - UNII:QFC21096ON)	LACTIPLANTIBACILLUS PLANTARUM	400 mg
LACTICASEIBACILLUS PARACASEI LPC-37 (UNII: GXW9U52VV9) (LACTICASEIBACILLUS PARACASEI LPC-37 - UNII:GXW9U52VV9)	LACTICASEIBACILLUS PARACASEI LPC-37	400 mg
LESSONIA NIGRESCENS (UNII: HTV58LVI9P) (LESSONIA NIGRESCENS - UNII:HTV58LVI9P)	LESSONIA NIGRESCENS	30 mg
BETA VULGARIS ROOT FRUCTOOLIGOSACCHARIDES (UNII: N2UDM48ZD6) (BETA VULGARIS ROOT FRUCTOOLIGOSACCHARIDES - UNII:N2UDM48ZD6)	BETA VULGARIS ROOT FRUCTOOLIGOSACCHARIDES	12 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
LEUCINE (UNII: GMW67QNF9C)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85477-712-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/23/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/23/2026	

Labeler - Oncora Pharma, LLC (119482542)

