

PRENYRA- prenyra tablet
Oncora Pharma, LLC

Prenyra

Health Claim

Prenyra Tablets - Prenatal/Postnatal/Folate Health Dietary Supplement
Dispensed by Prescription

SUPPLEMENTAL FACTS		
Serving size: 1 tablet		
Serving Per Container: 30		
Amount Per Serving:		% Daily Value
Vitamin C (as ascorbic acid)	125mg	104%
Vitamin D (as cholecalciferol)	12.5mcg (500 IU)	83%
Thiamine (as hydrochloride)	1.4mg	100%
Vitamin B6 (as pyridoxal-5-phosphate)	2.5mg	125%
Folate	1,666 DFE (1 mg folic acid)	278%
Vitamin B12 (as methylcobalamin)	1,000 mcg	35,714%
Calcium (from calcium carbonate)	200 mg	15%
Iron (as ferrous gluconate)	13 mg	48%
Iodine (as potassium iodide)	150 mcg	52%

**Other Ingredients: Microcrystalline Cellulose,
Magnesium Stearate, Silica, Glycerin, Vanilla Extract.**

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Description

Prenyra Tablets is an orally administered prescription vitamin formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced folate supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

Warnings

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal

poisoning in children under 6. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

CONTRAINDICATIONS: Prenyra Tablets are contraindicated in patients with a known hypersensitivity to any of the ingredients. Do not take this product if you are presently taking mineral oil, unless directed by a doctor.

Precaution

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B is deficient. Folic acid in doses above 1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. Prenyra Tablets should only be used under the direction and supervision of a licensed medical practitioner.

For external use only

Dosage & Administration

Usual adult dose is 1 tablet taken orally once or twice daily or as prescribed by a licensed medical practitioner.

STORAGE: Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.] Protect from heat, light and moisture.

Tamper Evident: Do not use if seal is broken or missing.

Manufactured for:

Oncora Pharma LLC

Dallas TX 75228

Principal Display Panel

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NDC 85477-923-30 Rx Only



— PRENATAL/POSTNATAL VITAMIN —

DIETARY SUPPLEMENT
Dispensed by Prescription

30 Tablets

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Distributed by:
Oncora Pharma
Dallas, TX 75228
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LOT:
EXP:

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PRENYRA

prenyra tablet

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:85477-923
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	125 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	.0125 mg
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (Thiamine ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	1.4 mg
PYRIDOXAL 5-PHOSPHATE (UNII: F06SGE49M6) (PYRIDOXAL 5-PHOSPHATE - UNII:F06SGE49M6)	PYRIDOXAL 5-PHOSPHATE	2.5 mg
IODIDE ION (UNII: 09G4I6V86Q) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	.15 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg

METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	1 mg
FERROUS GLUCONATE (UNII: U1B11I423Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	13 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6Z B)	CALCIUM CARBONATE	13 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICA (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:85477-923-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		04/01/2026	

Supplement Facts

Serving Size :		Serving per Container :	
	Amount Per Serving		% Daily Value
color			
scoring	1		
shape			
size (solid drugs)	19 mm		

Labeler - Oncora Pharma, LLC (119482542)

Registrant - Solubiomix (079640556)