

**PRENARA- prenara capsule**  
**Sterling-Knight Pharmaceuticals, 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](#).*

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**Prenara Capsules**  
**Dietary Supplement**

**DESCRIPTION:**

Prenara is an orally administered prescription dietary supplement 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.

Prenara is a prescription dietary supplement for use throughout pregnancy, during the prenatal and postnatal period for both lactating and non-lactating mothers and throughout the childbearing years. Prenara should be administered under the supervision of a licensed medical practitioner.

**Each softgel capsule contains:**

# SUPPLEMENT FACTS

Serving Size: 1 capsule

Servings Per Container: 30

Amount Per Serving		% Daily Value
Vitamin A (as beta carotene)	1000IU	20%
Vitamin C (as ascorbic acid)	100mg	167%
Vitamin D (as cholecalciferol)	750IU	188%
Vitamin E (as d-alpha-tocopheryl acetate)	30IU	100%
Vitamin B1 (as thiamin)	1.8mg	120%
Vitamin B2 (as riboflavin)	1.7mg	100%
Vitamin B3 (as niacinamide)	20mg	100%
Vitamin B6 (as pyridoxine HCl)	2.5mg	125%
Folate (as folic acid)	1mg	250%
Vitamin B12 (as cyanocobalamin)	500mcg	8333%
Calcium (as calcium carbonate)	100mg	10%
Iron (as ferrous fumarate)	15mg	83%
Iodine (potassium iodide)	150mcg	100%
Copper (cupric oxide)	2mg	100%
Magnesium (as oxide)	15mg	4%
Zinc (as oxide)	20mg	133%

\* Daily values not established

Other Ingredients: Soybean oil, gelatin (bovine), bees wax (yellow), lecithin, glycerin, deionized water, FD&C red #40, FD&C blue #1, titanium dioxide.

## INDICATIONS AND USAGE:

Prenara is a prescription dietary supplement for use throughout pregnancy, during the prenatal and postnatal period for both lactating and non-lactating mothers and throughout the childbearing years

## CONTRAINDICATIONS:

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

Prenara 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.

**WARNINGS AND PRECAUTIONS:**

This product should be administered with caution in patients with a history of liver disease, jaundice or diabetes mellitus.

Folic acid above 1mg daily may obscure pernicious anemia in that hematologic remission may occur while neurological manifestations remain progressive.

**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.**

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

**ADVERSE REACTION:**

Allergic sensitization has been reported following both oral and parental administration of folic acid.

**DOSAGE AND ADMINISTRATION:**

Usual dose is 1 to 2 capsules daily or as prescribed by licensed medical practitioner.

**HOW SUPPLIED:**

Prenara is supplied as a purple softgel capsules with 352 printed and dispensed in white HDPE plastic bottles of 30ct.

**69336-352-30**

**STORAGE:**

Store at controlled room temperature 15°-30°C (59°F-86°F). Keep in cool dry place. 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.**

**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:**

Sterling-Knight Pharmaceuticals, LLC  
Ripley, MS 38663

Item 35230

Rev. 0320-1

Prenara Label



DISPENSE BY PRESCRIPTION

69336-352-30

**Prepara**  
Full Spectrum Prenatal / Postnatal

30 CAPSULES  
DIETARY SUPPLEMENT

**Dosage:** Take 1 capsule once or twice daily or as directed by a physician

**INDICATIONS AND USAGE**

Prepara is an orally administered prescription folic Acid containing dietary supplement 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.

**KEEP OUT THE REACH OF CHILDREN.**

**Storage:** Store in controlled room temperature 15°-30° C (59°-86° F). Keep in cool dry place. Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088.



Rev 1218-1  
Item: 35230

**Supplement Facts**

Serving Size: 1 capsule  
Servings Per Container: 30

Amount Per Serving	% Daily Value	Amount Per Serving	% Daily Value
Vitamin A (as beta carotene)	1000IU 20%	Folate (as folic acid)	1mg 250%
Vitamin C (as ascorbic acid)	100mg 167%	Vitamin B12 (as cyanocobalamin)	500mcg 8333%
Vitamin D (as cholecalciferol)	750IU 188%	Calcium (as calcium carbonate)	100mg 10%
Vitamin E (as d-alpha-tocopherol acetate)	30IU 100%	Iron (as ferrous fumarate)	15mg 83%
Vitamin B1 (as thiamin mononitrate)	18mg 120%	Iodine (potassium iodide)	150mcg 100%
Vitamin B2 (as riboflavin)	17mg 100%	Copper (cupric oxide)	2mg 100%
Vitamin B3 (as niacinamide)	20mg 100%	Magnesium (as oxide)	15mg 4%
Vitamin B6 (as pyridoxine HCl)	25mg 125%	Zinc (as oxide)	20mg 153%

\* Daily values not established

**Other ingredients:** Soybean Oil, Gelatin (Bovine), Bees Wax (yellow), Lecithin, Glycerin, Deionized Water, FD&C Red #40, FD&C Blue #1, Titanium Dioxide.

**Manufactured for:**  
Sterling | Knight Pharmaceuticals, LLC  
Ripley, MS 38663

Prepara Carton



# PRENARA

prenara capsule

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:69336-352
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1000 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
VITAMIN D (UNII: 9VU1KI44GP) (CHOLECALCIFEROL - UNII:1C6V77QF41)	VITAMIN D	750 [iU]
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.8 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.7 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	2.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	0.5 mg
CALCIUM (UNII: SY7Q814VUP) (CALCIUM - UNII:SY7Q814VUP)	CALCIUM	100 mg
IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	0.15 mg
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	2 mg
MAGNESIUM (UNII: I38ZP9992A) (MAGNESIUM - UNII:I38ZP9992A)	MAGNESIUM	15 mg
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	20 mg

## Product Characteristics

Color	purple	Score	no score
Shape	capsule	Size	11mm
Flavor		Imprint Code	352
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69336-352-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/09/2020	

**Labeler** - Sterling-Knight Pharmaceuticals, LLC (079556942)

## Establishment

Name	Address	ID/FEI	Business Operations
Sterling-Knight Pharmaceuticals, LLC		079556942	manufacture(69336-352) , label(69336-352)

Revised: 3/2020

Sterling-Knight Pharmaceuticals, LLC