

**JENLIVA- ascorbic acid, cholecalciferol, thiamin, vitamin b6, folic acid, methylcobalamin, calcium carbonate, ferrous fumarate, iodine capsule**  
**Primary Pharmaceuticals, Inc.**

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**Jenliva**

**HEALTH CLAIM:**

Jenliva Capsules - Prenatal/Postnatal Dietary Supplement

Dispensed by Prescription

**Supplement Facts**

<b>Serving Size: 1 Capsule</b>		
Serving per Bottle: 30		
<b>Amount Per Serving:</b>		<b>% Daily Value</b>
Vitamin C (Ascorbic Acid)	125 mg	139%
Vitamin D (as Cholecalciferol)	12.5 mcg	63%
Thiamin (as Thiamin HCl)	1.4 mg	117%
Vitamin B6 (as Pyridoxine HCl)	2.5 mg	147%
Folate	1,666 mcg DFE (1000 mcg Folic Acid)	417%
Vitamin B12 (as Methylcobalamin)	1,000 mcg	41,667%
Calcium (from Calcium Carbonate)	200 mg	15%
Iron (as Ferrous Fumarate)	13 mg	72%
Iodine (as Potassium Iodide)	150 mcg	100%

**OTHER INGREDIENTS:** Hypromellose (Capsule), Rice Flour, and Magnesium Stearate.

**DESCRIPTION:**

Jenliva capsules are a prescription dietary supplement for use throughout pregnancy, during the postnatal period for both lactating and non-lactating mothers, and throughout the childbearing years. Jenliva capsules may be useful in improving the nutritional status of women prior to conception.

**WARNING AND PRECAUTIONS**

**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:**

Jenliva capsules 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. Jenliva capsules should only be used under the direction and supervision of a licensed medical practitioner.

**ADVERSE REACTIONS:**

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You may report side effects by calling the FDA at 1-800-FDA-1088.

**DOSAGE & ADMINISTRATION:**

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

**HOW SUPPLIED HEALTH CLAIM:**

Jenliva capsules are available as clear, standard-sized capsules and are available in 30-count bottles (72275-0301-30\*). This product is not an Orange Book product.

Dispensed by Prescription†

Manufactured for: Primary Pharmaceuticals, Inc Ocean Springs, MS 39564

Rev. 10/20

\*Primary Pharmaceuticals, Inc does not represent these product codes 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)

**STORAGE AND HANDLING:**

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.

Distributed by: Primary Pharmaceuticals, Inc , Ocean Springs, MS 39564.

## PRINCIPAL DISPLAY PANEL

**Jenliva**

**Prenatal/Postnatal**

**Dietary Supplement**

**DOSAGE:** Take one capsule daily by mouth or as directed by your physician.

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

Call your licensed medical practitioner about side effects. You may report side effects to Primary Pharmaceuticals or by calling 1-800-FDA-1088

**STORAGE:** Store at controlled room temperature - 20°-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F).

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



72275-301-30



**PRIMARY PHARMACEUTICALS**

# Jenliva

Prenatal/Postnatal  
Dietary Supplement

**30 Capsules**

**Supplement Facts**

Serving Size: 1 Veggie Capsule  
Servings per Container: 30

Amount per Serving	% Daily Value	
Vitamin C (Ascorbic Acid)	125 mg	139%
Vitamin D (as Cholecalciferol)	12.5 mcg	63%
Thiamin (as Thiamin HCl)	1.4 mg	117%
Vitamin B6 (as Pyridoxine HCl)	2.5 mg	147%
Folate	1,666.66 mcg DFE (1000 mcg Folic Acid)	417%
Vitamin B12 (as Methylcobalamin)	1000 mcg	41,667%
Calcium (as Calcium Carbonate)	200 mg	15%
Iron (as Ferrous Fumarate)	13 mg	72%
Iodine (as Potassium Iodide)	150 mcg	100%

**Other Ingredients:** Hypromellose (Capsule), Rice Flour, Magnesium Stearate.

Distributed by:  **PRIMARY PHARMACEUTICALS**  
**Primary Pharmaceuticals, Inc.**  
 1019 Government St, Suite E  
 Ocean Springs, MS 39564  
*For questions or information call 877-337-0682*

## JENLIVA

ascorbic acid, cholecalciferol, thiamin, vitamin b6, folic acid, methylcobalamin, calcium carbonate, ferrous fumarate, iodine capsule

### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:72275-301
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	125 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	0.0125 mg
<b>THIAMINE HYDROCHLORIDE</b> (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	1.4 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	2.5 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>METHYLCOBALAMIN</b> (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	1 mg

<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
<b>FERROUS FUMARATE</b> (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	13 mg
<b>POTASSIUM IODIDE</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	0.15 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>BROWN RICE</b> (UNII: 659G217HPG)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72275-301-30	30 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		11/06/2020	

Supplement Facts		
Serving Size :	Serving per Container :	
	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	23 mm	
scoring	1	

**Labeler** - Primary Pharmaceuticals, Inc. (066126126)

Revised: 7/2021

Primary Pharmaceuticals, Inc.