

# ZELDANA- folate, cyanocobalamin, thiamine hydrochloride, riboflavin, pyridoxine hydrochloride, niacinamide, ascorbic acid, pantothenic acid capsule

## Misemer Pharmaceutical

Zeldana

### Zeldana Label

**DOSAGE:**  
The usual adult dose is 1 to 2 capsule daily with or without food or as directed by a licensed medical practitioner.

**If you are pregnant or nursing a baby, ask a health professional before using this product.**

**Caution:** This product contains soy. This product has been manufactured in a facility that also manufactures products containing tree nuts, peanuts, fish, egg, wheat, soy and shell fish. Individuals with allergic tendencies to these ingredients should use caution.

**KEEP OUT OF REACH OF CHILDREN**  
Call your Doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088. 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.

**MISEMER** 0276-0708-30

**ZELDANA**  
159 mg

Dispense By Prescription

Store at 25°C (77°F); Excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature]. Avoid exposure above 30°C (86°F). Protect from light and moisture.

**Dietary Supplement** 30 Capsules

**SUPPLEMENT FACTS**  
Serving Size: 1 capsule  
Servings Per Container: 30

Amount Per Serving		% Daily Value
Folate (1mg folic acid)	1.67mg DFE	417%
Cyanocobalamin	0.5mg	20633%
Thiamine hydrochloride	5mg	417%
Riboflavin	5mg	365%
Pyridoxine hydrochloride	25mg	1471%
Niacinamide	37.5mg	*
Ascorbic Acid	65mg	72%
Pantothenic Acid	20mg	400%

\* Daily values not established.

**Other ingredients:** Yellow Wax (bees), Gelatin (bovine), Soybean Oil, Glycerin, Deionized Water, Lecithin (soy), Titanium Dioxide, FD&C Blue #1, FD&C Red #40.

**MISEMER**  
Manufactured for:  
Misemer Pharmaceutical, Inc.  
Ripley, MS 38663  
Made in Canada

Lot #  
Exp. Date

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Zeldana is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other specific medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of a normal diet alone.

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 physician's supervision. There are no implied or explicit claims on therapeutic equivalence

Manufactured for:

Misemer Pharmaceutical, Inc.

Ripley, MS 38663

Item 0708

Rev. 0821-1

Usual adult dosage is one to two capsule daily or as directed by a licensed medical practitioner. Zeldana capsules are supplied as purple capsules printed with "354", dispensed in HDPE plastic bottles of 30ct.

Folic Acid, when administered as a single agent in doses above .1mg daily, may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. The .5 mg of cyanocobalamin contained in Zeldana has been shown to provide an adequate amount of cyanocobalamin to address this precaution. A safe upper limit of 100 mg per day has been established for the unsupervised medical use of pyridoxine. Consider all sources of pyridoxine supplementation when prescribing Zeldana.

**If pregnant or planning to become pregnant or are currently breastfeeding, please contact your physician or health-care provider before using or continuing use.**

#### ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. Paresthesia and somnolence have been reported with pyridoxine HCl. Mild transient diarrhea, polythemia vera, peripheral vascular thrombosis, itching transitory exanthema and feeling of swelling of entire body has been associated with cyanocobalamin.

#### DRUG INTERACTIONS

Pyridoxine supplements should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine. However, pyridoxine may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa. Concurrent use of phenytoin and folacin (folic acid) may result in decreased phenytoin effectiveness.

#### PATIENT INFORMATION

Zeldana capsules are for use only under the direction and supervision of a licensed physician or health-care provider.

#### PREGNANCY and NURSING MOTHERS

Zeldana is not intended for use as a prenatal/postnatal multivitamin for lactating in non-lactating mothers. This product contains B Vitamins in active forms. Talk with your medical practitioner before using if pregnant or lactating.

Zeldana is an orally administered prescription supplement indicated for the distinct nutritional requirements of patients in need of dietary supplementation as determined by a licensed medical practitioner. Zeldana should be administered under the supervision of a licensed medical practitioner.

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B12 is deficient.

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.**

Dispense by Prescription

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

## ZELDANA

folate, cyanocobalamin, thiamine hydrochloride, riboflavin, pyridoxine hydrochloride, niacinamide, ascorbic acid, pantothenic acid capsule

### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:0276-0708
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	.5 mg
<b>THIAMINE HYDROCHLORIDE</b> (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	5 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	5 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	25 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	35.7 mg
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	65 mg
<b>PANTOTHENIC ACID</b> (UNII: 19F5HK2737) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	20 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>GELATIN TYPE B BOVINE (150 BLOOM)</b> (UNII: F5AJW0ONK4)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:0276-0708-30	30 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		12/01/2021	

## Supplement Facts

Serving Size :

Serving per Container :

	Amount Per Serving	% Daily Value
color		
imprint		
size (solid drugs)	14 mm	
shape		
scoring	1	

**Labeler** - Misemer Pharmaceutical (784121365)

**Registrant** - Misemer Pharmaceutical (784121365)

## Establishment

Name	Address	ID/FEI	Business Operations
Viva Pharmaceutical Inc		253288898	

Revised: 12/2021

Misemer Pharmaceutical