

OCUVEL- ocuvel capsule
Adler-Stern 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.

Ocuvel Capsules
Rx Only

DESCRIPTION

Ocuvel is an orally administered prescription Vitamin for the dietary management of patients with unique nutritional needs requiring increased folate levels and other nutritional supplementation. Ocuvel should be administered under the supervision of a licensed medical practitioner.

Each capsule contains:Folic Acid:0.5mg, Vitamin C (ascorbic acid):250mg, Vitamin E (dl-alpha tocopherol):200IU, Zinc(oxide)40mg, Copper (oxide): 1mg, Lutein :5 mg, Zeaxanthin:1 mg, Each capsule contains the following inactive ingredients: Gelatin, Magnesium Stearate, Silica, FD&C Blue #1, Titanium Dioxide

INDICATIONS AND USAGE

Ocuvel is indicated for dietary management of patients with unique nutritional needs requiring increased folate levels and other nutritional supplementation.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Tell your doctor if you have: kidney problems, thyroid disease. This medication should be used as directed during pregnancy or while breast-feeding. Consult your doctor about the risks and benefits.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient. Folic acid in doses above 1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

ADVERSE REACTIONS

This medication is generally well tolerated. Notify your doctor if you experience: nausea, loss of appetite, vomiting, stomach cramps, dry mouth, increased thirst, increased urination, muscle or bone pain,headache, weakness, weight loss, dizziness. If you notice other effects not listed above, contact your doctor or pharmacist.

DOSAGE AND ADMINISTRATION

Take two capsules daily with or without food or as directed by a physician.

HOW SUPPLIED

Ocuvel capsules are supplied as blue capsules printed with Ocuvel dispensed in HDPE plastic bottles of 60ct.

NDC 69054-211-60

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 AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

PRINCIPAL DISPLAY PANEL

Rx Only

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

Adler- Stern Pharmaeuticals,LLC

Tampa, FL 33629

Rev.12/02-3

OCUVEL			
ocuveL capsule			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69054-211
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Folic Acid (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	Folic Acid	0.5 mg	
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	250 mg	
ALPHA-TOCOPHEROL ACETATE (UNII: 8E9Y00D10X) (ALPHA-TOCOPHEROL	ALPHA-TOCOPHEROL		

ALPHA-TOCOPHEROL ACETATE (UNII: 9E8A80D2L0) (ALPHA-TOCOPHEROL - UNII:H4N855PNZ1)	ALPHA-TOCOPHEROL ACETATE	200 [iU]
Zinc oxide (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	Zinc oxide	40 mg
Copper (UNII: 789U1901C5) (copper - UNII:789U1901C5)	Copper	1 mg
Lutein (UNII: X72A60C9MT) (LUTEIN - UNII:X72A60C9MT)	Lutein	5 mg
Zeaxanthin (UNII: CV0IB81ORO) (ZEAXANTHIN - UNII:CV0IB81ORO)	Zeaxanthin	1 mg

Inactive Ingredients

Ingredient Name	Strength
Gelatin (UNII: 2G86QN327L)	
Magnesium Stearate (UNII: 70097M6B30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	capsule	Size	22mm
Flavor		Imprint Code	ocuvel
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69054-211-60	60 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/01/2014	

Labeler - Adler-Stern Pharmaceuticals, LLC (079403232)

Revised: 12/2014

Adler-Stern Pharmaceuticals, LLC