

FOLINEX- vitamin c, vitamin b12, vitamin k mk7, folate capsule
Vivera Pharmaceuticals, Inc.

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](#).

FOLINEX™

FACTS

Folinex™ is an orally administered prescription folate product for the dietary management of patients with unique nutritional needs requiring increased folate levels and other nutritional supplementation.

Folinex™ should be administered under the supervision of a licensed medical practitioner.

Folinex™ is used for dietary management of patients with unique nutritional needs requiring increased folate levels, or are in need of other nutritional supplementation. Folinex™ can be taken by women of childbearing age, pregnant women, and lactating and nonlactating mothers under the supervision of a licensed medical practitioner.

PRECAUTIONS

Tell your doctor if you have: kidney problems or 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 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

WARNINGS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You should call your doctor for medical advice about serious adverse events.

DOSAGE AND ADMINISTRATION

Usual adult dose is one (1) tablet once or twice daily or as prescribed by a licensed medical practitioner.*

If you are pregnant or nursing, ask a healthcare professional.

KEEP OUT OF THE REACH OF CHILDREN.

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.

Do not use if seal is broken or missing.

Folinex™ capsules are supplied as a solid, opaque, white, oblong capsule with “916” printed on one side, dispensed in child-resistant bottles of 30ct (72380-916-30*).

* This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels (AUG 2 1973 FR 20750), requires an Rx on the label because of increased risk associated with masking of B12 deficiency (pernicious anemia). Based on our assessment of the risk of obscuring pernicious anemia, this product requires licensed medical supervision, an Rx status, and a National Drug Code (NDC) – or similarly-formatted product code, as required by pedigree reporting requirements and supply-chain control as well as – in some cases, for insurance-reimbursement applications.

Package Label

NDC# 72380-916-30

**VIVERA™
PHARMACEUTICALS**

Folinex™

30 Capsules

Dispensed by Prescription Only

Supplement Facts

Serving Size: 1 Capsule Servings per container: 30

	<u>Amount Per Serving</u>	<u>%Daily Value</u>
Vitamin C (Ascorbic Acid)	500 mg	555%
Vitamin B12 (as Methylcobalamin)	1 mg	41,666%
Vitamin K MK7	100 mcg	83%
Folate (1 mg Folic Acid)	1700 mcg DFE	425%

Other ingredients: Gelatin, Magnesium Stearate, Microcrystalline Cellulose, Dicalcium Phosphate, Silicon Dioxide, Titanium Dioxide

Dosage: Adult dose is one (1) capsule once or twice daily or as prescribed by a licensed medical practitioner.

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KEEP OUT OF REACH OF CHILDREN

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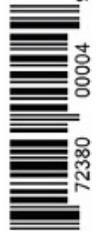
Manufactured for:

Vivera Pharmaceuticals, Inc.
 11100 Greenstone Ave.
 Santa Fe Springs, CA 90670

MADE IN THE U.S.A. REV120519

LOT NO:
EXP. DATE:
MFG. DATE:

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<p>Dosage: Adult dose is one (1) capsule once or twice daily or as prescribed by a licensed medical practitioner.</p> <p>If you are pregnant or nursing, ask a healthcare professional.</p> <p>KEEP OUT OF REACH OF CHILDREN</p> <p>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</p> <p>Manufactured for: Vivera Pharmaceuticals, Inc. 11100 Greenstone Ave. Santa Fe Springs, CA 90670</p> <p>MADE IN THE U.S.A.</p>	<p>NDC# 72380-916-30</p>  <h1 style="font-size: 2em; margin: 0;">Folinex™</h1> <p>30 Capsules Dispensed by Prescription Only</p>	<p>Supplement Facts</p> <p>Serving Size: 1 Capsule Servings per container: 30</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Amount Per Serving</th> <th style="text-align: center;">%Daily Value</th> </tr> </thead> <tbody> <tr> <td>Vitamin C (Ascorbic Acid)</td> <td style="text-align: center;">500 mg</td> <td style="text-align: center;">555%</td> </tr> <tr> <td>Vitamin B12 (as Methylcobalamin)</td> <td style="text-align: center;">1 mg</td> <td style="text-align: center;">41,666%</td> </tr> <tr> <td>Vitamin K MK7</td> <td style="text-align: center;">100 mcg</td> <td style="text-align: center;">83%</td> </tr> <tr> <td>Folate (1 mg Folic Acid)</td> <td style="text-align: center;">1700 mcg DFE</td> <td style="text-align: center;">425%</td> </tr> </tbody> </table> <p>Other ingredients: Gelatin, Magnesium Stearate, Microcrystalline Cellulose, Dicalcium Phosphate, Silicon Dioxide, Titanium Dioxide</p>		Amount Per Serving	%Daily Value	Vitamin C (Ascorbic Acid)	500 mg	555%	Vitamin B12 (as Methylcobalamin)	1 mg	41,666%	Vitamin K MK7	100 mcg	83%	Folate (1 mg Folic Acid)	1700 mcg DFE	425%	<p style="text-align: right; font-size: 0.8em;">LIFT HERE</p>  <p style="text-align: right; font-size: 0.8em;">LOT NO: 3 72389 00004 9 EXP. DATE: MFG. DATE:</p>
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FOLINEX			
vitamin c, vitamin b12, vitamin k mk7, folate capsule			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72380-916
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength

ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	355 mg
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	1 mg
VITAMIN K7 (UNII: HEE4JPA7DF) (VITAMIN K7 - UNII:HEE4JPA7DF)	VITAMIN K7	100 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	capsule	Size	16 mm
Flavor		Imprint Code	916
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72380-916-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/07/2020	

Labeler - Vivera Pharmaceuticals, Inc. (081244342)

Registrant - Vivera Pharmaceuticals, Inc. (081244342)