

ZYREXAL- vitamin c, thiamine, vitamin b6, folate, vitamin b12, vitamin b3, d-ribose, coenzyme q-10 tablet

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.

Zyrexal™

FACTS

Zyrexal™ is an orally administered prescription tablet formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced folate supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

WARNINGS AND PRECAUTIONS

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

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 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

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. To report adverse side effects or to obtain product information, contact Vivera™ Pharmaceuticals, at 1-844-484-8372.

DOSAGE & ADMINISTRATION

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

HOW SUPPLIED

Zyrexal™ tablets are supplied as a coated, white, flat, round tablet with “915” printed on one side, dispensed in a child-resistant bottle of 30ct. (72380-915-10*)

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.

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

KEEP OUT OF THE REACH OF CHILDREN. Do not use if seal is broken or missing.

* 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# 72380-915-10

VIVERA™
PHARMACEUTICALS

Zyrexal™

30 Tablets

Dispensed by Prescription Only

Supplement Facts

<u>Servings size: 1 Tablet</u>	<u>Servings per container: 30</u>
	Amount Per Serving %Daily Value
Vitamin C (As Ascorbic Acid)	125mg 138%
Thiamine (As Thiamine HCL)	25mg 2,083%
Vitamin B6 (As Pyridoxal Phosphate)	12.5mg 735%
Folate	1700 mcg DFE 425%
	(1 mg Folic Acid)
Vitamin B12 (As Methylcobalamin)	1mg 41,666%
Vitamin B3 (As Niacinamide)	60mg 375%
D-Ribose	50mg *
CoEnzyme Q-10 (As Ubiquinone)	75mg *

* % Daily Values have not been established.

Other ingredients: Microcrystalline Cellulose, Magnesium Stearate, Silicone Dioxide

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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:

3 72380 00005 6

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Vitamin B6 (As Pyridoxal Phosphate)	12.5mg	735%
Folate (1 mg Folic Acid)	1700 mcg DFE	425%
Vitamin B12 (As Methylcobalamin)	1mg	41,666%
Vitamin B3 (As Niacinamide)	60mg	375%
D-Ribose	50mg	*
CoEnzyme Q-10 (As Ubiquinone)	75mg	*

*% Daily Values have not been established.

Other ingredients: Microcrystalline Cellulose, Magnesium Stearate, Silicone Dioxide

LIFT HERE



LOT NO: 3
 EXP. DATE: 6
 MFG. DATE: 00005

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MADE IN THE U.S.A.
 REV120519



Manufactured for:
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 Santa Fe Springs, CA 90670
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RES

ZYREXAL			
Vitamin C, thiamine, vitamin B6, folate, vitamin B12, vitamin B3, D-ribose, Coenzyme Q-10 tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72380-915
Route of Administration	ORAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	125 mg
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	25 mg
PYRIDOXINE (UNII: KV2JZ1B16Z) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	12.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	1 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	60 mg
.BETA.-D-RIBOSE (UNII: IVV837V11N) (.BETA.-D-RIBOSE - UNII:IVV837V11N)	.BETA.-D-RIBOSE	50 mg
UBIDECARENONE (UNII: EJ27X76M46) (UBIDECARENONE - UNII:EJ27X76M46)	UBIDECARENONE	75 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	16mm
Flavor		Imprint Code	915
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72380-915-10	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 - Viverra Pharmaceuticals, Inc. (081244342)

Revised: 2/2020

Viverra Pharmaceuticals, Inc.