ZYVANA- zyvana capsule Sterling-Knight 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.

Zyvana Capsules Multi-Balanced Daily Immune Support Dietary Supplement Dispense by Prescription

DESCRIPTION

Zyvana is an orally administered prescription dietary supplement formulation.

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

SUPPLEMENT FACTS

Serving Size: 2 Softgels

Servings Per Container: 30

Amount Per Serving	% Daily Value	
Vitamin C (as Ascorbic Acid)	527 mg	590%
Vitamin D3 (as Cholecalciferol)	41 mcg	200%
Vitamin B6 (as Pyridoxine Hydrochloride)	12 mg	710%
Zinc (as Zinc Gluconate)	23 mg	210%
Selenium (as Selenium Yeast)	97 mcg	180%

^{*} Daily Value not established

Other Ingredients: Soybean Oil, Gelatin (bovine), Garlic Powder, Glycerin, Lecithin, Beeswax, Purified Water, Titanium Dioxide, FD&C Yellow #5.

INDICATIONS AND USAGE

Zyvana is an orally administered prescription dietary supplement formulation for the management of suboptimal nutritional status in patients where advanced

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. Zyvana 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.

DOSAGE AND ADMINISTRATION

The usual dose of Zyvana is 2 capsules per day. The daily dose may be taken as a single dose of 2 capsules or 1 capsule twice daily.

HOW SUPPLIED SECTION

Zyvana is supplied as yellow softgel capsule printed with 405 dispensed in white HDPE plastic bottles of 60ct. 69336-405-60

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 OUT OF THE REACH OF CHILDREN.

Reserved for Professional Recommendation

All prescriptions using this dietary supplement product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product may be administered under a physician's supervision. There are no implied or explicit claims on therapeutic equivalence.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Manufactured for:

Sterling-Knight Pharmaceuticals, LLC

Ripley, MS 38663

Item 40560

Rev. 0920-1



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

KEEP OUT OF REACH OF CHILDREN

Patients should be advised to swallow Zyvana capsules whole. Do not break open, dissolve, or chew Zyvana.

Store at 25° C (77° F); excursions permitted to 15° - 30°C (59°-86° F). [see USP Controlled Room Temperature].

Do not accept if seal on bottle opening is missing



Dispensed by Prescription

69336-405-60

562 mg

MULTI-BALANCED DAILY IMMUNE SUPPORT

Dietary Supplement

60 Capsules

Dosage: The usual dose of Zyvana is 2 capsules per day.

SUPPLEMENT FACTS Serving Size: 2 Softgels Servings Per Container: 30

Amount Per Serving % Daily Value 527 mg 590% Vitamin C (as Ascorbic Acid) Vitamin D3 (as Cholecalciferol) 41 mcg 200% 710% 210% Vitamin B6 (as Pyridoxine Hydrochloride) 12 mg Zinc (as Zinc Gluconate) 23 mg

* Daily Value not established

Other ingredients: Soybean Oil, Bovine Gelatin, Garlic Powder, Glycerin, Lecithin, Beeswax, Purified Water, Titanium Dioxide and FD&C Yellow #5.



Manufactured for: Sterling | Knight Pharmaceuticals, LLC Ripley, MS 38663

ZYVANA

zyvana capsule

Product Information

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:69336-405

Route of Administration ORAL

Active Ingredient/Active Moiety

Active ingredient/Active Plotety		
Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	527 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	0.041 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ1BI6Z)	PYRIDOXINE	12 mg
ZINC GLUCONATE (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLUCONATE	23 mg
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	0.097 mg

Inactive Ingredients

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Ingredient Name	Strength
SOYBEAN OIL (UNII: 241ATL177A)	
GELATIN (UNII: 2G86QN327L)	
GARLIC (UNII: V1V998DC17)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PEG-8 BEESWAX (UNII: 3C1QUF1TIR)	
WATER (UNII: 059QF0KO0R)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

Product Characteristics			
Color	yellow (softgel capsule)	Score	4 pieces
Shape	capsule	Size	14mm
Flavor		Imprint Code	405
Contains			

Packaging				
# Iter	n Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:0	69336- 60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/22/2021	

Marketing Information		
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	02/22/2021	
1	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date

Labeler - Sterling-Knight Pharmaceuticals, LLC (079556942)

Revised: 2/2021 Sterling-Knight Pharmaceuticals, LLC