

**UDAMIN SP- vitamin e, vitamin b6, folic acid, vitamin b12, zinc, selenium, saw palmetto, tocopherols and lycopene complex capsule, coated
Poly Pharmaceuticals, Inc.**

UDAMIN SP Caplets

STATEMENT OF IDENTITY:

UDAMIN SP caplets for oral administration is a 90-day dietary supplement that consists of 100 white film-coated, capsule shaped tablet each debossed with "PE820".

WARNING:

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B12 is deficient.

SAFE HANDLING WARNING:

Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

DOSAGE AND ADMINISTRATION:

Adults: One caplet twice daily, or as directed by a physician. UDAMIN SP is not recommended for women or adolescents.

<u>Supplement Facts</u>	
Serving Size 1 Caplet Servings Per Container 100	
Each White, Film-coated Capsule Shaped Tablet (caplet) for Oral Administration Contains)	
Vitamin E (as d-alpha tocopheryl acid succinate from soy)	75 IU
Vitamin B6 (as pyridoxine HCL)	12.5 mg
Folic Acid	1000 mcg
Vitamin B12 (as cyanocobalamin)	250 mcg
Zinc (as zinc gluconate)	7.5 mg
Selenium (as selenium chelate)	100 mcg
Saw Palmetto Extract	320 mg*
Other tocopherols: (d-gamma, d-delta, d-beta)	17 mg
Lycopene Complex	2.5 mg
*Yielding 144 mg of active ingredients, including free fatty acids.	

OTHER INGREDIENTS: Each caplet also contains the following inactive ingredients: microcrystalline cellulose, dibasic calcium phosphate, cellulose, calcium silicate, rice protein, partially pregelatinized

maize starch, silica, stearic acid, maltodextrin, sodium croscarmellose, magnesium stearate, gelatin (poultry), sucrose, corn starch, sodium selenite, ascorbyl palmitate, sodium ascorbate, D1-alpha tocopherol. Coating: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc.

HOW SUPPLIED: White film-coated, capsule shaped tablet—supplied in bottles of 100. Debossed with “PE820”. Store at controlled room temperature between 15°-30°C (59°-86°F).

Dispense in a tight, light resistant container as defined in the USP/NF with a child-resistant closure. NDC#50991-0231-01, 100 caplets per bottle. The listed product number is not a National Drug Code. Instead, Poly Pharmaceuticals has assigned a product code formatted according to standard industry practice to meet the formatting requirements of pharmacy and health insurance computer systems.

PRECAUTIONS/WARNING:

Folic acids in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. The 250 mcg of Vitamin B12 (as cyanocobalamin) contained in each caplet of UDAMIN SP should address this precaution.

Adverse Reactions

Allergic sensitization has been reported following both oral and parental administration of folic acid. Paresthesia, somnolence have been reported with pyridoxine HCl.

Drug Interactions

Pyridoxine daily can decrease the efficacy of levodopa in the treatment of Parkinsonism. However, this vitamin may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa. Concurrent use of phenytoin and folic acid may result in decreased phenytoin effectiveness.

STORAGE: Store controlled room temperature, 15°- 30°C (59°- 86°F)

HEALTH CLAIMS:

Because toxic reactions have been reported with injudicious use of certain vitamins and minerals, patients should be instructed to follow physician’s dosage regimen.

ALLERGEN STATEMENT: This product contains soy.

CONTRAINDICATIONS: UDAMIN SP is contraindicated in patients with a known hypersensitivity to any of its ingredients.

PRINCIPAL DISPLAY PANEL

– 100 Caplets container label

50991-231-01 RX ONLY

Udamin SP

DIETARY SUPPLEMENT

Manufactured For:

Poly Pharmaceuticals, Inc

Mobile, AL 36119

Protected by U.S. Patent #'s 7,002,350;7,186,421; and 7,390,511

Revised 07/11

8838

STORAGE: Store at controlled room temperature, 15°-30°C (59°-86°F). Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.

WARNING: Keep this product out of reach of children.

Protected by U.S. Patent #s 7,022,350; 7,186,421; and 7,390,511

Manufactured For:
Poly Pharmaceuticals, Inc.
Mobile, AL 36619

Rev. 07/11 8838

NDC 50991-0231-01

Udamin[®] SP
100 Caplets

Dietary Supplement
Rx Only

DOSAGE: One caplet twice daily, or as directed by a physician. See product literature for full prescribing information.

Supplement Facts	
Serving Size 1 Caplet	Servings Per Container 100
Amount Per Serving	% Daily Value
Vitamin E	75 IU..... 250%
(as d-alpha tocopheryl acid succinate from soy)	
Vitamin B6 (as pyridoxine HCL)	12.5 mg..... 625%
Folic Acid.....	1000 mcg..... 250%
Vitamin B12 (as cyanocobalamin).....	250 mcg..... 4166%
Zinc (as zinc gluconate).....	7.5 mg..... 50%
Selenium (as selenium chelate).....	100 mcg..... 142%
Saw Palmetto Extract.....	320 mg..... *
Other Tocopherols	17 mg..... *
(d-gamma, d-delta, d-beta)	
Lycopene Complex	2.5 mg..... *

*Daily Value not established

Other ingredients: microcrystalline cellulose, dibasic calcium phosphate, cellulose, calcium silicate, rice protein, partially pregelatinized maize starch, silica, stearic acid, maltodextrin, sodium croscarmellose, magnesium stearate, gelatin (poultry), sucrose, corn starch, sodium selenite, ascorbyl palmitate, sodium ascorbate, DL-alpha tocopherol. Coating: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc.

Allergen Statement: This product contains soy.

Lot No. Exp.

UDAMIN SP

vitamin e, vitamin b6, folic acid, vitamin b12, zinc, selenium, saw palmetto, tocopherols and lycopene complex capsule, coated

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:50991-231
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL	75 [iU]
PYRIDOXINE (UNII: KV2JZ1BI6Z) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	12.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	250 ug
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	7.5 mg
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	100 ug
SAW PALMETTO (UNII: J7WWH9M8QS) (SAW PALMETTO - UNII:J7WWH9M8QS)	SAW PALMETTO	320 mg
TOCOPHEROL (UNII: R0ZB2556P8) (TOCOPHEROL - UNII:R0ZB2556P8)	TOCOPHEROL	17 mg
LYCOPENE (UNII: SB0N2N0WV6) (LYCOPENE - UNII:SB0N2N0WV6)	LYCOPENE	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CALCIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: 701EKV9RMN)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

CROSCARMELOSE SODIUM (UNII: M28OL1HH48)
MAGNESIUM STEARATE (UNII: 70097M6I30)
GELATIN (UNII: 2G86QN327L)
SUCROSE (UNII: C151H8M554)
SODIUM SELENITE (UNII: HIW548RQ3W)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
SODIUM ASCORBATE (UNII: S033EH8359)
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)
POLYVINYL ALCOHOL (UNII: 532B59J990)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)
TALC (UNII: 7SEV7J4R1U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:50991-231-01	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		07/01/2011	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
imprint		
scoring	1	
shape		
size (solid drugs)	23 mm	

Labeler - Poly Pharmaceuticals, Inc. (198449894)