

**BACMIN- vitamin a acetate, .alpha.-tocopherol acetate, ascorbic acid, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, biotin, calcium pantothenate, folic acid, cyanocobalamin, flavone, ferrous fumarate, chromic chloride cr-51, magnesium oxide, manganese gluconate, cupric oxide, selenomethionine, and zinc oxide tablet, coated Marnel 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.*

-----  
**BACMIN**

**Vitamin/Mineral Nutritional Supplement**

**Rx ONLY**

Each BACMIN caplet contains:

---

<b>Quantity</b>	
<b><i>Fat-Soluble Vitamins</i></b>	
Vitamin A (vitamin A acetate)	2000 IU
Vitamin E (d-alpha tocopheryl acetate)	30 IU
<b><i>Water-Soluble Vitamins</i></b>	
Vitamin C (ascorbic acid)	500 mg
Vitamin B <sub>1</sub> (thiamine mononitrate)	20 mg
Vitamin B <sub>2</sub> (riboflavin)	20 mg
Niacin (niacinamide)	100 mg
Vitamin B <sub>6</sub> (pyridoxine HCl)	25 mg
Biotin	150 mcg
Pantothenic acid (D-calcium pantothenate)	25 mg
Folic acid	1.0 mg
Vitamin B <sub>12</sub> (cyanocobalamin)	50 mcg
Lemon Bioflavonoids	50 mg
<b>Minerals</b>	
Iron (ferrous fumarate)	27 mg
Chromium (chromium chloride)	0.1 mg
Magnesium (magnesium oxide)	50 mg
Manganese (manganese gluconate)	5 mg
Copper (cupric oxide)	3 mg
Selenium (L-selenomethionine)	50 mcg
Zinc (zinc oxide)	22.5 mg

---

**DESCRIPTION**

BACMIN is a prescription-only oral multivitamin/mineral caplet specially formulated for prophylactic or therapeutic nutritional supplementation in physiologically stressful conditions.

BACMIN supplies: therapeutic levels of water-soluble vitamins (ascorbic acid and all B-complex vitamins except biotin); supplemental levels of biotin, fat-soluble vitamins (A and E) and minerals (iron, chromium, manganese, copper, selenium and zinc); plus magnesium.

Inactive ingredients: microcrystalline cellulose, silicon dioxide, stearic acid, croscarmellose sodium and magnesium stearate. Coating contains: hydroxypropyl methylcellulose, maltodextrin, hydroxypropyl

cellulose, FD&C red No. 40 aluminum lake, triacetin, titanium dioxide, polyethylene glycol, FD&C blue No. 1 aluminum lake.

## **INDICATIONS**

BACMIN is indicated for prophylactic or therapeutic nutritional supplementation in physiologically stressful conditions. These include:

### **Conditions causing depletion, reduced absorption or bioavailability of essential vitamins and minerals-**

- Inadequate intake due to highly restricted or unbalanced diets such as those frequently associated with anorexic conditions and other states of severe malnutrition.
- Gastrointestinal disorders, chronic alcoholism, chronic or acute infections (especially those involving febrile illness), prolonged or wasting disease, congestive heart failure, hyperthyroidism, poorly controlled diabetes or other physiologic stress.
- Also, patients on estrogenic oral contraceptives or other estrogen therapy, anti-bacterials which affect intestinal microflora, or other interfering drugs.

### **Certain conditions resulting from severe B-Vitamin or ascorbic acid deficiency-**

- Recovery from surgery or trauma involving severe burns, fractures or other extensive tissue damage.
- Also, pregnant women and those with heavy menstrual bleeding.

## **CONTRAINDICATIONS**

BACMIN is contraindicated in patients hypersensitive to any of its components.

## **WARNINGS**

Not intended for treatment of pernicious anemia or other megaloblastic anemias where vitamin B<sub>12</sub> is deficient. Neurological involvement may develop or progress, despite temporary remission of anemia, in patients with vitamin B<sub>12</sub> deficiency who receive supplemental folic acid and who are inadequately treated with B<sub>12</sub>.

### **Drug and Treatment Interactions**

As little as 5 mg pyridoxine daily can decrease the efficiency of levodopa in the treatment of parkinsonism. Therefore, BACMIN is not recommended for patients undergoing such therapy.

## **ADVERSE REACTIONS**

Adverse reactions have been reported with specific vitamins and minerals, but generally at levels substantially higher than those in BACMIN. However, allergic and idiosyncratic reactions are possible at lower levels. Iron, even at the usual recommended levels, has been associated with gastrointestinal intolerance in some patients.

## **DOSAGE AND ADMINISTRATION**

Usual adult dosage: one caplet daily.

## **HOW SUPPLIED**

Dark red caplets. Bottles of 30, NDC 0682-3001-30. Bottles of 100, NDC 0682-3001-01.

Sample envelope - 2 caplets- NDC 0682-3001-02.

Imprint MMD on top with plain lower.

Manufactured for:  
Marnel Pharmaceuticals,  
Lafayette, LA 70506

Manufactured by:  
Nexgen Pharma, Inc.,  
Irvine, CA 92614

6381  
Rev. 08/07B

## PRINCIPAL DISPLAY PANEL - 100 Caplet Bottle Label

**MARNEL**

NDC 0682-3001-01

**BACMIN**  
CAPLETS  
VITAMIN/MINERAL NUTRITIONAL  
SUPPLEMENT

**Rx ONLY**

**100 CAPLETS**

Manufactured for:  
MARNEL PHARMACEUTICALS, INC.  
Lafayette, Louisiana 70506

The image shows a rectangular label for a bottle of BACMIN 100 Caplets. The label has a blue header with the word "MARNEL" in white. Below the header, the text reads "NDC 0682-3001-01", "BACMIN CAPLETS", "VITAMIN/MINERAL NUTRITIONAL SUPPLEMENT", "Rx ONLY", and "100 CAPLETS". At the bottom, it says "Manufactured for: MARNEL PHARMACEUTICALS, INC. Lafayette, Louisiana 70506". On the left side, there is a vertical text block: "Manufactured by: Nexgen Pharma, Inc. Irvine, CA 92614". In the center, there is a paragraph of text: "BACMIN is a prescription-only oral multi-vitamin/mineral caplet specially formulated for prophylactic or therapeutic nutritional supplementation in physically stressful conditions. BACMIN supplies therapeutic levels of water-soluble vitamins (ascorbic acid and all B-Complex vitamins except biotin); supplement levels of biotin, fat-soluble vitamins (A and E); and minerals (iron, chromium, manganese, copper, selenium, and zinc); plus magnesium." To the right of this paragraph, there is a "DOSAGE" section: "DOSAGE: Usual adult dosage - one caplet daily. Not recommended for children. See package insert for full prescribing information." Below the dosage, there is a storage instruction: "Store at controlled room temperature 15°-30°C (59°-86°F). Dispense in a tight, light resistant container as defined in the USP." At the bottom right, there is a table with two columns: "Lot No." and "Exp. Date". The "Lot No." is "6381" and the "Exp. Date" is "Rev. 08/07B". On the far right, there is a barcode with the number "3 06823 00101 0" below it.

## BACMIN

vitamin a acetate, .alpha.-tocopherol acetate, ascorbic acid, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, biotin, calcium pantothenate, folic acid, cyanocobalamin, flavone, ferrous fumarate, chromic chloride cr-51, magnesium oxide, manganese gluconate, cupric oxide, selenomethionine, and zinc oxide tablet, coated

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0682-3001
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	2000 [iU]
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL ACETATE	30 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	500 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	20 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	20 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	100 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	25 mg
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	150 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	50 ug
FLAVONE (UNII: S2V45N7G3B) (FLAVONE - UNII:S2V45N7G3B)	FLAVONE	50 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
CHROMIC CHLORIDE CR-51 (UNII: U4M5Y13FGM) (CHROMIUM CR-51 - UNII:9QAU17N705)	CHROMIC CHLORIDE CR-51	0.1 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	50 mg
MANGANESE GLUCONATE (UNII: 9YY2F980SV) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE GLUCONATE	5 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	3 mg
SELENOMETHIONINE (UNII: 964MRK2PEL) (SELENOMETHIONINE - UNII:964MRK2PEL)	SELENOMETHIONINE	50 ug
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	22.5 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
cellulose, microcrystalline (UNII: OP1R32D61U)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
stearic acid (UNII: 4ELV7Z65AP)	
croscarmellose sodium (UNII: M28OL1HH48)	
magnesium stearate (UNII: 70097M6I30)	
hypromelloses (UNII: 3NXW29V3WO)	
maltodextrin (UNII: 7CVR7L4A2D)	
hydroxypropyl cellulose (type h) (UNII: RFW2ET671P)	
FD&C red No. 40 (UNII: WZB9127XOA)	
aluminum oxide (UNII: LM26O6933)	
triacetin (UNII: XHX3C3X673)	
titanium dioxide (UNII: 15FIX9V2JP)	
polyethylene glycols (UNII: 3WJQ0SDW1A)	
FD&C blue No. 1 (UNII: H3R47K3TBD)	

### Product Characteristics

<b>Color</b>	RED (Dark Red)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	MMD
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0682-3001-01	100 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		04/01/2000	

**Labeler** - Marnel Pharmaceuticals, Inc. (053781795)

### Establishment

Name	Address	ID/FEI	Business Operations
Nexgen Pharma, Inc.		160356114	MANUFACTURE(0682-3001)

Revised: 5/2014

Marnel Pharmaceuticals, Inc.