

BAL-CARE DHA - beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, sodium feredetate, magnesium oxide, zinc oxide, cupric oxide, iron sucrose, iodine, omega 3 fatty acids
PruGen, 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.

Bal-Care DHA Rev 1.1

SUPPLEMENT FACTS

Serving Size 1 Tablet:

VITAMINS

A (beta carotene)	2,850 IU	36% Daily Value
C (ascorbic acid)	120 mg	200% Daily Value
D (cholecalciferol)840 IU	210% Daily Value
E (dl-alpha tocopheryl acetate)3 mg	10% Daily Value
B1 (thiamine mononitrate)	1.8 mg	106% Daily Value
B2 (riboflavin)4 mg	200% Daily Value
Niacinamide	20 mg	100% Daily Value
B6 (pyridoxine hydrochloride)50 mg	2000% Daily Value
Folic acid1 mg	125% Daily Value
B12 (cyanocobalamin)	12 mcg	150% Daily Value

MINERALS

Calcium (calcium carbonate)	219 mg	17% Daily Value
Iron (as sodium iron EDTA and polysaccharide iron complex)27 mg	150% Daily Value
Magnesium (magnesium oxide)	25 mg	6% Daily Value
Zinc (zinc oxide)25 mg	167% Daily Value
Copper (cupric oxide)2 mg	100% Daily Value

Service Size 1 Softgel:

430 mg purified omega-3 fatty acids including:

At least 295 mg DHA (docosahexaenoic acid); also contains at least 135 mg of other omega-3 fatty acids.

OTHER TABLET INGREDIENTS:

Microcrystalline Cellulose, Hydroxypropyl Methylcellulose, Crospovidone, Maltodextrin, Acacia Gum, Silicon Dioxide, Triacetin, Magnesium Stearate, Titanium Dioxide, Polydextrose, Yellow #6 Lake, Blue #2 Lake, Red #40 Lake.

OTHER SOFTGEL INGREDIENTS:

Ammonium Hydroxide, Ethylcellulose, Gelatin, Glycerin, Medium Chain Triglycerides, Oleic Acid, Sodium Alginate, Stearic Acid, Vanillin.
Softgel contains fish and soybeans

Directions:

Before, during and after pregnancy, one tablet and one enteric-coated softgel capsule taken by mouth

daily, or as directed by a physician.

Use: To provide vitamin and mineral supplementation throughout pregnancy and during the postnatal period for both the lactating and non lactating mother. It is also useful for improving nutritional status prior to conception.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

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

Precautions: Folic acid especially in doses above 1.0 mg daily may obscure pernicious anemia (hematologic remission may occur while neurological manifestations remain progressive). Caution should be exercised to ensure that the prescribed dose of DHA does not exceed 1 gram (1,000 mg) per day. Since daily ingestion of more than 3 grams (3,000 mg) per day of omega-3 fatty acids (including alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)) from fish oils may have potential antithrombotic activities and may increase bleeding times, administration of DHA should be avoided in patients with inherited or acquired bleeding diatheses, including those taking anticoagulants.

Store at room temperature

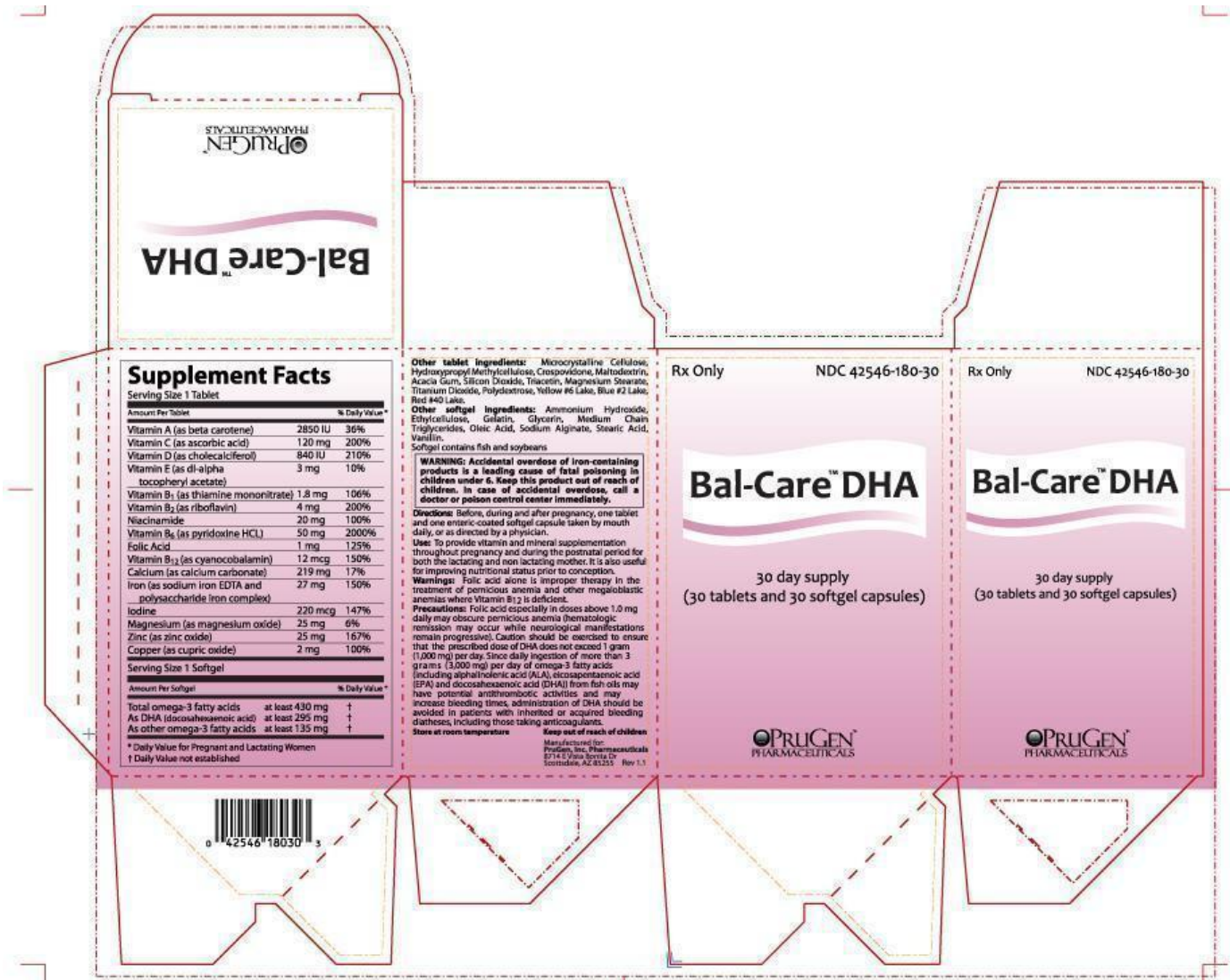
Keep out of reach of children

Manufactured for:

PruGen inc. Pharmaceuticals

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Scottsdale, AZ 85255



BAL-CARE DHA

beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, sodium ferredetate, magnesium oxide, zinc oxide, cupric oxide, iron sucrose, iodine, omega 3 fatty acids kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42546-180
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42546-180-30	6 in 1 CARTON		
1		1 in 1 BLISTER PACK		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		30
Part 2		30

Part 1 of 2

BAL-CARE DHA

beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, sodium ferredetate, magnesium oxide, zinc oxide, cupric oxide, iron sucrose, iodine, tablet

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BETA CAROTENE (UNII: 01YAE03M7J) (VITAMIN A - UNII:81G40H8B0T)	BETA CAROTENE	2850 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	840 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL ACETATE, DL- - UNII:WR1WPI7EW8)	.ALPHA.-TOCOPHEROL ACETATE, DL-	3 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE - UNII:X66NSO3N35)	THIAMINE MONONITRATE	1.8 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	4 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	50 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	.012 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM - UNII:SY7Q814VUP)	CALCIUM CARBONATE	219 mg
SODIUM FEREDETATE (UNII: 403J23EMFA) (IRON - UNII:E1UOL152H7)	SODIUM FEREDETATE	25.65 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM - UNII:I38ZP9992A)	MAGNESIUM OXIDE	25 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC - UNII:J41CSQ7QDS)	ZINC OXIDE	25 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (COPPER - UNII:789U1901C5)	CUPRIC OXIDE	2 mg
IRON SUCROSE (UNII: FZ7NYF5N8L) (IRON - UNII:E1UOL152H7)	IRON SUCROSE	1.35 mg
IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	.223 mg

Product Characteristics

Color	pink	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	102
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2012	

Part 2 of 2

BAL-CARE DHA

omega 3 fatty acids capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S) (OMEGA-3 FATTY ACIDS - UNII:71M78END5S)	OMEGA-3 FATTY ACIDS	430 mg

Product Characteristics

Color	brown	Score	no score
Shape	OVAL	Size	24mm
Flavor		Imprint Code	none
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		05/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2012	

Labeler - PruGen, Inc. (929922750)

Revised: 5/2012

PruGen, Inc.