

**BAL-CARE DHA ESSENTIAL - 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
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 Essential Rev 1.0

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 acid | .1 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:

374 mg purified omega-3 fatty acids including:

At least 262 mg DHA (docosahexaenoic acid); also contains at least 112 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

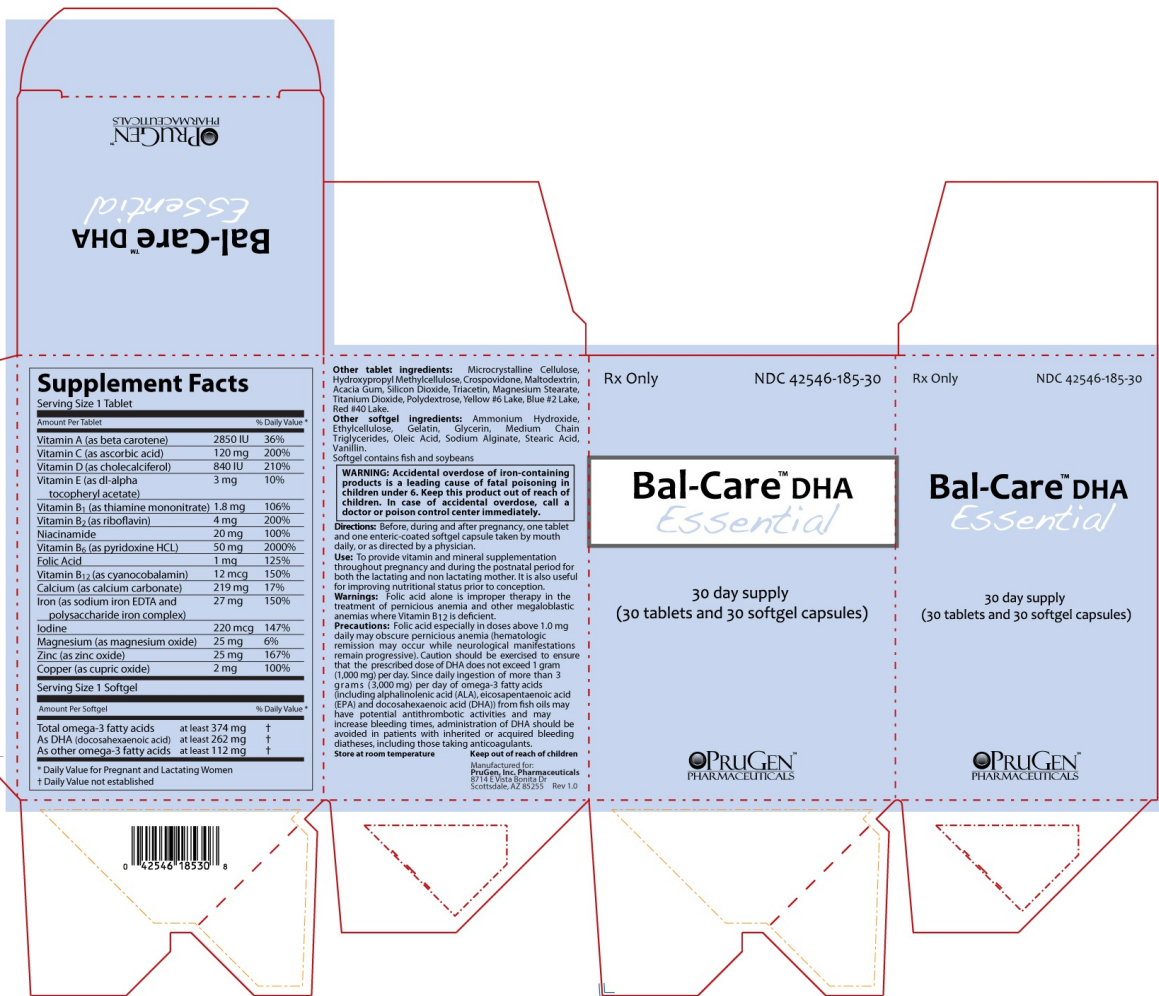
Keep out of reach of children

Manufactured for:

PruGen inc. Pharmaceuticals

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Scottsdale, AZ 85255



BAL-CARE DHA ESSENTIAL

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:42546-185 |
|---------------------|-------------------------|---------------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:42546-185-30 | 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 ESSENTIAL

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:KV2JZ1B16Z) | 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 ESSENTIAL

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 | 374 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.