

**CONCEPT DHA- vitamin- mineral omega-3 supplement capsule, liquid filled
U.S. Pharmaceutical Corporation**

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.

see all prescribing information for Concept DHA

DESCRIPTION: Each capsule contains: Ferrous Fumarate (Elemental Iron)
17.5 mg PolysaccharideIronComplex(ElementalIron).. 17.5mg
(Equivalent to about 35 mg of elemental iron) Vitamin C (from ProAscorb C†)
. 25 mg FolicAcid..... 1mg
ThiamineMononitrate(B1) 2mg Riboflavin(B2) 3mg Niacin
(B3, from ProAscorb C†) 1.8 mg d-
CalciumPantothenate(B5)..... 5mg PyridoxineHCl(B6) 25mg Biotin
(B7) 300 mcg Cyanocobalamin(B12)
12.5mcg Copper(asCopperSulfate)..... 2mg
Magnesium(asMagnesiumSulfate) Zinc(asZincSulfate)..... Omega-3
Fatty Acids
(Derived from 310 mg Fish Oil) Docosahexaenoic Acid (DHA) Eicosapentaenoic
Acid (EPA) 5mg 10mg 200 mg156 mg 39 mg

Clinical Studies: Because Ferrous Fumarate is an organic complex, it contains no free ions, either ferric or ferrous. Polysaccharide Iron Complex is clinically non-toxic. Prior studies in rats demonstrated that Polysaccharide Iron Complex (PIC), administered as a single oral dose to Sprague Dawley rats did not produce evidence of toxicity at a dosage level of 5000 mg Iron/kg: (An Acute Oral Toxicity Study in Rats with Polysaccharide-Iron Complex. T.N.Merriman, M. Aikman and R.E. Rush, Springborn Laboratories, Inc. Spencerville, Ohio Study No. 3340.1 March - April 1994). Other clinical studies had demonstrated that Polysaccharide Iron gives a good hematopoietic response with an almost complete absence of the side effects usually associated with oral iron therapy. Picinni and Ricciotti suggested in 1982, that "the therapeutic effectiveness of Polysaccharide Iron Complex when compared with iron fumarate in the treatment of iron deficiency anemia, appears to be as active as the iron fumarate and as well tolerated, however, it exerted a greater influence on the level of hemoglobin and on the number of red cells..." and that, "it has been exceptionally well tolerated by all patients" (Picinni, L.- Ricciotti, M. 1982. Therapeutic effectiveness of an iron-polysaccharide complex in comparison with iron fumarate in the treatment of iron deficiency anemias):

PANMINERVA MEDICA-EUROPA MEDICA, Vol. 24, No. 3, pp. 213-220 (July - September 1982). As mentioned above, the patented source of iron used in Concept DHATM (Ferrous Fumarate and Polysaccharide Iron Complex) provides a high level of elemental iron with a low incidence of gastric distress.

CONCLUSION: Based on the results of this study, the oral combination of Ferrous Fumarate and Polysaccharide Iron Complex was better tolerated and safer than the oral administration of Ferrous Fumarate alone. The conclusion of this research stated, that the addition of PIC to Ferrous Fumarate surprisingly allows the same concentration of Ferrous Fumarate to be better tolerated than the Ferrous Fumarate alone.

INDICATIONS: Concept DHATM is a prescription prenatal vitamin-mineral preparation

containing omega-3 fatty acid supplements designed to supply nutritional supplementation for women throughout pregnancy and during the postnatal period to lactating and non-lactating mothers. Concept DHA™ may also be used to improve the nutritional status of women before 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. **WARNING:** Ingestion of more than 3 grams of omega-3 fatty acids from fish oils per day may have potential antithrombotic effects, including an increased bleeding time and INR (international normalized ratio). DHA should be avoided in patients with inherited or acquired bleeding diatheses, including those taking anticoagulants.

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

PRECAUTIONS: General: Folic acid in doses above 0.1 mg - 0.4 mg daily may obscure pernicious anemia, in that hematological remission can occur while neurological manifestations remain progressive.

DOSAGE AND ADMINISTRATION: Adults (persons over 12 years of age), one (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage. Do not administer to children under the age of 12.

HOW SUPPLIED: Concept DHA™ are red maroon opaque Vcaps® capsules printed in white with "Concept DHA" on the cap "US" logo on the body. Packed in child-resistant cap and light resistant bottle of 30 capsules (52747-0621-30). The listed product number is not a National Drug Code. Instead, US Pharmaceutical Corporation has assigned this product code formatted according to standard industry practice to meet the formatting requirements of pharmacy and healthcare insurance computer systems.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Vcaps® and the Vcaps® Logo are trademarks used under license.

Packaging



52747-0621-30 30 Capsules Rx only
Concept DHA™
 Prenatal Multivitamin & Mineral Supplement
 Capsules with Omega-3 Fatty Acids - DHA & EPA

Consult package literature for full prescription information. You should contact your healthcare provider for medical advice about adverse events. To report a serious adverse event, contact US Pharmaceutical Corporation, P.O. Box 360465, Decatur, GA 30036. Marketed by US Pharmaceutical Corporation, Manufactured with Vcaps® capsule shells. Store at room temperature 15° to 30°C (59° to 86°F) and dry place. Manufactured in a FDA registered facility in the USA.

CAUTION: Rx only. Rev. 03/2022
 Patent Numbers: USA: 5,626,883; Mexico MX/a/ 2008/004461; Singapore: 200802623-9

Supplement Facts

Serving Size: 1 Capsule

| Amount Per Serving | % DV* Lactating Women | % Daily Value for Pregnant or Lactating Women |
|---|-----------------------|---|
| Iron (as Ferrous Fumarate) | 25 mg | 28% |
| Vitamin C (from ProAscorb C [™]) | 2 mg | 167% |
| Vitamin B ₁ (as Thiamine Mononitrate) | 3 mg | 231% |
| Vitamin B ₂ (Riboflavin) | 1.8 mg | 11% |
| Vitamin B ₃ (as Nicotinic Acid/ProBiosorb C [™]) | 25 mg | 1471% |
| Vitamin B ₆ (as Pyridoxine HCl) | 1 mg | 250% |
| Folic Acid | 12.5 mcg | 521% |
| Vitamin B ₁₂ (Cyanocobalamin) | 300 mcg | 1000% |
| Iron | 5 mg | 100% |
| Iron (as D-Calcium Panthothenate) | 35 mg | 194% |
| Iron (from Ferrous Fumarate; 17.5 mg from Polysaccharide Iron Complex) | 5 mg | 1% |
| Magnesium (as Magnesium Oxide) | 10 mg | 91% |
| Zinc (as Zinc Oxide) | 2 mg | 222% |
| Copper (as Cupric Oxide) | 200 mcg | † |
| Omega 3 Fatty Acids | 156 mg | † |
| Docosahexaenoic Acid (DHA) | 39 mg | † |
| Eicosapentaenoic Acid (EPA) | 43 mg | † |
| ProAscorb C is a proprietary blend of | | |
| Calcium Ascorbate, Ascorbic Acid, Ascorbyl Palmitate, Nicotinamide Ascorbate, Xylitol, Sodium Ascorbate, Magnesium Ascorbate, Lysine Acetate, Citrus Bioflavonoids, Potassium Ascorbate, Sodium Pyrophosphate, D-Ribofuranose, L-Cysteine, Glutathione and Hesperidin | | |

* Daily Values are based on a 2,000 calorie intake of adults and children 2 years and older. † Daily Value not established

Other Ingredients: Beeswax, Hypromellose, Titanium Oxide and FD&C Red #40

Lift Here for Full Prescription Information

Supplement Facts

Serving Size: 1 Capsule

| Amount Per Serving | % Daily Value for Pregnant or Lactating Women | |
|---|---|-------|
| | % DV* | % DV* |
| Vitamin C (from ProAscorb C**) | 25 mg | 28% |
| Vitamin B ₁ (as Thiamine Mononitrate) | 2 mg | 167% |
| Vitamin B ₂ (Riboflavin) | 3 mg | 231% |
| Vitamin B ₃ (as Niacinamide from ProAscorb C**) | 1.8 mg | 11% |
| Vitamin B ₆ (as Pyridoxine HCl) | 25 mg | 1471% |
| Folic Acid | 1 mg | 250% |
| Vitamin B ₁₂ (Cyanocobalamin) | 12.5 mcg | 521% |
| Biotin | 300 mcg | 1000% |
| Pantothenic Acid (as D-Calcium Pantothenate) | 5 mg | 100% |
| Iron (17.5 mg from Ferrous Fumarate; 17.5 mg from Polysaccharide Iron Complex) | 35 mg | 194% |
| Magnesium (as Magnesium Oxide) | 5 mg | 1% |
| Zinc (as Zinc Oxide) | 10 mg | 91% |
| Copper (as Cupric Oxide) | 2 mg | 222% |
| Derived from 310 mg Fish Oil | | |
| Omega 3 Fatty Acids | 200 mg | † |
| Docosahexaenoic Acid (DHA) | 156 mg | † |
| Eicosapentaenoic Acid (EPA) | 39 mg | † |

** ProAscorb C is a proprietary blend of 43 mg † †
Calcium Ascorbate, Ascorbic Acid, Ascorbyl Palmitate, Niacinamide
Ascorbate, Xylitol, Sodium Ascorbate, Magnesium Ascorbate, Lysine
Acetate, Citrus Bioflavonoids, Potassium Ascorbate, Sodium
Pyrophosphate, D-Ribofuranose, L-Cysteine, Glutathione and Hesperidin

* % Daily Values are based on a 2,000 calorie intake of adults and children
12 years and older. † Daily Value not established

Other Ingredients: Beeswax, Hypromellose, Titanium Oxide and FD&C Red 40

52747-0621-30

Concept DHA™

R_x only

Prenatal Multivitamin & Mineral Supplement Capsules
with Omega-3 Fatty Acids - DHA & EPA

INDICATIONS: Concept DHA™ is a prenatal supplement designed to improve the nutritional status of women throughout pregnancy and during the postnatal period to lactating and non-lactating mothers. Concept DHA™ may also be used to improve the nutritional status of women before conception.

CONTRAINDICATIONS: Concept DHA™ is contraindicated in patients with a known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. It is also contraindicated in patients suffering from pernicious anemia as folic acid may obscure its signs and symptoms.

Ferrous Fumarate and Polysaccharide Iron Complex (PIC): All Concept products include a unique patented source of iron, e.g. Ferrous Fumarate and Polysaccharide Iron Complex (U.S. Patent No: 11/243,043 Pending). "An increase in tolerability is observed with the formulation and is believed to occur as the result of distributing the total iron content in the composition among compounds that provide iron to the patient's blood stream via two different mechanisms. The ferrous salts are readily absorbed in the upper gut, by direct dissolution and absorption of the ferrous iron by the bloodstream. However, the iron available from PIC is absorbed in the lower gut, via an active protein transport mechanism".

Clinical Studies: Picinni, L-Ricciotti, M. 1982. Therapeutic effectiveness of an iron-polysaccharide complex in comparison with iron fumarate in the treatment of iron deficiency anemias: PANMINERVA MEDICA-EUROPA MEDICA, Vol. 24, No. 3, pp. 213-220 (July-September 1982).

Folic Acid: Folic Acid is one of the important hematopoietic agents necessary for proper regeneration of the blood-forming elements and their function. Additionally, folic acid increases jejunal glycolytic enzymes and is involved in the desaturation and hydroxylation of long-chain fatty acids in the brain. A deficiency in folic acid results in megaloblastic anemia.

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

PRECAUTIONS: Folic acid in doses above 0.1 mg - 0.4 mg daily may obscure the signs and symptoms of pernicious anemia, in that hematological remission can occur while neurological manifestations remain progressive.

OVERDOSE: Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300-mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted.

DOSAGE AND ADMINISTRATION: Adults (persons over 12 years of age), one (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage.

HOW SUPPLIED: Concept DHA™ are red maroon opaque Vcaps® capsules printed in white with "Concept DHA" on the cap and "US" Logo on the body. Packed in child-resistant cap and light resistant bottle of 30 capsules (52747-0621-30). The listed product number is not a National Drug Code. Instead, US Pharmaceutical Corporation has assigned this product code formatted according to standard industry practice to meet the formatting requirements of pharmacy and healthcare insurance computer systems.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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CONCEPT DHA

vitamin- mineral omega-3 supplement capsule, liquid filled

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:52747-621 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------------|----------|
| FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR) | FERROUS CATION | 17.5 mg |
| IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7) | IRON | 17.5 mg |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R) | ASCORBIC ACID | 25 mg |
| FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8) | FOLIC ACID | 1 mg |
| THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J) | THIAMINE | 2 mg |
| RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR) | RIBOFLAVIN | 3 mg |
| NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A) | NIACIN | 1.8 mg |
| CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737) | PANTOTHENIC ACID | 5 mg |
| PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z) | PYRIDOXINE | 25 mg |
| BIOTIN (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04) | BIOTIN | 300 ug |
| CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204) | CYANOCOBALAMIN | 12.5 ug |
| CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L) | CUPRIC CATION | 2 mg |
| MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838) | MAGNESIUM SULFATE, UNSPECIFIED FORM | 5 mg |
| ZINC SULFATE, UNSPECIFIED FORM (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 10 mg |
| OMEGA-3-ACID ETHYL ESTERS (UNII: D87YGH4Z0Q) (OMEGA-3 FATTY ACIDS - UNII:71M78END5S) | OMEGA-3-ACID ETHYL ESTERS | 200 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |

Product Characteristics

| | | | |
|-----------------|-------------|---------------------|--------------------------|
| Color | pink (pink) | Score | score with uneven pieces |
| Shape | CAPSULE | Size | 22mm |
| Flavor | | Imprint Code | Concept;DHA;US |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:52747-621-30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/24/2009 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| unapproved drug other | | 06/24/2009 | |

Labeler - U.S. Pharmaceutical Corporation (079467662)

Revised: 11/2022

U.S. Pharmaceutical Corporation