CONCEPT OB - vitamin mineral supplement capsule
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 OB

DESCRIPTION: Each capsule contains: Ferrous Fumarate (anhydrous) .....130 mg (Equivalent to about 42.5 mg of Elemental Iron) PolysaccharideIronComplex .....92.4mg (Equivalent to about 42.5 mg of Elemental Iron) Vitamin C (from ProAscorb C‡)..... 210 mg Folic Acid ..... 1 mg Thiamine Mononitrate (B1)..... 5 mg Riboflavin (B2)..... 5 mg Niacin (B3).....20 mg d-Calcium Pantothenate (B5)..... 7 mg Pyridoxine HCl (B6) .....25 mg Biotin (B7)..... 300 mcg Cyanocobalamin (B12) .....10 mcg Copper (as Copper Sulfate).....800 mcg Magnesium (as Magnesium Sulfate).....6.9 mg Manganese (as Manganese Sulfate).....1.3 mg Zinc (as Zinc Sulfate) ..... 18.2 mg Inactive Ingredients: Hypromellose, Silicon Dioxide, Magnesium Stearate, Carmine, and Candurin Silver Fine.

CLINICAL PHARMACOLOGY: Concept OBTM also supplies important prenatal vitamin minerals in a formulation that was especially designed to supplement the nutritional needs of pregnant women, before, during and after pregnancy. In Concept OBTM, patients receive the balanced support of 14 essential vitamins and minerals, including 1 mg of folic acid. The essential role of iron supplementation for pregnant women has long been recognized. Concept OBTM is unique in that it utilizes two (2) different forms of iron, i.e., Ferrous Fumarate and Polysaccharide Iron Complex (as cell-contracted akaganèite), making available a total of 85 mg of elemental iron per capsule as follows: Ferrous Fumarate (anhydrous) 130 mg Polysaccharide iron complex (PIC) 92.4 mg
Ferrous Fumarate: Provides about 42.5 mg of elemental iron per dose. Ferrous Fumarate is an anhydrous salt of a combination of ferrous iron and fumaric acid, containing 33% of iron per weight. The acute toxicity in experimental animals is low and Ferrous Fumarate is well tolerated clinically. As a ferrous salt, it is more efficiently absorbed in the duodenum. Ferrous Fumarate contrasts very favorably with the availability of the 20% of elemental iron of ferrous sulfate, and the 13% of elemental iron of ferrous gluconate.
Polysaccharide Iron Complex: Provides about 42.5 mg elemental iron, as a cell-contracted akaganèite. It is a product of ferric iron complexed to a low molecular weight polysaccharide. This polysaccharide is produced by the extensive hydrolysis of starch and is a dark brown powder that dissolves in water to form a very dark brown solution, which is virtually odorless and tasteless.
The most frequent cause of anemia in pregnant women is iron deficiency. Because of the continuous loss of iron due to monthly menstruation, most women enter pregnancy

with less than optimal iron stores. Supplementation of iron must suffice to meet the needs for maternal and fetal erythropoisis, and account for daily maternal gastrointestinal losses and obligate fetal transfer and growth. Iron requirements during pregnancy usually cannot be met with the average diet. (ACOG technical bulletin (1993): Nutrition during Pregnancy. p.4. Number 179-April 1993: The American College of Obstetricians and Gynecologists, Washington, D.C. 20024-2188).

Concept OBTM does not contain calcium, as calcium may inhibit iron absorption because of the binding or conversion of ferrous salts by calcium and other minerals. Calcium salts can always be prescribed separately for women at high nutritional risk, including those who do not eat adequate amounts of dairy products. The recommendation of the National Academy of Sciences Tenth Ed. 1989 National Academy Press, Washington, D.C., suggests the supplementation of 1200 mg of calcium for pregnant and lactating women for the prevention of calcium deficiency.

Folic acid is a hematopoetic vitamin and has been used extensively for the prevention of neural tube defects. The need for folic acid in pregnancy, with its increased demands of the fetus, or lactation, is not being met by normal dietary sources. Concept OBTM capsules contain 1 mg of folic acid. Neural tube defects (NTD's) are the most common birth defects that result in infant mortality and serious disability. For women with a previous pregnancy that resulted in a child with a neural tube malformation, the use of 4 mg/d of folic acid has been reported to be effective in preventing a recurrence (MRC Vitamin Study Research Group, 1991). However, earlier studies from the United Kingdom suggested that lower daily doses, for example 0.36 mg, might result in a comparable reduction of a recurrence of NTD's. Since neural tube closure is complete by four weeks following conception, beginning folic acid supplementation after that time is not likely to be of any value. It should be noted that a daily 4 mg dose of folic acid did not prevent all NTD's in the MRC study. Patients should be cautioned that folic acid supplementation does not preclude the need for consideration for prenatal testing for NTD's (ACOG Committee Opinion, Number 120, March 1993: The American College of Obstetricians and Gynecologists, Washington D.C. 20024-2188). The U.S. Public Health Service has recommended that all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid per day for reducing their risk of having a pregnancy affected with spina bifida or other NTD's (Center of Disease Control, 1992). Recommendation for the use of folic acid to reduce the number of cases of spina bifida and other neural tube defects: MMWR 1992: 41(RR14): 1-7). Concept OBTM has been formulated without the addition of vitamins A, D, E and K. These fat-soluble vitamins can accumulate and lead to birth defects. Supplementation of vitamins A, D, E and K should be based on an individual need assessment.

All ConceptTM 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 (patented formulation) and is believed to occur as the result of distributing the total iron content in the composition among compounds that

NDC 52747-620-30 Concept OBTM Prescription Prenatal Postnatal Vitamin Mineral Capsules

52747620300709

Back side Concept OB LC-10807 Rev 07/2009

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". The Concept OBTM formulation

also supplies additional important prenatal vitamin and minerals, which supplement the nutritional needs of pregnant women, before, during and after pregnancy. Deficiencies of these ingredients are common during pregnancy and lactation.

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

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

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: 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.

Pediatric Use: Safety and effectiveness of this product have not been established in pediatric patients.

Geriatric Use: No clinical studies have been performed in patients age 65 and over to determine whether older persons respond differently from younger persons. Dosage should always begin at the low end of the dosage scale and should consider that elderly persons may have decreased hepatic, renal, or cardiac function and or concomitant diseases.

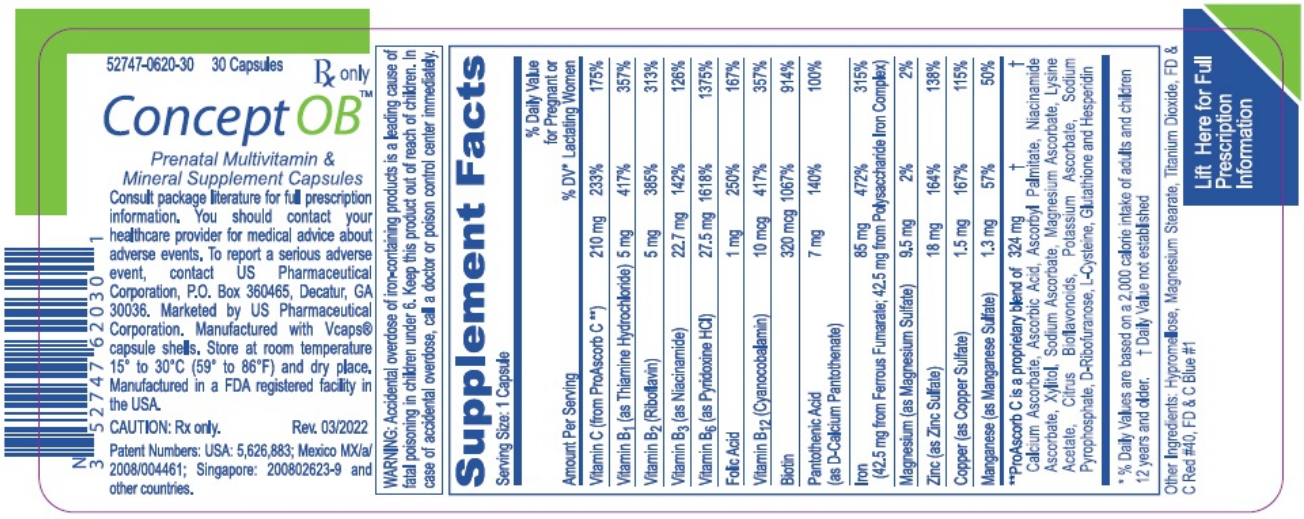
Adverse Reactions: Folic Acid: Allergic sensitizations have been reported following both oral and parenteral administration of folic acid. Ferrous Fumarate: Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and may subside with continuation of therapy. Although the absorption of iron is best when taken between meals, giving Concept OBTM after meals may control occasional G.I. disturbances. Concept OBTM is best absorbed when taken at bedtime.

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. Concept OBTM should be stored beyond the reach of children to prevent against accidental iron poisoning. Keep this and all other drugs out of the reach of children.
Treatment: For specific therapy, exchange transfusion and chelating agents should be used. For general management, perform gastric lavage with sodium bicarbonate solution or milk. Administer intravenous fluids and electrolytes and use oxygen.

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 OB™ are pearl red-orange opaque Vcaps® capsules printed in white with "Concept OB" on the cap and "US" logo on the body. Packed in child-resistant cap and light resistant bottle of 30 capsules (52747-0620-30). 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. Store at room temperature 15º to 30ºC (59º to 86ºF) and dry place.

Packaging



Supplement Facts

Serving Size: 1 Capsule

Amount Per Serving		% DV*	% Daily Value for Pregnant or Lactating Women
Vitamin C (from ProAscorb C **)	210 mg	233%	175%
Vitamin B_1 (as Thiamine Hydrochloride)	5 mg	417%	357%
Vitamin B_2 (Riboflavin)	5 mg	385%	313%
Vitamin B_3 (as Niacinamide)	22.7 mg	142%	126%
Vitamin B_6 (as Pyridoxine HCl)	27.5 mg	1618%	1375%
Folic Acid	1 mg	250%	167%
Vitamin B_{12} (Cyanocobalamin)	10 mcg	417%	357%
Biotin	320 mcg	1067%	914%
Pantothenic Acid (as D-Calcium Pantothenate)	7 mg	140%	100%
Iron (42.5 mg from Ferrous Fumarate; 42.5 mg from Polysaccharide Iron Complex)	85 mg	472%	315%
Magnesium (as Magnesium Sulfate)	9.5 mg	2%	2%
Zinc (as Zinc Sulfate)	18 mg	164%	138%
Copper (as Copper Sulfate)	1.5 mg	167%	115%
Manganese (as Manganese Sulfate)	1.3 mg	57%	50%
**ProAscorb C is a proprietary blend of 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	324 mg	†	†

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

Other Ingredients: Hypromellose, Magnesium Stearate, Titanium Dioxide, FD & C Red #40, FD & C Blue #1

52747-0620-30

Concept OB™

℞ only

Prenatal Multivitamin & Mineral Supplement Capsules

INDICATIONS: Concept OB™ 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 OB™ may also be used to improve the nutritional status of women before conception.

CONTRAINDICATIONS: Concept OB™ 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 B_{12} 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 OB™ are pearl red-orange opaque Vcaps® capsules printed in white with "Concept OB" on the cap and "US" Logo on the body. Packed in child-resistant cap and light resistant bottle of 30 capsules (52747-0620-30). 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. Store at room temperature 15° to 30°C (59° to 86°F) and dry place.

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.

CONCEPT OB

vitamin mineral supplement capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52747-620
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	42.5 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	42.5 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	210 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	5 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	5 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	20 mg
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	7 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	25 mg
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	300 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	10 ug
CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	800 ug
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE, UNSPECIFIED FORM	6.9 mg
MANGANESE SULFATE (UNII: W00LYS4T26) (MANGANOUS CATION - UNII:H6EP7W5457)	MANGANOUS CATION	1.3 mg
ZINC SULFATE, UNSPECIFIED FORM (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	18.2 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	pink (pearl red opaque)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	Concept;OB;US
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52747-620-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2009	
2	NDC:52747-620-10	10 in 1 BOX	01/01/2009	
2	NDC:52747-620-04	4 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2009	

Labeler - U.S. Pharmaceutical Corporation (079467662)

Revised: 11/2022 U.S. Pharmaceutical Corporation