ACCENTRATE PNV- prenatal multivitamin tablet and combination omega-3 softgel/mineral capsule
Key Therapeutics

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.

DESCRIPTION

Accentrate® PNV (Folate/Omega-3/Iron) (6 mg-210 mg-10 mg) is an orally administered Prescription Prenatal Multivitamin Tablet and combination Omega-3 Softgel/Mineral Capsule. Accentrate® PNV contains a prenatal tablet, omega-3 softgels, and mineral capsules. Each one tablet contains 6 mg of L-methylfolate Calcium, each two softgel serving contains 210 mg of EPA and DHA, and each three capsule serving contain 10 mg of iron.

Each prenatal tablet contains:

L-methylfolate Calcium	6 mg
Pyridoxal-5-phosphate (Vitamin B6)	10 mg
Methylcobalamin (Vitamin B12)	1 mg
Riboflavin-5-phosphate (Vitamin B2)	3 mg
Niacinamide (Vitamin B3)	5 mg
Pantothenate (Vitamin B5)	15 mg
Thiamine (Vitamin B1)	1 mg
Vitamin D3	1200 IU / 30 mcg
Vitamin C	85 mg
Tyrosine	150 mg
Other Ingredients: L-Glutathione, Starch, Croscarmellose Sodium, Silicon Dioxide, USP, Magnesium Stearate, Microcrystalline Cellulose.	

Each two omega-3 softgel serving contains:

LYSOVETA® LPC which contains	1000 mg
Lysophosphatidylcholine (LPC)	260 mg
Eicosapentaenoic Acid	140 mg
Docosahexaenoic Acid	70 mg
Other Ingredients: Lysophosphatidylcholine (LPC)-Rich Oil, Extract of Antarctic Krill (Euphausia superba), Gelatin (bovine), Glycerin, Sorbitol, Water.	

CONTAINS: Shellfish (Krill)

Each three mineral capsule serving contains:

Magnesium (magnesium glycinate chelate)	290 mg
Zinc (zinc glycinate chelate)	35 mg
Iron (ferrous bisglycinate chelate)	10 mg
Other Ingredients: Potato starch, ascorbic acid, magnesium stearate, fumed silica, hypomellose, copper bisglycinate.	

INDICATIONS AND USAGE

Accentrate® PNV (Folate/Omega-3/Iron) (6 mg-210 mg-10 mg) is a Prescription Prenatal Multivitamin Tablet and combination Omega-3 Softgel/Mineral Capsule indicated for preventing neural tube defects and use in improving the nutritional status of women prior to conception, throughout pregnancy, and in the postnatal period for both lactating and nonlactating mothers.

PREGNANCY AND NURSING MOTHERS

Accentrate®PNV is intended for women of childbearing age who are – or desire to become, pregnant regardless of lactation status. Accentrate® PNV may be preferred for women at risk of dysregulated dopamine or serotonin regulation, which may include depression as a result of folate or cobalamin deficiency as well as folate-induced

postpartum depression, or are at risk of folate-induced birth defects such as may be found with spina bifida and other neural tube defects (NTDs). It has been shown that folate enhances the synthesis and/or regeneration of tetrahydrobiopterin (BH_4), which is an essential cofactor in the biosynthesis of monoamine neurotransmitters serotonin, dopamine and norepinephrine [i, ii, iii]. The conversion of tryptophan to serotonin also requires BH_4.

Accentrate® PNV may also be an appropriate source of folate for those at high risk of NTDs because of the amount and bioavailability of L-methylfolate contained therein. Accentrate® PNV is Pregnancy Category A; however, Accentrate® PNV is NOT a standard complete prenatal/postnatal supplement for the following reasons:

Accentrate® PNV contains over 1,000% of DV of folate for pregnant and lactating women, which may or may not be important depending upon your genetic disposition and previous pregnancies; please consult with your licensed medical practitioner on advanced folate supplementation during pregnancy for women at risk of NTDs and/or suboptimal folate/depression/postpartum.

Accentrate® PNV contains over 600% of DV for cobalamin for pregnant and lactating women.

Accentrate® PNV contains less than have the DV–only 37%–of iron for pregnant and lactating women, and Accentrate® PNV does not contain other vitamins and minerals that might be more suitable to your specific metabolic needs or part of a standard prenatal/postnatal multivitamin/multimineral/dietary supplement. [iv, v, vi, vii]

DOSAGE AND ADMINISTRATION

The usual adult dose may be taken as one (1) white vitamin tablet (Neuro 110™), two (2) red omega-3 softgels (Omega 110™), and three (3) white mineral capsules (Minerals 110™) daily, before, during and after pregnancy, or as directed by a physician.

FOLATE is essential for the production of certain coenzymes in many metabolic systems such as purine and pyrimidine synthesis. About 70% of food folate and cellular folate is comprised of L-methylfolate. It is the primary form of folate in circulation, and is also the form transported across membranes – particularly across the blood brain barrier – into peripheral tissues. In the cell, L-methylfolate is used in the remethylation of homocysteine to form methionine and tetrahydrofolate (THF). L-methylfolate is converted into functional, metabolically active coenzyme forms for use in the body, and supplies the active folate substrate, THF (tetrahydrofolate) for use in transformylation and methylation biochemistry.

Folates are best known for reducing the incidence of fetal neural tube defects (NTDs). [viii, ix,x] NTDs are congenital malformations produced by failure of the neural tube to form and close properly during embryonic development. [xi,xii] During the first four weeks of pregnancy – when many women do not even realize that they have conceived, adequate maternal folate intake is essential to reduce the risk of NTDs. Folate is also essential in the synthesis and maintenance of nucleoprotein in erythropoiesis. It also promotes white blood cell (WBC) and platelet production in folate-deficiency anemia. Folate is associated with methylation and transformylation biochemistry. Folate is involved in transformylation and methylation metabolism as well as, indirectly, succinylation metabolism (through the “methyl trap” hypothesis). Folate plays a central role in the formation of nucleic acid precursors, such as thymidylic acid and purine nucleotides, which are essential for nucleic acid synthesis and cell division. IOM/NAS (1998) noted that the evidence for a protective effect from folate supplements is much stronger than that for food folate. Other ingredients are added to folate as cofactors, coenzymes and co-metabolites; in studies by Czeizel and Dudas (1992) and Berry et al. (1999), factors other than folate intake may affect the magnitude of risk reduction or participate in a co-protective effect with folate. [4,5]

L-methylfolate supplementation increases the formation of endothelian nitric oxide synthase resulting in increase nitric oxide. This causes vasodilation to the nerves, increasing blood supply to the nerves, and reducing vascular oxidative stress. [xiv] L-methylfolate supplementation also increases nitric oxide levels by increasing the amount of tetrahydrobioterin (BH4). BH4 is required for nitric oxide synthesis. [xv]

FOLATE COENZYMES, COFACTORS, AND COMETABOLITES - The following ingredients are added to enhance the bioavailable potential of folate, and include:

COBALAMIN - Methylcobalamin is required for two important reactions: the conversion of methylmalonyl CoA to succinyl CoA, a Krebs cycle intermediate, and the conversion of homocysteine to methionine, a reaction in which the methyl group of L-methylfolate is donated to remethylate homocysteine. Homocysteine has been found to stimulate or alter transcription factors involved in inflammation, with an important ancillary consequence of BH_4 depletion. For example, it has been reported that homocysteine-

mediated activation of sterol regulatory element binding protein (SREBP) upregulates expression of 3-hydroxy-3-methyl-glutaryl-coenzyme (HMG-CoA reductase) with increased biosynthesis and cellular uptake of cholesterol, the depletion of BH_4 being a secondary effect.

PYRIDOXAL-5'-PHOSPHATE (PLP) is the active form of vitamin B. The amino acid decarboxylase considered to decarboxylate both dihydroxyphenylalanine (DOPA) and 5-hydroxytryptophan (5-HTP) requires pyridoxal phosphate as coenzyme. Deficient levels of plasma PLP are significantly associated with depressive symptomatology in human studies. [xvi]

OTHER B VITAMINS - Thiamine pyrophosphate (TPP) is the biologically active derivative of thiamine, vitamin B Flavin adenine dinucleotide (FAD) is the active substrate of riboflavin, vitamin B . It has been reported that deficiencies of thiamine and riboflavin are associated with depressive symptoms. , Nicotinamide adenine dinucleotide (NADH) is a reduced form of niacin, or vitamin B Niacin-dependent dihydropteridine reductase (DHPR) is involved in BH regeneration.

IRON – Accentrate® PNV supplies iron as a pure amino acid iron-chelate, which provides pure elemental iron – an essential component in the formation of hemoglobin. Iron therapy is necessary in advanced folate supplementation due to interference between iron and folate metabolism. Sufficient amounts are required for effective erythropoiesis. According to the USDA, "The impact of iron deficiency on folate metabolism is most dramatic during the reproductive and neonatal stages of the life cycle."

Iron is one of the primary cofactors in BH reactions. Tyrosine hydroxylase requires iron and tetrahydrobiopterin to catalyze the conversion of tyrosine (also contained in Accentrate® PNV) to DOPA, which is then converted to dopamine by the enzyme DOPA decarboxylase. Dopamine β-hydroxylase transforms dopamine to norepinephrine, which can be further transformed to epinephrine.

OMEGA-3 FATTY ACIDS - Docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) are omega-3 fatty acids. Accentrate® PNV contains LYSOVETA® LPC which comprises the omega-3 fatty acid-derivatives EPA and DHA conjugated to lysophosphatidylcholine (LPC). LPC-EPA and LPC-DHA are the forms of EPA and DHA that is absorbed by the brain through the MSFD2a receptor active on the blood brain barrier. Accretion of EPA and DHA in LPC form has been shown to be significantly higher than triglyceride, phospholipid (PC), and free fatty acid form.

DHA bound to LPC was shown to be 4 times higher in umbilical circulation than maternal circulation, which may indicate that omega-3 fatty acids in LPC form is preferred for omega-3 supplementation during pregnancy. Evidence suggests that LYSOVETA® LPC provides a neuroprotective effect against neonatal brain injury. [xxii]

FOLATE REGULATION: The Federal Register Notices from 1971 to 1973 establish that increased folate is proper supplement in megaloblastic anemias of tropical and nontropical sprue, nutritional origin, pregnancy, infancy, and childhood. [xxiii,xxiv,xxv] Folate metabolism may be affected by malabsorption issues that differ widely among population groups. The March 5, 1996 Federal Register Notice (61 FR 8760) states "The agency concluded that ***the scientific literature did not support the superiority of any one source of folate over others, and that the data were insufficient to provide a basis for stating that a specific amount of folate is more effective than another amount*** [emphasis added]. [xxvi] The actual amount and source of folate require the supervision of a licensed medical practitioner to achieve a satisfactory maintenance level, and may exceed the 0.8 mg UL. The Federal Register Notice of August 2, 1973 (38 FR 20750) specifically states that "dietary supplement preparations are available without a prescription (21 CFR 121.1134). **Levels higher than dietary supplement amounts are available only with a prescription. Oral preparations supplying more than 0.8 mg of folate per dosage unit would be restricted to prescription dispensing** and that a dietary supplement furnishing 0.8 mg could be prescribed when a maintenance level of 0.8 mg per day was indicated. When clinical symptoms have subsided and the blood picture and/or CSF folate levels have become normal, a maintenance level should be used. "Patients should be kept under supervision of a licensed practitioner and adjustment of the maintenance level made if relapse appears imminent. In the presence of alcoholism, hemolytic anemia, anticonvulsant therapy, or chronic infection, the maintenance level may need to be increased [emphasis added]. " In the Letter Regarding Dietary Supplement Health Claim for Folic Acid, Vitamin B_6, and Vitamin B_{12} and Vascular Disease (Docket No. 99P-3029) dated November 28, 2000, FDA wrote "… high intakes of folate may partially and temporarily correct pernicious anemia while the neurological damage of vitamin B_{12} deficiency progresses. IOM/NAS (1998) set the UL for all adults of 1 mg per day because of devastating and irreversible neurological consequences of vitamin B_{12} deficiency, the data suggesting that ***pernicious anemia may develop at a younger***

age in some racial or ethnic groups, and the uncertainty about the extent of the occurrence of vitamin B12 deficiency in younger age groups (IOM/NAS, 1998) [emphasis added]. [xxviii]"

Summary: This product is a Prescription Prenatal Multivitamin Tablet containing folate that, due to advanced folate levels, requires administration under the care of a licensed medical practitioner. "Rx Only" on the label is to ensure prescription dispensing and that the product is administered under the supervision of a licensed medical practitioner due to the increased risk associated with masking of B12 deficiency (pernicious anemia). The "Rx Only" status and a National Drug Code (NDC), or similar Product Code, facilitate pedigree reporting requirements and supply-chain control as well as, in some cases, insurance-reimbursement applications.

CONTRAINDICATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the articles contained in this product. This product is contraindicated for individuals with conditions for which any of the ingredients are contraindicated.

Iron therapy is contraindicated in patients with hemochromatosis and patients with iron storage disease or the potential for iron storage disease due to chronic hemolytic anemia (e.g., inherited anomalies of hemoglobin structure or synthesis and/or red cell enzyme deficiencies, etc.), pyridoxine responsive anemia, or cirrhosis of the liver.

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 a Poison Control Center immediately **.**

WARNINGS/PRECAUTIONS:

Caution is recommended in patients with a family history of bipolar illness. Mood elevation is possible in this population.

Caution is also recommended in patients taking anticonvulsant medications as folate may interfere with anticonvulsant medication, and may lower seizure threshold. Furthermore, it has been reported that anticonvulsant medications interfere with folate metabolism, but the exact action is unclear; therefore caution is recommended with patients in this therapeutic group.

Patients undergoing cancer treatment should consult their licensed medical practitioner for advice.

Folate alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient. Folate in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission may occur while neurological manifestations progress. Daily ingestion of more than 3 grams per day of omega-3 fatty acids (DHA, ALA, and EPA) may have potential antithrombotic activities, or effects, and may increase bleeding times. Administration of omega-3 fatty acids, including DHA, should be avoided in patients with inherited or acquired bleeding diathesis, including those taking anticoagulants. Exercise caution to ensure that the prescribed dosage of DHA does not exceed 1 gram (1000 mg) per day.

ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral and parenteral folate. [xxix] Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, and the feeling of swelling of the entire body have been associated with methylcobalamin. [xxx] Allergic reactions, acne, skin reactions, photosensitivity, nausea, vomiting, abdominal pain, loss of appetite, paresthesia, somnolence, nausea, and headaches have been associated with pyridoxal-5'-phosphate. [xxxi]

Call your medical practitioner about side effects. You may report side effects to the FDA at 1-800- FDA-1088 or call Key Therapeutics, LLC. at 888-981-8337.

DRUG INTERACTIONS

Talk to your licensed medical practitioner, healthcare practitioner, personal physician, and/or pharmacist before taking or using any prescription, over-the-counter medicines,

or herbal/health supplements alongside this product. Drugs which may interact with folate include:

• Antiepileptic drugs (AED): The AED class including, but not limited to, phenytoin, carbamazepine, primidone, valproic acid, fosphenytoin, valproate, phenobarbital and lamotrigine have been shown to impair folate absorption and increase the metabolism of circulating folate.

• Additionally, concurrent use of folic acid has been associated with enhanced phenytoin metabolism, lowering the level of the AED in the blood and allowing breakthrough seizures to occur. Caution should be used when prescribing this product among patients who are receiving treatment with phenytoin and other anticonvulsants.

• Cholestyramine: Reduces folic acid absorption and reduces serum folate levels.

• Colestipol: Reduces folic acid absorption and reduces serum folate levels. Cycloserine: Reduces folic acid absorption and reduces serum folate levels.

• Fluoxetine: Fluoxetine exerts a noncompetitive inhibition of the 5-methyltetrahydrofolate active transport in the intestine.

• Isotretinoin: Reduced folate levels have occurred in some patients taking isotretinoin.

• L-dopa, triamterene, colchicine, and trimethoprim may decrease plasma folate levels.

• Nonsteroidal Anti-inflammatory Drugs (NSAIDs): NSAIDs have been shown to inhibit some folate dependent enzymes in laboratory experiments.

• NSAIDs include ibuprofen, naproxen, indomethacin and sulindac.

• Oral Contraceptives: Serum folate levels may be depressed by oral contraceptive therapy.

• Methylprednisolone: Reduced serum folate levels have been noted after treatment with methylprednisolone.

• Pancreatic Enzymes: Reduced serum folate levels have occurred in some patients taking pancreatic extracts, such as pancreatin and pancrelipase.

• Pentamidine: Reduced folate levels have been seen with prolonged intravenous pentamidine.

• Pyrimethamine: High levels of folic acid may result in decreased serum levels of pyrimethamine.

• Smoking and Alcohol: Reduced serum folate levels have been noted.

• Sulfasalazine: Inhibits the absorption and metabolism of folic acid. Metformin treatment in patients with type 2 diabetes decreases serum folate.

• Warfarin can produce significant impairment in folate status after a 6-month therapy.

Caution should be exercised with the concomitant use of folinic acid and trimethoprim-sulfamethoxazole for the acute treatment of *Pneumocystis carinii* pneumonia in patients with HIV infection as it is associated with increased rates of treatment failure and mortality in a placebo-controlled study.

Drugs which may interact with vitamin B_{12} (Methylcobalamin):

• Antibiotics, cholestyramine, colchicines, colestipol, metformin, para-aminosalicylic, and potassium chloride may decrease the absorption of vitamin B_{12}.

• Nitrous oxide can produce a functional vitamin B_{12} deficiency

***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.**

HOW SUPPLIED

Accentrate® PNV (Folate/Omega/Iron) (6 mg-210 mg-10 mg) is available in a carton with NDC † 70868-510-30 containing: Neuro 110™ in a bottle with 30 (white) tablets with the imprint “110”, Omega 110™ in a bottle with 60 (red) softgels, and Minerals 110™ in a bottle with 90 (white) capsules.

†This product is a prescription folate with or without other dietary ingredients, due to increased folate levels (AUG 2 1973 FR 20750). The “Rx” on the label is to ensure prescription dispensing and that the product is administered under the supervision of a licensed medical practitioner due to the increased risk associated with masking of B_{12} deficiency (pernicious anemia).

Based on the risk of obscuring pernicious anemia, this product requires supervision of a licensed medical practitioner. The “Rx Only” status and a National Drug Code (NDC), or similar Product Code, facilitate pedigree reporting requirements and supply-chain control as well as, in some cases, insurance-reimbursement applications.

FOR THE PHARMACIST

This product is not an Orange Book (OB) rated product, therefore all prescriptions using this product shall be pursuant to state statutes as applicable. There are no claims of bioequivalence or therapeutic equivalence.

This product may, under certain circumstances, be dispensed through a certified mail-order program as long as there is record of prescription AND confirmation that the patient is under the supervision of a licensed medical practitioner.

Store in a dry place at 71°F or below. [See USP]. Protect from light and moisture. Dispense in a tight, light-resistant container. **KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.**

MANUFACTURED for Key Therapeutics, LLC. Flowood, MS 39232

NDC: 70868-510-30 **Accentrate® PNV** combo kit is packaged in a carton containing each bottle separately:

NDC: 70868-511-30 Prenatal Multivitamin Tablets as Accentrate® Neuro 110,

Product Code: 70868-512-60 Omega-3 softgels as Accentrate® Omega 110, and

Product Code: 70868-513-90 Mineral capsules as Accentrate® Minerals 110.

MADE IN USA

Trademarks: Accentrate® is a trademark of Fenix Health Science, LLC. LYSOVETA® LPC is a trademark of Aker BioMarine Human Ingredients AS.

Distributed by Key Therapeutics, LLC. in partnership with Fenix Health Science, LLC.

Key Therapeutics, LLC. Fenix Health Science, LLC.

232 Market Street 1000 Parkwood Cir. SE

Building K Number 252 Suite 900

Flowood, MS 39232 Atlanta, GA 30339

www.keyrx.com www.fenixhealthscience.com

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Accentrate® PNV (Folate/Omega/Iron) (6 mg-210 mg-10 mg)

Prescription Prenatal Multivitamin Tablet and combination Omega-3 Softgel/Mineral Capsule

NDC: 70868-510-30

R_x Only

REFERENCES

i Miller AL. “The methylation, neurotransmitter, and antioxidant connections between folate and depression.” Altern Med Rev. 2008 Sep;13(3):216-26.

ii Bottiglieri T, et al. “Homocysteine, folate, methylation, and monoamine metabolism in depression.” J Neurol Neurosurg Psychiatry. 2000 Aug; 69(2):228-32.

iii Young SN. “Folate and depression a – neglected problem.” J Psychiatry Neurosci 2007 March; 32(2):80-82.

iv Letter Regarding Dietary Supplement Health Claim for Folic Acid, Vitamin B6, and Vitamin B12 and Vascular Disease (Docket No. 99P3029). November 28, 2000.

v Letter Regarding Dietary Supplement Health Claim for Folic Acid With Respect to Neural Tube Defects (Docket No. 91N-100H). October 10, 2000.

vi Hendler SS, Rorvik D, eds. PDR for Nutritional Supplements. Montvale, NJ: Thomson Healthcare; 2001.

vii Hendler SS, Rorvik D. PDR for Nutritional Supplements. 2nd ed. Montvale, NJ. Physicians’ Desk Reference Inc; 2008.

viii Hendler SS, Rorvik D, eds. PDR for Nutritional Supplements. Montvale, NJ: Thomson Healthcare; 2001. 10.

ix Hendler SS, Rorvik D. PDR for Nutritional Supplements. 2nd ed. Montvale, NJ. Physicians' Desk Reference Inc; 2008. 11.

x Bendich A, "Preventive Nutrition: The Comprehensive Guide for Health Professionals." 2009. Dietary Supplement Facts Regulations at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm2006823.htm.

xi Letter Regarding Dietary Supplement Health Claim for Folic Acid With Respect to Neural Tube Defects. October 10, 2000.

xii Veves A. et al. Diabetes 1998. 47:457-463

xiii Verhaar, MC. Atherosclerosis, Thrombosis, Vascular Biology, 2001.

xv Federal Register Notice of April 9, 1971 (36 FR 6843).

xvi Federal Register Notice of August 2, 1973 (38 FR 20750).

xvii Letter Regarding Dietary Supplement Health Claim for Folic Acid, Vitamin B6, and Vitamin B12 and Vascular Disease. November 28, 2000.

xvii Zhang G, et al. "Thiamine nutritional status and depressive symptoms are inversely associated among older Chinese adults." J Nutr. 2013 Jan;143(1):53-8.

xviii Naghashpour M, et al. "Riboflavin status and its association with serum hs-CRP levels among clinical nurses with depression." J Am Coll Nutr. 2011 Oct;30(5):340-7.

xix Nguyen, L., et al. "Mfsd2a is a transporter for the essential omega-3 fatty acid DHA in the brain." Nature, 509 (2014). (7501), 503–506.

xx Sugasini, D. "Enrichment of brain docosahexaenoic acid (DHA) is highly dependent upon the molecular carrier of dietary DHA: lysophosphatidylcholine is more efficient than either phosphatidylcholine or triacylglycerol." J Nutr Biochem. 2019 Dec; 74:108231.

xxi Ferchaud-Roucher, V, et al. "A potential role for lysophosphatidylcholine in the delivery of long chain polyunsaturated fatty acids to the fetal circulation." Biochimica et Biophysica Acta (BBA)-Molecular and Cell Biology of Lipids 1864.3 (2019): 394-402.

xxii Hermans, E, et al. "Dietary LPC-Bound n-3 LCPUFA Protects against Neonatal Brain Injury in Mice but Does Not Enhance Stem Cell Therapy." Nutrients 16.14 (2024): 2252.

xxiii Federal Register Notice of April 9, 1971 (36 FR 6843).

xxiv Federal Register Notice of August 2, 1973 (38 FR 20750).

xxv Federal Register Notice of October 17, 1980 (45 FR 69043 at 69044).

xxvi Federal Register Notice of March 5, 1996 (61 FR 8760).

xxvii Federal Register Notice of August 2, 1973 (38 FR 20750).

xxviii Letter Regarding Dietary Supplement Health Claim for Folic Acid, Vitamin B6, and Vitamin B12 and

Vascular Disease (Docket No. 99P3029). November 28, 2000.

xxix Natural Standard Research Collaboration (NIH). Folate (folic acid) Monograph 2009.

xxx Natural Standard Research Collaboration (NIH). Vitamin B12 Monograph 2009.

xxxi Alternative Medicine Review Vitamin B6 Monograph Volume 6, Number 1, 2001.

ACCENTRATE PNV

prenatal multivitamin tablet and combination omega-3 softgel/mineral capsule kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70868-510

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70868-510-30	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	02/25/2025	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	30
Part 2	1 BOTTLE	60
Part 3	1 BOTTLE	90

Part 1 of 3

NEURO 110

multivitamin tablet tablet

Product Information	
Item Code (Source)	NDC:70868-511
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U)	TYROSINE	150 ug
PANTOTHENIC ACID (UNII: 19F5HK2737) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	15 mg
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	1 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	1200 [USP'U]
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1 mg
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	6 mg
RIBOFLAVIN 5'-PHOSPHATE (UNII: 7N464URE7E) (RIBOFLAVIN 5'-PHOSPHATE - UNII:7N464URE7E)	RIBOFLAVIN 5'-PHOSPHATE	3 mg
PYRIDOXAL 5-PHOSPHATE (UNII: F06SGE49M6) (PYRIDOXAL 5-PHOSPHATE -	PYRIDOXAL 5-	10 mg

UNII:F06SGE49M6)	PHOSPHATE	10 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	5 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	85 ug

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GLUTATHIONE (UNII: GAN16C9B8O)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, POTATO (UNII: 8I089SAH3T)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor		**Imprint Code**	110
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70868-511-30	30 in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/16/2025	

Part 2 of 3

OMEGA 110

omega-3 softgel capsule

Product Information

Item Code (Source)	NDC:70868-512
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
1-STEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE (UNII: 2GZO7EJ6ZE) (1-STEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE - UNII:2GZO7EJ6ZE)	1-STEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE	260 ug
EICOSAPENTAENOIC ACID (UNII: AAN7QOV9EA) (EICOSAPENTAENOIC ACID - UNII:AAN7QOV9EA)	EICOSAPENTAENOIC ACID	140 ug
DOCOSAHEXAENOIC ACID (UNII: ZAD9OKH9JC) (DOCOSAHEXAENOIC ACID - UNII:ZAD9OKH9JC)	DOCOSAHEXAENOIC ACID	70 ug

Inactive Ingredients

Ingredient Name	Strength
GELATIN TYPE B BOVINE (160 BLOOM) (UNII: 1T8387508X)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
EUPHAUSIA KRILL (UNII: B9AJZ544PE)	

Product Characteristics

Color	red	**Score**	no score
Shape	OVAL (Softgel)	**Size**	15mm

Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70868-512-30	60 in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

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

Part 3 of 3

MINERALS 110

mineral capsule capsule

Product Information

Item Code (Source)	NDC:70868-513
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERROUS BISGLYCINATE (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	10 mg
MAGNESIUM GLYCINATE (UNII: IFN18A4Y6B) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM GLYCINATE	290 mg
ZINC GLYCINATE (UNII: 681VJX72FE) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLYCINATE	35 mg

Inactive Ingredients

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
COPPER GLYCINATE (UNII: 68VAV8QID7)	
SILICA (UNII: ETJ7Z6XBU4)	
STARCH, POTATO (UNII: 8I089SAH3T)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	white	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70868-513-30	90 in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/17/2025	

Labeler - Key Therapeutics (080318791)

Revised: 3/2025

Key Therapeutics