



NATURE'S ACTIVE FOLATE FOR PRENATAL CARE

NÉVO® Caplets

Névo® is a prescription prenatal multivitamin/multimineral caplet for the dietary management of women under a doctor's care who face high to intermediate risk pregnancies, older OB patients and patients unable to fully metabolize folic acid.

Description

Each oval coated pink colored caplet contains:

Dietary Ingredients

L-Methylfolate (6(S)-5-MTHF) (Metafolin®)	1mg
Elemental Iron (polysaccharide iron complex)	29mg
Vitamin C (ascorbic acid)	80mg
Vitamin D ₃ (cholecalciferol)	400IU
Vitamin E (dl-alpha-tocopheryl acetate)	30IU
Vitamin B ₁ (thiamine mononitrate)	3mg
Vitamin B ₂ (riboflavin)	3.4mg
Vitamin B ₃ (niacinamide)	20mg
Vitamin B ₅ (d-calcium pantothenate)	7mg
Vitamin B ₆ (pyridoxine HCl)	2.6mg
Vitamin B ₉ (folic acid)	400mcg
Vitamin B ₁₂ (cyanocobalamin)	500mcg
Biotin	30mcg
Copper (oxide)	2mg
Zinc (oxide)	15mg
Calcium (carbonate)	200mg
Magnesium (oxide)	40mg

Other Ingredients

Corn Starch, Mono & Diglycerides, Microcrystalline Cellulose, Gelatin, Hypromellose, Acacia, Crospovidone, Titanium Dioxide, Polydextrose, Dicalcium Phosphate, Magnesium Stearate, Sucrose, Polyethylene Glycol, Sodium Citrate, Silicon Dioxide, Citric Acid, Triacetin, Coconut Oil, Sorbic Acid, Sodium Benzoate, FD&C Red #40 Lake, Tricalcium Phosphate, FD&C Yellow #6 Lake, Carnauba Wax, dl-alpha Tocopherol.

Névo® caplets do not contain lactose, yeast or gluten.

Indication and Usage

Névo® caplets are indicated for the distinct nutritional requirements of those women under a physician's treatment for vitamin deficiency¹ throughout pregnancy and the postnatal period for both lactating² and non-lactating mothers, with particular emphasis for those individuals who have or are at risk for the folate 677C>T polymorphism^{3,4,5} and/or women over 35 years of age who are associated with higher risk pregnancies^{6,7,8,9}. It can be used prior to conception to improve nutritional status.

Contraindications

Known hypersensitivity to any of the components in this product is a contraindication.

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.

Precautions

Folates, when administered as a single agent in doses above 0.1mg daily, may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive.

Adverse Reactions

While allergic sensitization has been reported following both oral and parenteral administration of folic acid, allergic sensitization has not been reported with the use of Metafolin®. Paresthesia, somnolence, nausea and headaches have been reported with pyridoxine hydrochloride. Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body has been associated with cyanocobalamin.

Drug Interactions

Pyridoxine hydrochloride should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine hydrochloride. However, pyridoxine hydrochloride may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa. While the concurrent use of phenytoin and folic acid may result in decreased phenytoin effectiveness, no such decreased effectiveness has been reported with the use of Metafolin®. Capecitabine (Xeloda®) toxicity may increase with the addition of leucovorin (5-formyltetrahydrofolate) (folate).

Pharmacology

L-methylfolate

L-methylfolate or 6(S)-5-methyltetrahydrofolate [6(S)-5-MTHF], is the primary biologically active isomer of folate and the form of folate in circulation. It is also the form which is transported across membranes into peripheral tissues, particularly across the blood brain barrier. In the cell, 6(S)-5-MTHF is used in the methylation of homocysteine to form methionine and tetrahydrofolate (THF). THF is the immediate acceptor of one carbon units for the synthesis of thymidine-DNA, purines (RNA and DNA) and methionine. About 70% of food folate and cellular folate is comprised of 6(S)-5-MTHF. Folic acid, the synthetic form of folate, must undergo enzymatic reduction by methylenetetrahydrofolate reductase (MTHFR) to become biologically active. Genetic mutations of MTHFR¹⁰ result in a cell's inability to convert folic acid to 6(S)-5-MTHF.

Patient Information

Névo® should be used only under the direction and supervision of a licensed physician.

Dosage and Administration

Usual adult dose is one caplet daily or as directed by a physician.

How Supplied

Available as an oval coated pink colored caplet. Névo® caplet is debossed with a "fleur-de-lis" symbol on one side and an "N" on the other side. Commercial product is supplied in bottles of 90 caplets or 500 caplets. Sample product is supplied in a carton containing five blisters with one caplet in each blister.

Storage

Store at controlled room temperature 15°C to 30°C (59°F to 86°F) (See USP). Protect from light and moisture. Dispense commercial product (90 caplets) in original light-resistant container. Dispense sample product in original blister.

Commercial Product (90 caplets)

0525-2010-90 Prescription Only

Commercial Product (500 caplets)

0525-2010-50 Prescription Only

Sample Product (5 caplets)

0525-2010-05 Professional Samples – Not for sale.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Patents

Some or all of the following patents may apply:

U.S. Patent No. 4,940,658
U.S. Patent No. 6,207,651
U.S. Patent No. 5,563,126
U.S. Patent No. 6,254,904
U.S. Patent No. 5,795,873
U.S. Patent No. 6,297,224
U.S. Patent No. 5,997,915
U.S. Patent No. 6,528,496
U.S. Patent No. 6,011,040
and other pending patent applications.

References

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