BIOPAR DELTA-FORTE- 1 nf units, 50 mcg cbl, 2.5 mg f-thf, 1 mg pteglu-, 7 mg me-thf capsule
Jaymac Pharma

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.

Biopar™ *delta*-FORTE

DESCRIPTION

[**1 NF Units**] [50 mcg CBl] [*2.5 mg F-THf*] [*1 mg PteGlu-*] [*7 mg Me-THf*]

*Prescription **Hematopoietic** Preparation For **Therapeutic Use***

Multiphasic Softgels (30ct carton)

NDC 64661-**793**-30
Rx ONLY

Biopar™*delta*-FORTE is an orally administered prescription hematopoietic preparation for therapeutic use formulated for adult macrocytic anemia patients – *specifically including pernicious anemia patients*, ages 12 and up, who are under specific direction and monitoring of cobalamin and folate status by a physician.

INGREDIENTS

Cobalamin-intrinsic factor concentrate (*non-inhibitory*)[1] ..... 1 NF Units[§]

Adenosylcobalamin (*coenzyme B_{12}*) ..... 50 mcg

Formyl folic acid, L-FTHf ..... 2.5 mg[2]

Oxidized folic acid, DHf**+** ..... 1 mg[2]

Methyl folic acid, L-MeTHf ..... 7 mg[2]

[1] *50 mcg Vitamin B_{12} (activity equivalent) and 50 mg of intrinsic factor concentrate[§] from ultra-purified, porcine-derived stomach substance from a porcine, disease-free country; together these equal 1 NF Units. Cobalamin has hematopoietic activity apparently identical to that of the anti-anemia factor in purified liver-stomach extract*

[2] *Total folates is from l-methylfolate magnesium (molar equivalent) from amorphous, diastereoisomerically pure l-methylfolate (less than 1% d-isomer), DHF-dependent*

provitamin B_9 (folic acid included) and the levo-isomer of folinic acid (label claim molar equivalent).

INACTIVES

ALSO CONTAINS:

25 mg ascorbates[4a] (*24 mg magnesium l-ascorbate, 1 mg zinc l-ascorbate*) [antioxidant], 13.6 mg chelates (*Cys-Fe[3] as cysteinated pure amino acid chelate subsisting of 1.5 mg elemental iron[4a]*) [colorant], phospholipids (phosphatidylserine-docosahexaenoic acid complex[5])

OTHER INGREDIENTS:

Annatto [colorant], betaine (trimethylglycine) [acidifier], citrates (citric acid, sodium citrate) [stabilizers], flavin adenine dinucleotide (B_2-vitamer)[4b], gelatin (bovine), glycerine, nicotinamide adenine dinucleotide hydride (B_3-vitamer)[4b], phospholipids (sunflower lecithin) [emulsifiers], piperine [bioavailability enhancer], purified water, pyridoxal 5' phosphate (B_6-vitamer)[4b], thiamine pyrophosphate (B_1-vitamer)[4b], ubidecarenone [antioxidant], yellow beeswax.

[3] *Pure amino acid, cysteinated iron chelate.*

[4a] *30% daily value (DV) of VITAMIN C, and 10% DV IRON for geriatric patients.*

[4b] *Contains less than 2% (<25 mcg/each) of vitamins B_1, B_2, B_3 and B_6.*

[5] *Contains at least 12 mg phosphatidylserine (PS) – of which approximately 6.4 mg as PS-DHA, and less than 1% EPA (<800 mcg PS-EPA)*

CONTAINS

FISH/KRILL/PORCINE (Intrinsic Factor/Cobalamin**)/SOY**

Certified 3rd-party GLUTEN-FREE. No artificial colorants. No dairy, wheat, sugar or egg

INDICATIONS & USAGE

Biopar™ *delta*-FORTE is specifically indicated as a primary and adjunctive treatment in pernicious anemia patients having idiosyncrasy or sensitivity to parenteral administration - or when parental therapy is refused;

MECHANISM OF ACTION

COBALAMIN [**TREATMENT**]; FOLATE [*PREVENTION*]; INTRINSIC FACTOR [**B_{12}-ADJUVENT**] -

Cobalamin is essential for the synthesis of methionine from homocysteine - a reaction which also requires folate. In the absence of cobalamin - ie, cobalamin deficiency, tetrahydrofolate cannot be regenerated from l-methylfolic acid, and a functional folate deficiency occurs - ie, "methyl trap hypothesis". Gastrointestinal absorption of cobalamin depends on the presence of sufficient intrinsic factor, and lack of intrinisic factor results in cobalamin deficiency.

DOSAGE & ADMINISTRATION

The adult dose is one capsule daily preferably on an empty stomach.

A deficiency of cobalamin may present first as folate deficiency - which is why folate supplementation may mask the symptoms that would normally result and also why advanced folate supplementation requires licensed medical supervision; because of this, reticulocyte plasma count, cobalamin and folate must be obtained prior to treatment**.** *Requirements of cobalamin and/or folate in excess of normal (due to pregnancy, thyrotoxicosis, hemolytic anemia, hemorrhage, malignancy, hepatic and renal disease) can usually be met with oral supplementation.*

As a general rule - in Pernicious Anemia patients, treatment will be required for the remainder of the patient's life, and usually requires weekly or monthly injections at the doctor's office. Patients that are non-compliant with parenteral therapy (injections) may use this product as a substitute ***ONLY UNDER THE DIRECT SUPERVISION OF A LICENSED MEDICAL PRACTITIONER****.*

ADVERSE REACTIONS

Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, feeling of swelling of entire body may occur with administration of cobalamin. Allergic sensitization has been reported following both oral and parenteral administration of folate.

Sensitivity to porcine intrinsic factor derived from liver substance has been reported in patients, and may occur at any time; **Biopar^{TM}*delta*-FORTE** contains a non-inhibitory form of intrinsic factor that is not derived from liver substance but rather just the mucosa (stomach substance) - in which such senstitivity is less likely to occur, however caution is advised and continuous monitoring under licensed medical supervision is required.

WARNING

USE OF THIS PRODUCT WITHOUT DIRECT SUPERVISION OF A PHYSICIAN IS DANGEROUS;
Some patients afflicted with pernicious anemia may or not respond to the orally ingested vitamin B_{12}, and there is no known way to predict which patients may respond and which patients may cease to respond;
Periodic examinations and laboratory studies of pernicious anemia patients are essential and recommended; and -
The parenteral administration of (*cyano*)cobalamin - or vitamin B_{12}, is generally recognized as a fully effective treatment of pernicious anemia. Parenteral *alkyl*-cobalamin preparations have not been and are not authorized for use except by or on the prescription of a physician.

PRECAUTIONS

GENERAL:

0.1 mg or more of folic acid daily may obscure pernicious anemia in that the hematological remission may occur while neurological manifestations remain progressive. The safe tolerable limit for folic acid (*in preparations*) is 1 mg [emphasis added];

Folic acid is not a substitute for vitamin B_{12} - although it may improve vitamin B_{12}-deficient anemias. **Exclusive use of folic acid in treating vitamin B_{12}-deficient anemias could result in progressive and irreversible neurologic damage**. Specifically, vitamin B_{12} deficiency allowed to progress over 3 months may produce permanent degenerative lesions of the spinal cord - as observed when folate therapy is used as the only hematopoietic agent;

Doses of vitamin B_{12} exceeding 10 mcg daily may produce hematologic response in patients with folate deficiency. Indiscriminate administration may mask the true diagnosis; and -

A dietary deficiency of only vitamin B_{12} is rare; multiple vitamin deficiency is expected in any dietary deficiency. No single regimen fits all cases, and the status of the patient observed in follow-up is the final criterion for adequacy of therapy.

DRUG INTERACTIONS:

Colchicine, para-aminosalicylic acid, and heavy alcohol intake for longer than 2 weeks may produce malabsorption of cobalamin.

Epileptic, antineoplastic and Parkinson's medications are cautioned in the concimant use with folate supplementation.

HOW SUPPLIED

Biopar™ *delta*-FORTE is supplied as oval, annatto (”orangish-brown”) softgels* with imprint "**7N3**". Provided as a carton with 30 softgels in blister cards. NDC 64661-**793**-30.

REGULATORY

Biopar™ *delta*-FORTE is regulated as a drug to ensure it's use is under medical supervision, and because of this, advanced folate supplementation is possible [*21 CFR 250.201*]. Intrinsic Factor was first marketed as Extralin(R) in 1932, and Extralin-B(R) with B-vitamins in 1936, followed by the Becotin(R) product which contained all the equivalent vitamins as this product plus intrinsic factor. "Old" drugs, including virtamins, which were considered safe prior to 1938, were permitted to continue on the market without further review. However, FDA maintained the authority to review these old drugs if possible safety concerns became apparent. In 1951, the Durham-Humphrey Act was passed. This act formally differentiated between prescription and OTC drugs. - *44 FR 16131 (March 16, 1979)*.

STORAGE AND HANDLING

Call your medical practitioner about side effects. You may report side effects by calling (337) 662-5962.

KEEP THIS OUT OF THE REACH OF CHILDREN.

(*Tamper Evident: Do not use if seal is broken or missing*)

Do not exceed the recommended dose.

STORAGE: Store at 20°-25° C (68°-77° F)

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION

[Rx ONLY]

PATENTS: Patent(s) pending.

TRADEMARKS: **Biopar™** *delta*-FORTEis a registered mark of JayMac Pharmaceuticals. DeltaFolateTM is a use-trademark of Jaymac Pharmaceuticals.

JAYMAC Pharmaceuticals, LLC

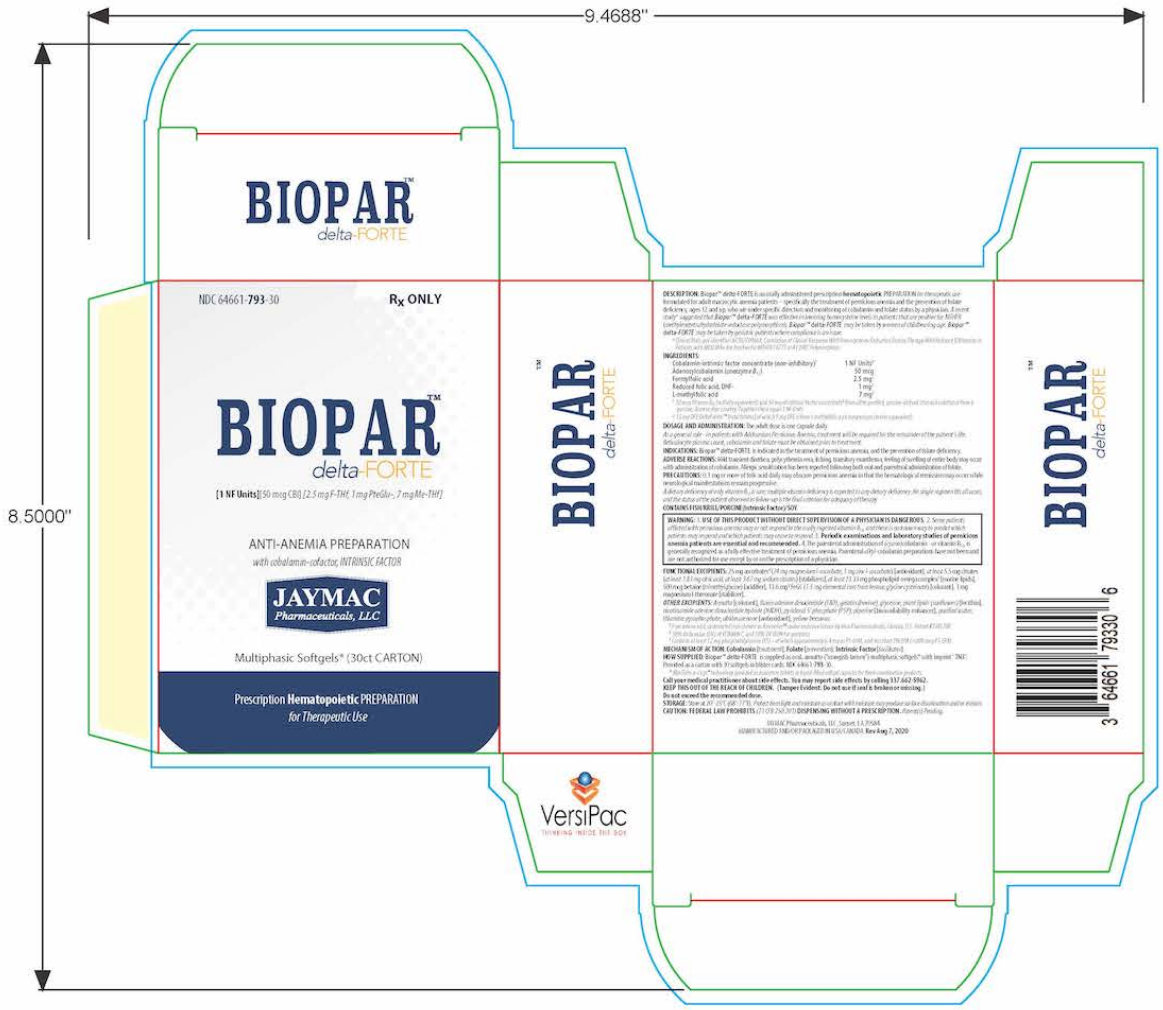
Sunset, LA 70584

MANUFACTURED AND/OR PACKAGED IN USA/CANADA

Revision

Dec 28, 2021

CARTON IMAGES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BIOPAR™
delta-FORTE
NDC 64661-793-30
Rx ONLY
BIOPAR™
delta-FORTE
[1 NF Units][50 mcg CBI] [2.5 mg F-THF, 1 mg PteGlu-, 7 mg Me-THF]
ANTI-ANEMIA PREPARATION
with cobalamin-cofactor, INTRINSIC FACTOR
JAYMAC Pharmaceuticals, LLC
Multiphasic Softgels* (30ct CARTON)
Prescription Hematopoietic PREPARATION
for Therapeutic Use
BIOPAR™
delta-FORTE
DESCRIPTION:
INGREDIENTS:
DOSAGE AND ADMINISTRATION:
INDICATIONS:
ADVERSE REACTIONS:
PRECAUTIONS:
CONTAINS FISH/BEEF/PORCINE (Intrinsic Factor)/SOY
WARNING:
FUNCTIONAL EXCIPIENTS:
OTHER EXCIPIENTS:
HOW SUPPLIED:
MECHANISM OF ACTION:
Call your medical practitioner about side effects. You may report side effects by calling 337-662-5962.
KEEP THIS OUT OF THE REACH OF CHILDREN. (Tamper Evident. Do not use if seal is broken or missing.)
Do not exceed the recommended dose.
STORAGE:
CAUTION: FEDERAL LAW PROHIBITS
DISPENSING WITHOUT A PRESCRIPTION.
JAYMAC Pharmaceuticals, LLC, Sunset, LA 70584
MANUFACTURED AND PACKAGED IN USA/CANADA. Rev Aug 7, 2020
VersiPac
THINKING INSIDE THE BOX
BIOPAR™
delta-FORTE
3 64661 79330 6


BIOPAR
NDC 64661-793-30
Rx ONLY
BIOPAR™
delta-FORTE
[1 NF Units][50 mcg CBI] [2.5 mg F-THf, 1 mg PteGlu-, 7 mg Me-THf]
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BIOPAR


BIOPAR™
delta-FORTE
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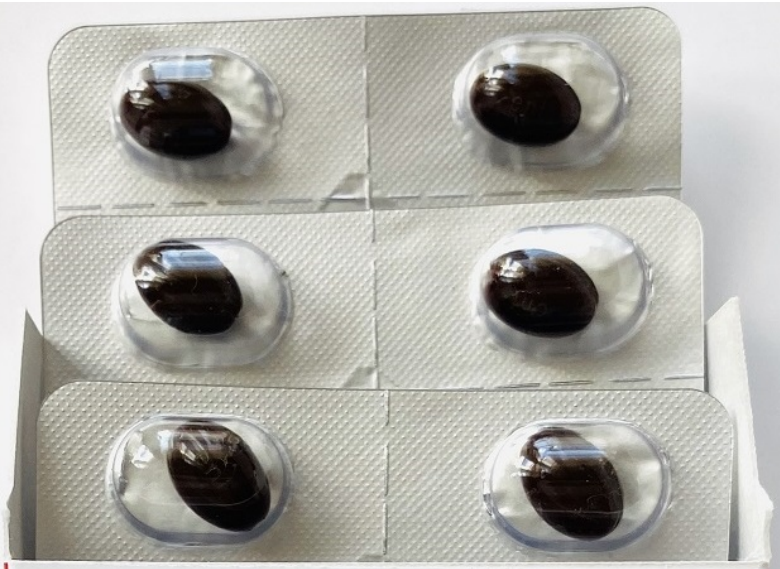

DESCRIPTION: Biopar™ *delta*-FORTE is an orally administered prescription **hematopoietic** PREPARATION *for therapeutic use* formulated for adult macrocytic anemia patients – specifically the treatment of pernicious anemia and the prevention of folate deficiency, ages 12 and up, who are under specific direction and monitoring of cobalamin and folate status by a physician. *A recent study[+] suggested that* ***Biopar™* delta-*FORTE*** *was effective in lowering homocysteine levels in patients that are positive for MTHFR (methylenetetrahydrofolate reductase polymorphism).* ***Biopar™* delta-*FORTE*** *may be taken by women of childbearing age.* ***Biopar™* delta-*FORTE*** *may be taken by geriatric patients where compliance is an issue.*

[+] ClinicalTrials.gov identifier: NCT02709668, Correlation of Clinical Response With Homocysteine Reduction During Therapy With Reduced B Vitamins in Patients with MDD Who Are Positive for MTHFR C677T or A1298C Polymorphism.

INGREDIENTS:

Cobalamin-intrinsic factor concentrate (*non-inhibitory*)[1]	**1 NF Units[5]**
Adenosylcobalamin (*coenzyme* B_{12})	**50 mcg**
Formylfolic acid	**2.5 mg[2]**
Reduced folic acid, DHF-	**1 mg[2]**
L-methylfolic acid	**7 mg[2]**

[1] 50 mcg Vitamin B_{12} (activity equivalent) and 50 mg of intrinsic factor concentrate[6] from ultra-purified, porcine-derived stomach substance from a porcine, disease-free country. Together these equal 1 NF Units

[2] 15 mg DFE DeltaFolate™ (total folates) of which 9 mg DFE is from l-methylfolic acid magnesium (molar equivalent)

DOSAGE AND ADMINISTRATION: The adult dose is one capsule daily.

As a general rule - in patients with Addisonian Pernicious Anemia, treatment will be required for the remainder of the patient's life. Reticulocyte plasma count, cobalamin and folate must be obtained prior to treatment.

INDICATIONS: Biopar™ *delta*-FORTE is indicated in the treatment of pernicious anemia, and the prevention of folate deficiency.

ADVERSE REACTIONS: Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, feeling of swelling of entire body may occur with administration of cobalamin. Allergic sensitization has been reported following both oral and parenteral administration of folate.

PRECAUTIONS: 0.1 mg or more of folic acid daily may obscure pernicious anemia in that the hematological remission may occur while neurological manifestations remain progressive.

A dietary deficiency of only vitamin B_{12} is rare; multiple vitamin deficiency is expected in any dietary deficiency. No single regimen fits all cases, and the status of the patient observed in follow-up is the final criterion for adequacy of therapy.

CONTAINS FISH/KRILL/PORCINE(Intrinsic Factor)/SOY.

WARNING: 1. **USE OF THIS PRODUCT WITHOUT DIRECT SUPERVISION OF A PHYSICIAN IS DANGEROUS.** 2. *Some patients afflicted with pernicious anemia may or not respond to the orally ingested vitamin B_{12}, and there is no known way to predict which patients may respond and which patients may cease to respond.* 3. **Periodic examinations and laboratory studies of pernicious anemia patients are essential and recommended.** 4. The parenteral administration of *(cyano)*cobalamin - or vitamin B_{12}, is generally recognized as a fully effective treatment of pernicious anemia. Parenteral *alkyl*-cobalamin preparations have not been and are not authorized for use except by or on the prescription of a physician.

FUNCTIONAL EXCIPIENTS: 25 mg ascorbates[4] (*24 mg magnesium l-ascorbate, 1 mg zinc l-ascorbate*) [antioxidant], *at least* 5.5 mg citrates (*at least 1.83 mg citric acid, at least 3.67 mg sodium citrates*) [stabilizers], *at least* 23.33 mg phospholipid-omega complex[5] [marine lipids], 500 mcg betaine (*trimethylglycine*) [acidifier], 13.6 mg[3] FeGC (*1.5 mg elemental iron from ferrous glycine cysteinate*) [colorant], 1 mg magnesium l-threonate [stabilizer].

OTHER EXCIPIENTS: *Annatto* [colorant], *flavin adenine dinucleotide (FAD), gelatin (bovine), glycerine, plant lipids (sunflower)* [lecithin], *nicotinamide adenine dinucleotide hydride (NADH), pyridoxal 5' phosphate (P5P), piperine* [bioavailability enhancer], *purified water, thiamine pyrophosphate, ubidecarenone* [antioxidant], *yellow beeswax.*

[3] Pure amino acid, cysteinated iron chelate as AminoFer™ under exclusive license by Viva Pharmaceuticals, Canada, U.S. Patent #7341708

[4] 30% daily value (DV) of VITAMIN C, and 10% DV IRON for geriatrics

[5] Contains at least 12 mg phosphatidylserine (PS)– of which approximately 6.4 mg as PS-DHA, and less than 1% EPA (<800 mcg PS-EPA)

MECHANISM OF ACTION: Cobalamin [*treatment*]; **Folate** [*prevention*]; **Intrinsic Factor** [*facilitator*].

HOW SUPPLIED: **Biopar™ *delta*-FORTE** is supplied as oval, annatto ("orangish-brown") multiphasic softgels* with imprint "**7N3**". Provided as a carton with 30 softgels in blister cards. NDC 64661-**793**-30.

** MiniTabs-n-Caps* technology provided as miniature tablets in liquid-filled softgel capsules for fixed-combination products.*

Call your medical practitioner about side effects. You may report side effects by calling 337.662-5962.
KEEP THIS OUT OF THE REACH OF CHILDREN. (Tamper Evident: Do not use if seal is broken or missing.)
Do not exceed the recommended dose.

STORAGE: Store at 20°-25°C (68°-77°F). *Protect from light and moisture as contact with moisture may produce surface discoloration and/or erosion.*

CAUTION: FEDERAL LAW PROHIBITS *(21 CFR 250.201)* **DISPENSING WITHOUT A PRESCRIPTION.** *Patent(s) Pending.*

JAYMAC Pharmaceuticals, LLC ,Sunset, LA 70584
MANUFACTURED AND/OR PACKAGED IN USA/CANADA **Rev Aug 7, 2020**

PACKAGE INSERT

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Biopar™ *delta*-FORTE
Same formula but now with added intrinsic factor concentrate!
[1 NF Units] [50 mcg CBI] [2.5 mg F-THf] [1 mg PteGlu-] [7 mg Me-THf]
Prescription ***Hematopoietic*** *Preparation For* ***Therapeutic Use***
Multiphasic Softgels (30ct carton)
NDC 64661-793-30
R_x ONLY
GLUTEN-FREE

DESCRIPTION:
Biopar™ *delta*-FORTE is an orally administered prescription **hematopoietic** PREPARATION *for therapeutic use* formulated for adult macrocytic anemia patients – *specifically including pernicious anemia patients*, ages 12 and up, who are under specific direction and monitoring of cobalamin and folate status by a physician. *A recent study suggested that* **Biopar™ delta-*FORTE*** *was effective in lowering homocysteine levels in patients that are positive for MTHFR (methylenetetrahydrofolate reductase polymorphism).* **Biopar™ delta-*FORTE*** *may be taken by women of childbearing age.* **Biopar™ delta-*FORTE*** *may be taken by geriatric patients where compliance is an issue.*

[+] *ClinicalTrials.gov Identifier: NCT02709668, Correlation of Clinical Response With Homocysteine Reduction During Therapy With Reduced B Vitamins in Patients with MDD Who Are Positive for MTHFR C677T or A1298C Polymorphism. .*

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[1] *50 mcg Vitamin B_{12} (activity equivalent) and 50 mg of intrinsic factor concentrate[5] from ultra-purified, porcine-derived stomach substance from a porcine, disease-free country; together these equal 1 NF Units. Cobalamin has hematopoietic activity apparently identical to that of the anti-anemia factor in purified liver-stomach extract*

[2] *15 mg DFE DeltaFolate™ (total folates) of which 9 mg DFE is from l-methylfolate magnesium (molar equivalent) from amorphous, diastereoisomerically pure l-methylfolate (less than 1% d-isomer)*

FUNCTIONAL EXCIPIENTS: 25 mg ascorbates[4a] (*24 mg magnesium l-ascorbate, 1 mg zinc l-ascorbate*) [antioxidant], 13.6 mg chelates (*FeGC[3] as ferrous glycine cysteinate subsisting of 1.5 mg elemental iron[4c]*) [colorant].

OTHER EXCIPIENTS: Annatto [colorant], betaine (trimethylglycine) [acidifier], citrates (citric acid, sodium citrate) [stabilizers], flavin adenine dinucleotide (B_2-vitamer)[4b], gelatin (bovine), glycerine, nicotinamide adenine dinucleotide hydride (B_3-vitamer)[4b], phospholipids (sunflower lecithin, phosphatidylserine-docosahexaenoic acid complex[5]) [emulsifiers], piperine [bioavailability enhancer], purified water, pyridoxal 5' phosphate (B -vitamer)[4b], thiamine pyrophosphate (B -vitamer)[4b], ubidecarenone [antioxidant], yellow beeswax.

[3] *Pure amino acid, cysteinated iron chelate as AminoFer™ under exclusive license by Viva Pharmaceuticals, Canada, U.S. Patent #7341708*

[4a] *30% daily value (DV) of VITAMIN C, and 10% DV IRON for geriatric patients.*

[4b] *Contains less than 2% (<25 mcg/each) of vitamins B_1, B_2, B_3 and B_6.*

[5] *Contains at least 12 mg phosphatidylserine (PS) – of which approximately 6.4 mg as PS-DHA, and less than 1% EPA (<800 mcg PS-EPA)*

CONTAINS FISH/KRILL/PORCINE(Intrinsic Factor/Cobalamin)/**SOY**.
Certified 3rd-party ***GLUTEN-FREE****. No artificial colorants. No dairy, wheat, sugar or egg.*

INDICATIONS & USAGE:
Biopar™ *delta*-FORTE is indicated in the treatment of pernicious anemia, and the prevention of folate deficiency.

Biopar™ *delta*-FORTE is specifically indicated as a primary and adjunctive treatment in pernicious anemia patients having idiosyncrasy or sensitivity to parenteral administration - or when parenteral therapy is refused.

Biopar™ *delta*-FORTE is further indicated in the maintenance of normal hematologic status (hematopoiesis) in macrocytic anemia conditions which are caused by either cobalamin and/or folate deficiency, and where increased intrinsic factor is desired - including:

1. Malabsorption of cobalamin resulting from structural or functional damage to the stomach - where intrinsic factor is secreted, or to the ileum, where intrinsic factor facilitates cobalamin absorption. Folate deficiency in these patients is usually more severe than cobalamin deficiency.
2. Genetic polymorphisms such as MTHFR that impede folate metabolism and the effective use of synthetic folic acid (oxidized form); and
3. Inadequate secretion of intrinsic factor, resulting from lesions that destroy the gastric mucosa (ingestion of corrosives, extensive neoplasia), and a number of conditions associated with a variable degree of gastric atrophy (certain endocrine disorders, iron deficiency, and subtotal gastrectomy). *Total gastrectomy always produces cobalamin deficiency. Structural lesions leading to cobalamin deficiency include regional ileitis, ileal resections, malignancies, etc*

MECHANISM OF ACTION:
Cobalamin [*treatment*]; **Folate** [*prevention*]; **Intrinsic Factor** [*facilitator*].
Cobalamin is essential for the synthesis of methionine from homocysteine - a reaction which also requires folate. In the absence of cobalamin - ie, cobalamin deficiency, tetrahydrofolate cannot be regenerated from l-methylfolic acid, and a functional folate deficiency occurs - ie, "methyl trap hypothesis". Gastrointestinal absorption of cobalamin depends on the presence of sufficient intrinsic factor, and lack of intrinsic factor results in cobalamin deficiency.

DOSAGE AND ADMINISTRATION:
The adult dose is one capsule daily preferably on an empty stomach.
A deficiency of cobalamin may present first as folate deficiency - which is why folate supplementation may mask the symptoms that would normally result and also why advanced folate supplementation requires licensed medical supervision; because of this, reticulocyte plasma count, cobalamin and folate must be obtained prior to treatment. *Requirements of cobalamin and/or folate in excess of normal (due to pregnancy, thyrotoxicosis, hemolytic anemia, hemorrhage, malignancy, hepatic and renal disease) can usually be met with oral supplementation.*

As a general rule - in Pernicious Anemia patients, treatment will be required for the remainder of the patient's life , and usually requires weekly or monthly injections at the doctor's office. Patients that are non-compliant with parenteral therapy (injections) may use this product as a substitute ONLY UNDER THE DIRECT SUPERVISION OF A LICENSED MEDICAL PRACTITIONER.

ADVERSE REACTIONS:
Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, feeling of swelling of entire body may occur with administration of cobalamin. Allergic sensitization has been reported following both oral and parenteral administration of folate.

Sensitivity to porcine intrinsic factor derived from liver substance has been reported in patients, and may occur at any time; **Biopar *delta*-FORTE** contains a non-inhibitory form of intrinsic factor that is not derived from liver substance but rather just the mucosa (stomach substance) - in which such sensitivity is less likely to occur, however caution is advised and continuous monitoring under licensed medical supervision is required.

WARNINGS:
1. **USE OF THIS PRODUCT WITHOUT DIRECT SUPERVISION OF A PHYSICIAN IS DANGEROUS.**
2. Some patients afflicted with pernicious anemia may not respond to the orally ingested Intrinsic Factor containing products, and there is no known way to predict which patients will respond and which patients may cease to respond to the orally ingested products.
3. **Periodic examination and laboratory studies of pernicious anemia patients are essential and recommended.**
4. The parenteral administration of (*cyano*)cobalamin – or vitamin B_{12}, is generally recognized as a fully effective treatment of pernicious anemia. Parenteral *alkyl*-cobalamin preparations have not been and are not authorized for use except by or on the prescription of a physician.

PRECAUTIONS:
GENERAL:
0.1 mg or more of folic acid daily may obscure pernicious anemia in that the hematological remission may occur while neurological manifestations remain progressive. The safe tolerable limit for folic acid (*in preparations*) is 1 mg [emphasis added].

Folic acid is not a substitute for vitamin B_{12} - although it may improve vitamin B_{12}-deficient megaloblastic anemia. **Exclusive use of folic acid in treating vitamin B_{12}-deficient megaloblastic anemia could result in progressive and irreversible neurologic damage.** Specifically, vitamin B_{12} deficiency allowed to progress over 3 months may produce permanent degenerative lesions of the spinal cord - as observed when folate therapy is used as the only hematopoietic agent.

Doses of vitamin B_{12} exceeding 10 mcg daily may produce hematologic response in patients with folate deficiency. Indiscriminate administration may mask the true diagnosis.

A dietary deficiency of only vitamin B_{12} is rare; multiple vitamin deficiency is expected in any dietary deficiency. No single regimen fits all cases, and the status of the patient observed in follow-up is the final criterion for adequacy of therapy.

DRUG INTERACTIONS:
Colchicine, para-aminosalicylic acid, and heavy alcohol intake for longer than 2 weeks may produce malabsorption of cobalamin. Epileptic, antineoplastic and Parkinson's medications are cautioned in the concimant use with folate supplementation.

HOW SUPPLIED: **Biopar™ *delta*-FORTE** is supplied in oval, annatto ("orangish-brown") multiphasic softgels with imprint "**7N3**". Provided as a carton with 30 softgels in blister cards. NDC 64661-**793**-30.

REGULATORY: Biopar™ *delta*-FORTE is regulated as a drug to ensure it's use is under medical supervision, and because of this, advanced folate supplementation is possible [21 CFR 250.201].

STORAGE AND HANDLING:
Call your medical practitioner about side effects. You may report side effects by calling 337.662-5962.
KEEP OUT OF THE REACH OF CHILDREN.
Tamper Evident: *Do not use if seal is broken or missing*.
Do not exceed recommended dose.
Store at 20°-25°C (68°-77°F). *Protect from light and moisture as contact with moisture may produce surface discoloration and/or erosion.*
Caution: **Federal law prohibits** *(21 CFR 250.201)* **dispensing without a prescription.**
[Rx Only]

PATENTS: Patent(s) pending.

TRADEMARKS: **Biopar™ *delta*-FORTE** is a registered mark of JayMac Pharmaceuticals. DeltaFolate™ is a use-trademark of JayMac Pharmaceuticals.

MANUFACTURED FOR:
JayMac Pharmaceuticals, LLC; Sunset, LA 70584.
MANUFACTURED AND/OR PACKAGED IN USA/CANADA.

Revision-b (*Aug 7 2020*)

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PILL/CAPSULE IMAGE

BLISTER CARD

Rev Oct 25, 2020

NDC 64661-**793**-30

Biopar™ *delta*-FORTE

[1 NF Units][50 mcg CBI] *[2.5 mg F-THf, 1 mg PteGlu-, 7 mg Me-THf]*

Prescription **Hematopoietic** PREPARATION
for Therapeutic Use

WARNING: 1. **USE OF THIS PRODUCT WITHOUT DIRECT SUPERVISION OF A PHYSICIAN IS DANGEROUS.** 2. *Some patients afflicted with pernicious anemia may not respond to the orally ingested Instrinsic Factor containing products, and there is no known way to predict which patients will respond and which patients may cease to respond to the orally ingested products.* 3. **Periodic examinations and laboratory studies of pernicious anemia patients are essential and recommended.** 4. The parenteral administration of *(cyano)*cobalamin - or vitamin B_{12}, is generally recognized as a fully effective treatment of pernicious anemia. Parenteral *alkyl*-cobalamin preparations have not been and are not authorized for use except by or on the prescription of a physician.

DOSAGE AND ADMINISTRATION: The adult dose is one capsule daily.

HOW SUPPLIED: Biopar™ *delta*-FORTE is supplied as oval, annatto ("orangish-brown") multiphasic softgels with imprint "**7N3**". Provided as a carton with 30 softgels in blister cards. NDC 64661-**793**-30.

JAYMAC Pharmaceuticals, LLC ,Sunset, LA 70584
MANUFACTURED AND/OR PACKAGED IN USA/CANADA

3 64661 79330 6

Lot: **Exp:**

BIOPAR DELTA-FORTE

1 nf units, 50 mcg cbl, 2.5 mg f-thf, 1 mg pteglu-, 7 mg me-thf capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64661-793
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
INTRINSIC FACTOR (UNII: 70BT6OQT2Q) (INTRINSIC FACTOR - UNII:70BT6OQT2Q)	INTRINSIC FACTOR	50 mg
COBALAMIN (UNII: 8406EY2OQA) (COBALAMIN - UNII:8406EY2OQA)	COBALAMIN	50 ug
COBAMAMIDE (UNII: F0R1QK73KB) (COBAMAMIDE - UNII:F0R1QK73KB)	COBAMAMIDE	50 ug
levoLEUCOVORIN (UNII: 990S25980Y) (LEVOLEUCOVORIN - UNII:990S25980Y)	levoLEUCOVORIN	2.5 mg
DIHYDROFOLIC ACID (UNII: KXP0KNM559) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
LEVOMEFOLATE MAGNESIUM (UNII: 1VZZ62R081) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	7 mg

Inactive Ingredients

Ingredient Name	Strength
FERROUS CYSTEINE GLYCINATE (UNII: 8B4OP7RK5N)	13.6 mg
1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM (UNII: 6WJM73T46K)	6.4 mg
1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM (UNII: 9ABD9DRK7B)	800 ug
PHOSPHATIDYL SERINE (UNII: 394XK0IH40)	12 mg
PYRIDOXAL PHOSPHATE ANHYDROUS (UNII: F06SGE49M6)	25 ug
FLAVIN ADENINE DINUCLEOTIDE (UNII: ZC44YTI8KK)	25 ug
NADH (UNII: 4J24DQ0916)	25 ug
COCARBOXYLASE (UNII: Q57971654Y)	25 ug
MAGNESIUM ASCORBATE (UNII: 0N1G678593)	24 mg
ZINC ASCORBATE (UNII: 9TI35313XW)	1 mg
RIBOFLAVIN (UNII: TLM2976OFR)	5 mg
MAGNESIUM L-THREONATE (UNII: 1Y26ZZ0OTM)	1 mg
BETAINE (UNII: 3SCV180C9W)	500 ug
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	1.83 mg
SODIUM CITRATE (UNII: 1Q73Q2JULR)	3.67 mg
ANNATTO (UNII: 6PQP1V1B6O)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PIPERINE (UNII: U71XL721QK)	
WATER (UNII: 059QF0KO0R)	
UBIDECARENONE (UNII: EJ27X76M46)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

Product Characteristics

Color	brown (ORANGISH-BROWN)	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	7N3
Contains			

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64661-793-30	30 in 1 CARTON	06/01/2024	06/01/2024
1		1 in 1 BLISTER PACK; Number of Units = 3; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2024	

Labeler - Jaymac Pharma (830767260)

Registrant - Jaymac Pharma (830767260)

Establishment

Name	Address	ID/FEI	Business Operations
Viva Pharmaceuticals INC		253288898	manufacture(64661-793)

Revised: 7/2024 Jaymac Pharma