

**VIVA CT PRENATAL- folic acid, ferrous fumarate, ascorbic acid, cholecalciferol, .alpha-tocopherol acetate, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, zinc oxide, cupric sulfate anhydrous, and selenomethionine tablet, chewable**  
**JayMac Pharmaceuticals LLC**

*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.*

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**Viva<sup>®</sup> CT Prenatal Chewable**  
**IRON SUPPLEMENT**

**Rx Only**

30ct round, light pink to pink-colored, fruit-flavored chewable tablets, embossed VCT

Prescription PRENATAL/POSTNATAL Vitamin

**DESCRIPTION**

Viva<sup>®</sup> CT Prenatal Chewable is an orally administered, chewable prescription PRENATAL/POSTNATAL vitamin specifically formulated for the dietary management of individuals with unique nutritional needs requiring increased folate levels. Viva<sup>®</sup> CT Prenatal Chewable should be administered under the supervision of a licensed medical practitioner.

Each ROUND, LIGHT TO PINK-colored, chewable tablet contains the following dietary ingredients:

|   |                     |
|---|---------------------|
| Folic Acid                                    | 1 mg <sup>*</sup>   |
| Iron (ferrous fumarate)                       | 28 mg <sup>*</sup>  |
| Vitamin C (ascorbic acid)                     | 100 mg <sup>*</sup> |
| Vitamin D <sub>3</sub> (cholecalciferol)      | 400 IU <sup>*</sup> |
| Vitamin E (acetate)                           | 30 IU <sup>*</sup>  |
| Vitamin B <sub>1</sub> (thiamine mononitrate) | 3 mg <sup>*</sup>   |
| Vitamin B <sub>2</sub> (riboflavin)           | 3 mg <sup>*</sup>   |
| Vitamin B <sub>6</sub> (pyridoxine HCl)       | 50 mg <sup>*</sup>  |
| Vitamin B <sub>12</sub> (cyanocobalamin)      | 15 mcg <sup>*</sup> |
| Zinc (oxide)                                  | 20 mg <sup>*</sup>  |
| Copper (sulfate)                              | 1 mg <sup>*</sup>   |
| L-(+)-Selenomethionine <sup>†</sup>           | 50 mcg <sup>*</sup> |

\* Daily Value not established for individuals with unique nutritional needs who are in need of nutritional supplementation as directed by a licensed medical practitioner.

† L-(+)-Selenomethionine as Selenium SeLECT<sup>®</sup> is a registered trademark of Sabinsa Corporation, Piscataway, NJ. It has CAS #3211-76-5, and is chemically known as the diastereoisomerically pure (S)-(+)-2-Amino-4(methylseleno)-butanoic acid.

**Other Ingredients**

Xylitol, Microcrystalline Cellulose, Povidone, Magnesium Stearate, Talc, Fruit Punch Flavor, Sucralose.

**FOLATE REGULATION**

The term "folate" are B vitamins that include folic acid and any forms of active pteroylglutamates regardless of the reduction state of the molecule. Folates, or vitamin B9, are primarily hydrolyzed in the intestinal jejunum and the liver to the active circulating form of folate, L-methylfolate, with an intermediate stable form, 5,10-methylenetetrahydrofolate. Folic acid, including the reduced forms<sup>1</sup> such as folinic acid, may obscure pernicious anemia above 0.1 mg doses, and must be administered under the supervision of a licensed medical practitioner.

The 1971, 1972, 1973, 1980, 1984, 2000, and 2010 Federal Register Notices addressed this concern while establishing that increased folate was proper therapy in megaloblastic anemias - specifically where homocysteine levels were elevated or risk of neural tube defects (NTDs) was at issue. 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.* Folic acid - including reduced forms, may be added to medical foods as defined in section 5(b) (3) of the Orphan Drug Act (21 USC 360ee(b)(3)), or to food (21 CFR 172.345).

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<sup>1</sup> *This product is a dietary supplement that - due to increased folate levels (AUG 3 1973 FR 20750), requires an Rx on the label because of increased risk associated with masking of vitamin B<sub>12</sub> deficiency. As such, this product requires licensed medical supervision, an Rx status, and a National Drug Code (NDC) as required by pedigree reporting requirements.*

## INDICATIONS AND USAGE

Viva<sup>®</sup> CT Prenatal Chewable is indicated for the distinct nutritional requirements of individuals in need of PRENATAL/POSTNATAL dietary supplementation as determined by a licensed medical practitioner. This product can be used for dietary management prior to conception. Viva<sup>®</sup> CT Prenatal Chewable should be administered under the supervision of a licensed medical practitioner.

## CONTRAINDICATIONS

Viva<sup>®</sup> CT Prenatal Chewable is contraindicated in individuals with a known hypersensitivity to any of the ingredients.

## WARNINGS

### WARNING

**Accidental overdose** of iron-containing products is the leading cause of poisoning of children under 6. **KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.** In case of accidental overdose, call a doctor or poison control center immediately.

## PREGNANCY and NURSING MOTHERS

Viva<sup>®</sup> CT Prenatal Chewable is intended for use as a PRENATAL/POSTNATAL vitamin for lactating and non-lactating mothers. Talk with your medical practitioner to ensure adequate prenatal/postnatal supplementation. Consult with your licensed medical practitioner before using Viva<sup>®</sup> CT Prenatal Chewable if pregnant or nursing.

## PRECAUTIONS

Folate alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B<sub>12</sub> is deficient. Folate in doses above 0.1 mg daily may obscure pernicious anemia in

that hematologic remission can occur while neurological manifestations progress.

## **PATIENT INFORMATION**

Viva<sup>®</sup> CT Prenatal Chewable is a prescription PRENATAL/POSTNATAL vitamin to be used only under licensed medical supervision.

## **DRUG INTERACTIONS**

### **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 individuals who are receiving treatment with phenytoin and other anticonvulsants.
- Capecitabine: Folinic acid (5-formyltetrahydrofolate) may increase the toxicity of Capecitabine.
- 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.
- Dihydrofolate Reductase Inhibitors (DHFRIs): DHFRIs block the conversion of folic acid to its active forms, and lower plasma and red blood cell folate levels. DHFRIs include aminopterin, methotrexate, pyrimethamine, triamterene, and trimethoprim.
- Fluoxetine: Fluoxetine exerts a noncompetitive inhibition of the 5-methyltetrahydrofolate active transport in the intestine.
- Isotretinoin: Reduced folate levels have occurred in some individuals 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 folate levels have occurred in some individuals 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 individuals with type 2 diabetes decreases serum folate.
- Warfarin can produce significant impairment in folate status after a 6-month therapy.
- Heme-iron: Can compete for transport and reduce folate absorption. Ensure adequate medical supervision to ensure proper iron levels.
- Folinic acid may enhance the toxicity of fluorouracil.
- Concurrent administration of chloramphenicol and folinic acid in folate-deficient patients may result in antagonism of the haematopoietic response to folate.
- 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.

*\*\*Folate is a broad term that includes folic acid and all reduced forms including L-methylfolate and folinic*

acid. Viva® CT Prenatal Chewable does not contain L-methylfolate or folinic acid but these warnings are included as general folate information.

**Drugs which interact with vitamin B<sub>6</sub>:**

- Vitamin B<sub>6</sub> should not be given to individuals receiving the drug levodopa because the action of levodopa is antagonized by vitamin B<sub>6</sub>. However, vitamin B<sub>6</sub> may be used concurrently in individuals receiving a preparation containing both carbidopa and levodopa.

**Drugs which may interact with vitamin B<sub>12</sub>:**

- Antibiotics, cholestyramine, colchicines, colestipol, metformin, para-aminosalicylic acid, and potassium chloride may decrease the absorption of vitamin B<sub>12</sub>.
- Nitrous oxide can produce a functional vitamin B<sub>12</sub> deficiency.

**ADVERSE REACTIONS**

Allergic sensitization has been reported following both oral and parenteral administration of folate. Paresthesia, somnolence, nausea, and headaches have been reported with vitamin B<sub>6</sub>. Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body have been associated with vitamin B<sub>12</sub>.

**DOSAGE AND ADMINISTRATION**

Chew and swallow one tablet daily, or as directed by a licensed medical practitioner.

**STORAGE**

Store at Controlled Room Temperature 15°- 30°C (59°- 86°F). [See USP]. Dispense in a tight, light-resistant container.

**HOW SUPPLIED**

Viva® CT Prenatal Chewable is supplied as round, light pink to pink-colored chewable tablets embossed VCT, and are dispensed in bottles of 30 tablets.

NDC<sup>1</sup> 64661-811-30

**Call your medical practitioner about side effects. You may report side effects by calling 866-280-5961.**

**KEEP THIS OUT OF REACH OF CHILDREN.**

**Rx Only**

All prescriptions using this product shall be pursuant to State statutes as applicable.

Manufactured by: Sancilio & Company, Inc.,  
3874 Fiscal Court, Suite 200, Riviera Beach, FL 33404

**JAYMAC**

*Pharmaceuticals, LLC*

**MADE IN CHINA**

**REV 4/2012**

**PRINCIPAL DISPLAY PANEL - 30 Chewable Tablet Label**

**Rx**

Patent Protected

30 ct. Fruit-flavored,  
Chewable Tablets

Viva® CT

Prenatal Chewable

Manufactured for:

JAYMAC

Pharmaceuticals, LLC

Sunset, LA 70584

Prescription Vitamin

NDC\*\*64661-811-30

**DOSAGE AND ADMINISTRATION:** Chew and swallow one tablet daily, or as directed by a licensed medical practitioner.

**STORAGE:** Store at controlled room temperature 15°-30°C (59°-86°F). [See USP]. Protect from light and moisture. Dispense in a tight, light-resistant container.

**KEEP THIS OUT OF REACH OF CHILDREN**  
All prescriptions using this product shall be pursuant to State statutes as applicable. Call your medical practitioner about side effects. You may report side effects by calling 866-280-5961.

**WARNING:** Accidental overdose of iron-containing products is the leading cause of poisoning of children under 6. KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

Manufactured by: Sancilio & Company, Inc.,  
3874 Fiscal Court, Suite 200, Riviera Beach, FL 33404

Lot #  
Exp. Date:

**Rx Patent Protected**

**30 ct. Fruit-flavored, Chewable Tablets**



Manufactured for:  
**JAYMAC**  
Pharmaceuticals, LLC  
Sunset, LA 70584

**Prescription Vitamin**  
NDC\*\*64661-811-30

**DESCRIPTION:** Viva® CT Prenatal Chewable is an orally administered, chewable prescription prenatal/postnatal vitamin specifically formulated for the dietary management of individuals with unique nutritional needs requiring increased folate levels. It should be administered under the supervision of a licensed medical practitioner.

**INGREDIENTS:** Each round, light pink to pink-colored, chewable tablet, embossed VCT, contains the following dietary ingredients:

|   |         |
|---|---------|
| Folic Acid                                    | 1 mg*   |
| Iron (ferrous fumarate)                       | 28 mg*  |
| Vitamin C (ascorbic acid)                     | 100 mg* |
| Vitamin D <sub>3</sub> (cholecalciferol)      | 400 IU* |
| Vitamin E (acetate)                           | 30 IU*  |
| Vitamin B <sub>1</sub> (thiamine mononitrate) | 3 mg*   |
| Vitamin B <sub>2</sub> (riboflavin)           | 3 mg*   |
| Vitamin B <sub>6</sub> (pyridoxine HCl)       | 50 mg*  |
| Vitamin B <sub>12</sub> (cyanocobalamin)      | 15 mcg* |
| Zinc (oxide)                                  | 20 mg*  |
| Copper (sulfate)                              | 1 mg*   |
| L-(+)-Selenomethionine                        | 50 mcg* |

\*See booklet for full ingredients, symbol references and prescribing information.

REV 4/2012

## VIVA CT PRENATAL

folic acid, ferrous fumarate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, zinc oxide, cupric sulfate anhydrous, and selenomethionine tablet, chewable

### Product Information

|                         |                         |                    |               |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type            | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:64661-811 |
| Route of Administration | ORAL                    |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength          | Strength |
|--|----------------------------|----------|
| FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)                         | FOLIC ACID                 | 1 mg     |
| FERROUS FUMARATE (UNII: R5L488RY0Q) (IRON - UNII:E1UOL152H7)                         | FERROUS FUMARATE           | 28 mg    |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)                   | ASCORBIC ACID              | 100 mg   |
| CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)               | CHOLECALCIFEROL            | 400 [iU] |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1) | .ALPHA.-TOCOPHEROL ACETATE | 30 [iU]  |
| THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE - UNII:X66NSO3N35)                 | THIAMINE MONONITRATE       | 3 mg     |
| RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)                         | RIBOFLAVIN                 | 3 mg     |

|  |                             |       |
|--|-----------------------------|-------|
| <b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68 Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z) | PYRIDOXINE<br>HYDROCHLORIDE | 50 mg |
| <b>CYANOCOBALAMIN</b> (UNII: P6 YC3EG204) (CYANOCOBALAMIN - UNII:P6 YC3EG204)      | CYANOCOBALAMIN              | 15 ug |
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)                | ZINC OXIDE                  | 20 mg |
| <b>CUPRIC SULFATE ANHYDROUS</b> (UNII: KUW2Q3U1VV) (COPPER - UNII:789U1901C5)      | CUPRIC SULFATE<br>ANHYDROUS | 1 mg  |
| <b>Selenomethionine</b> (UNII: 964MRK2PEL) (Selenomethionine - UNII:964MRK2PEL)    | Selenomethionine            | 50 ug |

### Inactive Ingredients

| Ingredient Name                                       | Strength |
|---|----------|
| <b>XYLITOL</b> (UNII: VCQ006KQ1E)                     |          |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U) |          |
| <b>POVIDONE</b> (UNII: FZ989GH94E)                    |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)          |          |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                        |          |
| <b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)                   |          |

### Product Characteristics

|                 |                           |                     |          |
|-----------------|---------------------------|---------------------|----------|
| <b>Color</b>    | PINK (light pink to pink) | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND                     | <b>Size</b>         | 8mm      |
| <b>Flavor</b>   | FRUIT PUNCH               | <b>Imprint Code</b> | VCT      |
| <b>Contains</b> |                           |                     |          |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:64661-811-30 | 30 in 1 BOTTLE      |                      |                    |

### Marketing Information

| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| UNAPPROVED DRUG OTHER |  | 05/01/2012           |                    |

**Labeler** - JayMac Pharmaceuticals LLC (830767260)

### Establishment

| Name     | Address | ID/FEI    | Business Operations |
|----------|---------|-----------|---------------------|
| Sancilio |         | 176681257 | MANUFACTURE         |