

## PART III: CONSUMER INFORMATION



### Vitamin-Mineral Supplement Tablets for Prenatal and Postpartum Use

This leaflet is part III of a three-part Product Monograph document designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PregVit®. Contact your doctor, pharmacist or healthcare professional if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### What the medication is used for:

PregVit® is a vitamin-mineral supplement specially formulated for use in women at least 2-3 months prior to conception, throughout pregnancy and during the postnatal period. Taking PregVit® does not eliminate the need for a balanced nutrition.

##### What it does:

PregVit® provides a supplement of vitamins and minerals.

There is strong evidence that preventative treatment with folic acid, prior to and during pregnancy, can reduce the risk of fetal neural tube defects (NTDs). NTDs result from improper development and closure of the neural tube during the third and fourth week of development. Pregnancies affected by a NTD may result in a miscarriage or stillbirth, and children born with a NTD may have mild to severe disability or die in early childhood.

Although the use of a folic acid supplement from before conception to early pregnancy reduces the number of NTDs, they can not be completely avoided through folate supplementation because of their various origins. For women who had a prior history of an NTD pregnancy, the recurrence rate of another NTD pregnancy is 2-3%.

There is evidence that increasing the diet with an additional 0.4 mg/day of folic acid would reduce the risk of neural tube defects for all women planning a pregnancy by about 36%, 1 mg per day would reduce the risk by about 57% and the use of 1.1 mg daily would reduce the risk by about 59%.

##### When it should not be used:

You should not take PregVit® if you are allergic to any of the ingredients of PregVit® or component of the container (see list of medicinal and nonmedicinal ingredients below this section).

##### What the medicinal ingredients are:

Each oval shaped, pink (a.m.), film-coated, immediate release tablet contains:

Beta-Carotene (source of vitamin A)	2700 IU
Vitamin B <sub>1</sub> (thiamine mononitrate)	3 mg
Vitamin B <sub>2</sub> (riboflavin)	3.4 mg
Niacinamide	20 mg
Pantothenic Acid (calcium pantothenate)	5 mg
Vitamin B <sub>6</sub> (pyridoxine HCl)	10 mg
Vitamin C (ascorbic acid)	120 mg
Vitamin E (dl-alpha tocopheryl acetate)	30 IU
Copper (cupric oxide)	2 mg
Iodine (potassium iodide)	0.15 mg
Iron (ferrous fumarate)*	35 mg
Magnesium (magnesium oxide)	50 mg
Zinc (zinc oxide)	15 mg

\* Elemental amount

Each oval shaped, blue (p.m.), film coated, immediate release tablet contains:

Folic Acid	1.1 mg
Vitamin B <sub>12</sub> (cyanocobalamin)	12 µg
Vitamin D <sub>3</sub> (cholecalciferol)	250 IU
Calcium (calcium carbonate)*	300 mg

\* Elemental amount

##### What the important nonmedicinal ingredients are:

###### PregVit® pink (a.m.) tablet contains:

ammonium hydroxide, N-butyl alcohol, carnauba wax, D&C Red #27, FD&C Blue #1, FD&C Blue #2, FD&C Red #40, FD&C Yellow #6, isopropyl alcohol, macrogol/PEG 3350, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, propylene glycol, shellac glaze, simethicone, sodium croscarmellose, sodium lauryl sulfate, starch (corn starch), talc, titanium dioxide.

###### PregVit® blue (p.m.) tablet contains:

ammonium hydroxide, N-butyl alcohol, carnauba wax, D&C Red #27, FD&C Blue #2, FD&C Red #40, FD&C Yellow #6, isopropyl alcohol, macrogol/PEG 3350, magnesium stearate, polyvinyl alcohol, propylene glycol, shellac glaze, simethicone, sodium croscarmellose, sodium lauryl sulfate, talc, titanium dioxide.

This product does not contain lactose, gliadin-gluten or tartrazine.

This product is certified Kosher  and Halal .

##### What dosage forms it comes in:

PregVit® is supplied in a 30-day blister pack containing 30 oval, pink (a.m.) tablets and 30 oval, blue (p.m.) tablets. Each tablet is imprinted with a pink image of a pregnant woman.



## WARNINGS AND PRECAUTIONS

BEFORE you use PregVit<sup>®</sup> talk to your doctor or healthcare professional if:

- You have a vitamin B<sub>12</sub> deficiency. Folic acid should be taken with vitamin B<sub>12</sub> in order to avoid potential problems of the nervous system. Any dose of folic acid over 1 mg per day may require monitoring for vitamin B<sub>12</sub> by a doctor or healthcare professional.
- You have seizure disorders controlled on anticonvulsant medications (e.g. carbamazepine, phenobarbital, phenytoin, primidone, valproic acid). You may have an increase in seizures when folic acid is taken.

Keep this product out of the reach of children. Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Each PregVit<sup>®</sup> pink (a.m.) tablet contains 35 mg of elemental iron. No iron is contained in the PregVit<sup>®</sup> blue (p.m.) tablet

## INTERACTIONS WITH THIS MEDICATION

As with most medications, interaction with other drugs is possible.

Tell your doctor, pharmacist or healthcare professional if you are taking any other medications, including prescription, non-prescription or natural health products, or vitamin-mineral supplements.

In particular, the drugs that may interact with PregVit<sup>®</sup> include:

- Thyroid hormone medications. Absorption of thyroid medications could be reduced if taken at the same time as iron or calcium supplements. Thyroid medications should be taken four hours before or after the pink (a.m.) and the blue (p.m.) tablets of PregVit<sup>®</sup>.
- Dihydrofolate reductase inhibitors. Dihydrofolate reductase inhibitors (including sulphasalazine, trimethoprim, triamterene) inhibit the absorption and metabolism of folic acid.
- Antiepileptic drugs. Antiepileptic drugs reduce folic acid absorption. Folic acid supplements have worsened seizure control in some people with epilepsy.

## PROPER USE OF THIS MEDICATION

### Usual dosage schedule:

Take one pink (a.m.) tablet every morning on an empty stomach, one hour before breakfast, with a glass of water. Do not take any food for one hour after taking the pink (a.m.) tablet to help the iron absorption. If you suffer from nausea and/or vomiting in the morning (morning sickness), take the pink (a.m.) tablet two hours or more after breakfast. Take one blue (p.m.) tablet every evening with a glass of water, within one hour of the evening meal to help calcium absorption.

This product is specifically prescribed for you based on your current state of health. Do not give it to others, even if you think they could benefit from taking it, and you yourself must not use it for any other condition than the one for which it was prescribed.

Tablets are not intended to be crushed or split. If you have difficulty swallowing tablets, let your doctor or healthcare professional know.

Special cases:

- For women taking calcium rich food for breakfast, the PregVit<sup>®</sup> pink (a.m.) tablet may be taken two (2) hours or more after breakfast. Following administration of the pink (a.m.) tablet a wait of one (1) additional hour is recommended before eating in order to optimize the absorption of iron.
- For women suffering from nausea and/or vomiting in the morning where it is difficult to take vitamin-mineral supplements on an empty stomach, the PregVit<sup>®</sup> pink (a.m.) tablet may be taken two (2) hours or more after breakfast. Following administration of the pink (a.m.) tablet a wait of one (1) additional hour is recommended before eating in order to optimize the absorption of iron.
- For women taking levothyroxine hormone in the morning, it is recommended to take the PregVit<sup>®</sup> pink (a.m.) tablet at least four (4) hours apart to optimize the absorption of levothyroxine hormone. For women taking levothyroxine hormone at bedtime, it is recommended to take the PregVit<sup>®</sup> blue (p.m.) tablet at least four (4) hours apart to optimize the absorption of levothyroxine hormone.

### Overdose:

In case of accidental overdose, contact a doctor or a **regional Poison Control Centre** immediately.

Do not exceed the recommended dose.

### Missed dose:

When a dose has been missed, it should be taken as soon as possible and one pink (a.m.) and one blue (p.m.) tablet should be taken within a 24-hour period. It is recommended that PregVit<sup>®</sup> pink (a.m.) and blue (p.m.) tablets be taken at least four (4) hours apart in order to optimize the absorption of nutrients.

The prescribed dosing schedule should then continue as directed by doctor or healthcare professional.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

**Side effects:** The most common adverse reactions associated with vitamin-mineral supplements are gastrointestinal symptoms such as constipation, diarrhea, nausea and gastric irritation.

*This is not a complete list of side effects.*

*For any unexpected effects while taking PregVit<sup>®</sup>, contact your doctor, pharmacist or healthcare professional.*

## HOW TO STORE IT

Store at room temperature (15 to 30°C).

Protect from moisture. Contact with moisture may produce surface discoloration or erosion of the tablet.

Keep in a safe place out of reach of children.

### **REPORTING SUSPECTED SIDE EFFECTS**

**To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:**

**By toll-free telephone: 866-234-2345**

**By toll-free fax 866-678-6789**

**Online: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)**

**By email: [CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)**

**By regular mail:**

**Canada Vigilance National Office  
Marketed Health Products Safety and  
Effectiveness Information Bureau  
Marketed Health Products Directorate  
Health Products and Food Branch  
Health Canada  
Tunney's Pasture, AL 0701C  
Ottawa ON K1A 0K9**

***NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.***

## MORE INFORMATION

This document plus the full Product Monograph, prepared for healthcare professionals can be obtained by contacting the sponsor, Duchesnay Inc. at:  
2925 Boul. Industriel  
Laval, Quebec, Canada  
H7L 3W9  
Tel: 1-888-666-0611  
Fax: 1-888-588-8508

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