

PART III: CONSUMER INFORMATION



Vitamin-Mineral Supplement Tablets High Dose of Folic Acid for Prenatal 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 folic 5[®]. 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 folic 5[®] is for use in women who are planning pregnancy or pregnant and have the following conditions:

- a previous pregnancy affected by a neural tube defect, or
- a family history of neural tube defects,
- diabetes or malabsorption disorders,
- are taking medications used for seizure control or that are known to decrease folate levels,
- a folate deficiency requiring a high dose of folic acid supplement.

PregVit folic 5[®] should be taken at least 2-3 months prior to conception, continuing up to 10-12 weeks after the last menstrual period, or throughout the pregnancy. Taking PregVit folic 5[®] does not eliminate the need for a balanced nutrition.

What it does:

PregVit folic 5[®] provides a supplement of vitamins and minerals and 5 mg of folic acid.

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 cannot be completely avoided through folate supplementation because of their various origins. For women who had prior history of an NTD pregnancy, the recurrence rate of another NTD pregnancy is 2-3%. Consuming 5 mg of folic acid daily has the potential of reducing the incidence of another NTD pregnancy to a recurrence rate of 1%.

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 a 5 mg tablet daily would reduce the risk by about 85%.

When it should not be used:

You should not be given PregVit folic 5[®] if you are allergic to any of the ingredients of PregVit folic 5[®] 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 ₁ (thiamine mononitrate)	3 mg
Vitamin B ₂ (riboflavin)	3.4 mg
Niacinamide	20 mg
Pantothenic Acid (calcium pantothenate)	5 mg
Vitamin B ₆ (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, dark blue (p.m.), film coated, immediate release tablet contains:

Folic Acid	5 mg
Vitamin B ₁₂ (cyanocobalamin)	12 µg
Vitamin D ₃ (cholecalciferol)	250 IU
Calcium (calcium carbonate)*	300 mg

* Elemental amount

What the important nonmedicinal ingredients are:

PregVit folic 5[®] 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 folic 5[®] dark blue (p.m.) tablet contains:

ammonium hydroxide, N-butyl alcohol, carnauba wax, D&C red #27, FD&C Blue #1, FD&C Blue #2, 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 folic 5[®] is supplied in a 30-day blister pack containing 30 oval, pink (a.m.) tablets and 30 oval, dark blue (p.m.) tablets. Each tablet is imprinted with a pink image of a pregnant woman.



WARNINGS AND PRECAUTIONS

BEFORE you use PregVit folic 5[®] talk to your doctor or healthcare professional if:

- You have a vitamin B₁₂ deficiency. Folic acid should be taken with vitamin B₁₂ 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 B₁₂ 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 folic 5[®] pink (a.m.) tablet contains 35 mg of elemental iron. No iron is contained in the PregVit folic 5[®] dark blue (p.m.) tablet.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, 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, these drugs that may interact with PregVit folic 5[®] 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 dark blue (p.m.) tablets of PregVit folic 5[®].
- 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 dark 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 folic 5[®] **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 folic 5[®] **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 folic 5[®] **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 folic 5[®] **dark 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 **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 dark blue (p.m.) tablet should be taken within a 24-hour period. It is recommended that PregVit folic 5[®] pink (a.m.) and dark 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 folic 5[®], 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

By email: 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

This leaflet was prepared by Duchesnay Inc.

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