

PART III: CONSUMER INFORMATION

Pregvit[®] folic 5 **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 Pregelvit[®] 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:

Pregelvit[®] folic 5 is for use in women who are planning pregnancy or are pregnant and have any of 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, or
- are requiring a high dose of folic acid supplement in the opinion of their doctor.

Pregelvit[®] 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 Pregelvit[®] folic 5 does not eliminate the need for balanced nutrition.

What it does:

Pregelvit[®] 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 an NTD may result in a miscarriage or stillbirth, and children born with an 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 supplementing 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 Pregelvit[®] folic 5 if you are allergic to any of the ingredients of Pregelvit[®] 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	1.6 mg
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)	13.5 mg AT [†]
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

[†] *RRR*- α -tocopherol (AT)

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

Folic Acid	5 mg
Vitamin B ₁₂ (cyanocobalamin)	12 μ g
Vitamin D ₃ (cholecalciferol)	600 IU
Calcium (calcium carbonate)	300 mg

What the nonmedicinal ingredients are:

Pregelvit[®] folic 5 pink (a.m.) tablet contains:

microcrystalline cellulose, pregelatinized starch, sodium croscarmellose, polyvinyl alcohol, fish gelatin, mono and diglycerides, titanium dioxide, macrogol/PEG 3350, alginate, hydroxypropyl methyl cellulose, calcium silicate, sodium lauryl sulfate, magnesium stearate, talc, acacia gum, pea starch, silicon dioxide, FD&C Red #40 Aluminum Lake, carnauba wax, FD&C Blue #1 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, ammonium hydroxide, D&C Red #27 Aluminum Lake, FD&C Blue #2 Aluminum Lake, isopropyl alcohol, n-butyl alcohol, propylene glycol, shellac glaze, and simethicone.

Pregvit[®] folic 5 dark blue (p.m.) tablet contains: pregelatinized corn starch, sodium croscarmellose, polyvinyl alcohol, titanium dioxide, talc, macrogol/PEG 3350, acacia gum, sucrose, magnesium stearate, sodium lauryl sulfate, modified starch, FD&C Blue #1 Aluminum Lake, triglycerides, trisodium citrate, citric acid, carnauba wax, dl-alpha-tocopherol, silicon dioxide, ammonium hydroxide, D&C Red # 27 Aluminum Lake, FD&C Blue #2 Aluminum Lake, isopropyl alcohol, n-butyl alcohol, propylene glycol, shellac glaze, and simethicone.

This product does not contain lactose, gluten or tartrazine.

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 with 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, the 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 dose:

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 with a glass of water close to the evening meal (before or after), i.e. 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, chewed 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:

Do not exceed the recommended dose.

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at www.healthcanada.gc.ca/medeffect

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

Fax toll-free to 1-866-678-6789, or

Mail to:

Canada Vigilance Program

Health Canada

Postal Locator 0701E

Ottawa, Ontario

K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect[™] Canada Web site at www.healthcanada.gc.ca/medeffect.

***NOTE:** Should you require information related to the management of side effects, contact your health professional. 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:

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