

Preggy-Mama®

PROFESSIONAL INFORMATION

Complementary Medicine – Health Supplement

SCHEDULING STATUS

To be assigned

1. NAME OF THE MEDICINE

Preggy-Mama® Film-coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each White Multivitamin and Mineral Tablet contains:

Vitamin A derived from Vitamin A Acetate 2 mg	1 000	IU
Vitamin B1 derived from Thiamine Hydrochloride 6 mg	5	mg
Vitamin B2 derived from Riboflavin 2 mg	2	mg
Vitamin B3 derived from Nicotinamide 15 mg	15	mg
Vitamin B5 derived from Calcium-d-Pantothenate 5 mg	5	mg
Vitamin B6 derived from Pyridoxal-5-Phosphate Monohydrate 5 mg	5	mg
Vitamin B12 derived from Methylcobalamin 5 µg	5	µg
Vitamin C derived from Ascorbic Acid 100 mg	100	mg
Vitamin D3 derived from Cholecalciferol 10 mg	1 000	IU
Vitamin E derived from dl-α-Tocopherol Acetate 15 mg	10	IU
Biotin	100	µg
Calcium derived from Calcium Carbonate 625 mg	250	mg
Copper derived from Copper Sulphate 4 mg	1	mg
Folate derived from (6S)-5-Methyltetrahydrofolate 565 µg	500	µg
Inositol derived from Myo-Inositol 100 mg	100	mg
Iron derived from Ferrous Bisglycinate 120 mg	24	mg
Magnesium derived from Magnesium Oxide 166 mg	100	mg
Manganese derived from Manganese Sulphate Monohydrate 9 mg	3	mg
Potassium derived from Potassium Sulphate 2 mg	1	mg
Selenium derived from Selenium Glycinate 750 µg	15	µg
Zinc derived from Zinc Oxide 6 mg	5	mg

All minerals are expressed in their elemental and non-elemental forms.

Sucrose, Lactose, Gluten and Tartrazine Free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated Tablet.

White oval shaped Film-coated Tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Preggy-Mama® is a health supplement intended for the nutritional support of adults prior to conception, during pregnancy and whilst breastfeeding.

4.2 Posology and method of administration

For oral use.

Take one White Multivitamin and Mineral Tablet daily with a meal.

Take 2 hours before or after taking other medications or natural health products.

4.3 Contraindications

Do not use if you have a hypersensitivity to any of the ingredients, including the excipients listed in section 6.1.

Preggy-Mama® should not be used by persons suffering from:

- conditions associated with hypercalcaemia and hypercalciuria, and in renal impairment (chronic);
- renal osteodystrophy with hyperphosphataemia (risk of metastatic calcification).

4.4 Special warnings and precautions for use

High dose Zinc supplementation may cause a Copper or Iron deficiency.

Vitamin D may increase the risk of hypercalcaemia.

Not suitable for children below the age of 18 years (due to the Manganese, Selenium, and Potassium content) unless under the direct supervision of a qualified healthcare professional.

4.5 Interactions with other medicines

Alcohol: excessive intake of alcohol induces thiamine deficiency, may increase renal excretion of Magnesium and increases the turnover of pyridoxine.

Calcitonin: effect of calcitonin may be antagonised by Vitamin D.

Digoxin: caution because hypercalcaemia caused by Vitamin D may potentiate effects of digoxin, resulting in cardiac arrhythmias.

4-Quinolones: Magnesium may reduce absorption of 4-quinolones if not given 2 hours apart.

Tetracyclines: Magnesium and Zinc may reduce absorption of tetracyclines if not taken 2 hours apart.

Thiazide diuretics: Vitamin D may increase risk of hypercalcaemia and may increase excretion of Magnesium.

Vitamin D analogues (alfacalcidol, calcitriol, dihydrotachysterol): increased risk of toxicity with Vitamin D supplements.

Zinc: may cause a reduced absorption of ciprofloxacin and penicillamine.

4.6 Fertility, Pregnancy and Breastfeeding

Always check with your doctor or pharmacist before taking any medicines if you are pregnant, planning to have a baby or breastfeeding.

The active ingredients contained in Preggy-Mama® are commonly included in pregnancy products.

4.7 Effects on ability to drive and use of machines

None.

4.8 Undesirable effects

Organ System	Less Frequent
Gastrointestinal discomfort	Nausea, diarrhoea, constipation, indigestion, bloating and flatulence

Reporting of suspected adverse reactions:

If you experience any adverse reactions not mentioned in this leaflet, report it to AnaStellar Brands (Pty) Ltd via pharmacist@anastellar.co.za, (011) 792 4601 or <https://anastellar.co.za>

4.9 Overdose

Treatment of overdose should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Biotin: Biotin functions as an integral part of the enzymes that transport carboxyl units and fix carbon dioxide. Biotin enzymes are important in carbohydrate and lipid metabolism, and are involved in gluconeogenesis, fatty acid synthesis, propionate metabolism and the catabolism of amino acids.

Calcium: Calcium plays a structural role in bones and teeth and is essential for cellular structure, blood clotting, muscle contraction, nerve transmission, enzyme activation and hormone function.

Copper: Copper functions as an essential component of several enzymes (e.g., superoxide dismutase) and other proteins. It plays a role in bone formation and mineralisation, and in the integrity of the connective tissue of the cardiovascular system. Copper has pro-oxidant effects in vitro but antioxidant effects in vivo; there is accumulating evidence that adequate copper is required to maintain antioxidant effects within the body.

Folate: Folates are involved in a number of single carbon transfer reactions, especially in the synthesis of purines and pyrimidines (and hence the synthesis of deoxyribonucleic acid (DNA)), glycine and methionine. They are also involved in some amino acid conversions and the formation and utilisation of formate. Deficiency leads to impaired cell division (effects most noticeable in rapidly regenerating tissues).

Inositol: Plays an important role as the structural basis for a number of secondary messengers in eukaryotic cells, including inositol phosphates, phosphatidylinositol (PI) and phosphatidylinositol phosphate (PIP) lipids.

Iron: Iron is a component of haemoglobin, myoglobin and many enzymes that are involved in a variety of metabolic functions, including transport and storage of oxygen, the electron transport chain, DNA synthesis and catecholamine metabolism.

Magnesium: Magnesium is an essential cofactor for enzymes requiring adenosine triphosphate (ATP) (these are involved in glycolysis, fatty acid oxidation and amino acid metabolism). It is also required for the synthesis of ribonucleic acid (RNA) and replication of deoxyribonucleic acid (DNA); neuromuscular transmission; and calcium metabolism.

Manganese: Manganese activates several enzymes, including hydroxylases, kinases, decarboxylases and transferases. It is also a constituent of several metalloenzymes, such as arginase, pyruvate carboxylase, and also superoxide dismutase, which protects cells from free radical attack. It may have a role in the regulation of glucose homeostasis and in calcium mobilisation.

Potassium: Potassium is the principal intracellular cation and is fundamental to the regulation of acid-base and water balance. It contributes to transmission of nerve impulses, control of skeletal muscle contractility and maintenance of blood pressure.

Selenium: Selenium functions as an integral part of the enzyme glutathione peroxidase and other selenoproteins. Glutathione peroxidase prevents the generation of oxygen free radicals that cause the destruction of polyunsaturated fatty acids in cell membranes. Selenium spares the requirement for vitamin E and vice versa. It has additional effects, particularly in relation to the immune response and cancer prevention, which are not entirely due to these enzymatic functions.

Vitamin A: Vitamin A (in the form of retinal) is essential for normal function of the retina, particularly for visual adaption to darkness. Other forms (retinol, retinoic acid) are necessary to maintain the structural and functional integrity of epithelial tissue and immune system, cellular differentiation and proliferation and bone growth. Vitamin A may act as a cofactor in biochemical reactions.

Vitamin B1: Thiamine functions as a coenzyme in the oxidative decarboxylation of alpha ketoacids (involved in energy production) and in the transketolase reaction of the pentose phosphate pathway (involved in carbohydrate metabolism). Thiamine is also important in nerve transmission (independently of coenzyme function).

Vitamin B2: Riboflavin functions as a component of two flavin coenzymes – flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD). It participates in oxidation-reduction reactions in numerous metabolic pathways and in energy production. Examples include the oxidation of glucose, certain amino acids and fatty acids; reactions with several intermediaries of the Krebs cycle; conversion of pyridoxine to its active coenzyme; and conversion of tryptophan to niacin. Riboflavin has a role as an antioxidant. It may be involved in maintaining the integrity of erythrocytes.

Vitamin B3: As a vitamin, niacin functions as a component of two coenzymes, nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide diphosphate (NADP). These coenzymes participate in many metabolic processes including glycolysis, tissue respiration, lipid, amino acid and purine metabolism.

Vitamin B5: Pantothenic acid functions mainly as a component of coenzyme A and acyl carrier protein. Coenzyme A has a central role as a cofactor for enzymes involved in the metabolism of lipids, carbohydrates and proteins; it is also required for the synthesis of cholesterol, steroid hormones, acetylcholine and porphyrins. As a component of acyl carrier protein, pantothenic acid is involved in various transfer reactions and in the assembly of acetate units into longer-chain fatty acids.

Vitamin B6: Vitamin B6 is converted in erythrocytes to pyridoxal phosphate and, to a lesser extent, pyridoxamine phosphate. It acts as a cofactor for enzymes that are involved in more than 100 reactions affecting protein, lipid and carbohydrate metabolism. Pyridoxal phosphate is also present in the synthesis of several neurotransmitters; the metabolism of several vitamins (e.g., the conversion of tryptophan to niacin); and haemoglobin and sphingosine formation.

Vitamin B12: Vitamin B12 is active in the recycling of folate coenzymes and the degradation of valine. It is also required for nerve myelination, cell replication, haematopoiesis and nucleoprotein synthesis.

Vitamin C: The functions of vitamin C are based mainly on its properties as a reducing agent. It is required for the formation of collagen and other organic constituents of the intercellular matrix in bone, teeth and capillaries, and the optimal activity of several enzymes. Vitamin C also acts as an antioxidant (reacting directly with aqueous free radicals), which is important in the protection of cellular function and to enhance the intestinal absorption of non-haem iron.

Vitamin D: Vitamin D is essential for promoting the absorption and utilisation of calcium and phosphorus and normal calcification of the skeleton. Along with parathyroid hormone (PTH) and calcitonin, it regulates serum calcium concentration by altering serum calcium and phosphate blood levels as needed, and mobilising calcium from bone. It maintains neuromuscular function and various other cellular processes, including the immune system and insulin production.

Vitamin E: Vitamin E is an antioxidant, protecting polyunsaturated fatty acids in membranes and other critical cellular structures from free radicals and products of oxidation. It works in conjunction with dietary selenium (a cofactor for glutathione peroxidase), and also with vitamin C and other enzymes, including superoxide dismutase and catalase.

Zinc: Zinc is an essential component of over 200 enzymes. It plays an important role in the metabolism of proteins, carbohydrates, lipids and nucleic acids. It is a cofactor in a range of biochemical processes, including the synthesis of DNA, RNA and protein.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:
Magnesium Stearate
Maize Starch
Microcrystalline Cellulose
Povidone
Silicon Dioxide

Tablet Coating:

Castor Oil
Flexicoat White
Shellac

6.2 Incompatibilities

None.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.
Protect from light and moisture.
Keep the blister strips in the outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

10 x Film-coated Tablets contained in each of 3 x PVC/PVDC/Aluminium blister strips.

Packed product:
3 x Blister strips enclosed within a cardboard carton.
Pack size of 30 Film-coated Tablets.

6.6 Special precautions for disposal

No special requirements.

7. Holder of Certificate of Registration

AnaStellar Brands (Pty) Ltd.
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2032
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8. Registration number

To be assigned

9. Date of first authorisation

Not applicable

10. Date of revision of the text

January 2025

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety, or intended use.