

PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

1 NAME OF THE MEDICINE

PREGNAVIT M (capsules)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Per capsule
Calcium (from calcium carbonate)	230 mg
Vitamin C (as ascorbic acid)	50 mg
Iron (from ferrous fumarate)	20 mg
Vitamin B3 (as nicotinamide)	10 mg
Vitamin B1 (from thiamine mononitrate)	3 mg
Vitamin B2 (as riboflavin)	2 mg
Vitamin B6 (as pyridoxine hydrochloride)	1 mg
Potassium (from potassium sulphate)	0,84 mg
Magnesium (from magnesium oxide)	0,5 mg
Copper (from copper bisglycinate 10%) Glycine (from copper bisglycinate 10%) 0,35 mg	0,15 mg
Zinc (from zinc oxide)	0,085 mg
Manganese (from manganese bisglycinate 10%) Glycine (from manganese bisglycinate 10%) 0,137 mg	0,05 mg
Molybdenum (from molybdenum glycinate 0,2 %) Glycine (from molybdenum glycinate 0,2 %) 0.059 mg	0,025 mg
Iodine (from potassium iodide)	0,01 mg
Vitamin A (from vitamin A acetate)	2 666 IU
Vitamin D3 (as cholecalciferol)	400 IU
Folic acid	500 µg
Vitamin B12 (as cyanocobalamin)	2 µg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Blue and white capsules marked "Pregnavit M"

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

PREGNAVIT M is a health supplement for women to help support the additional nutritional requirements before, during and after pregnancy.

4.2 Posology and method of administration

Take one capsule daily with food, as directed by a healthcare provider.

4.3 Contraindications

Do not use PREGNAVIT M if you are hypersensitive to any of the ingredients, including the excipients.

4.4 Special warnings and precautions for use

PREGNAVIT M should be used with caution in patients with hypercalcaemia or renal calculi.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on PREGNAVIT M. The following interactions are noted on the monographs of the active ingredients:

Antacids should be taken at least 2 hours before or after PREGNAVIT M, as they may reduce the absorption of vitamins and minerals

4.6 Fertility, pregnancy and lactation

PREGNAVIT M is suitable for use during pregnancy and lactation at the recommended dose.

4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been studied.

4.8 Undesirable effects

Possible side effects are gastrointestinal discomfort (nausea, vomiting, heartburn, abdominal pain, bloating, dyspepsia, diarrhoea, constipation)

4.9 Overdose

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine: Health Supplement
D34.12 Multiple Substance Formulation

5.2 PHARMACOLOGICAL ACTION

- Vitamin A contributes to the maintenance of good eyesight, skin, membranes and immune function.
- The B Vitamins help to metabolise carbohydrates, fats and proteins, contribute to normal psychological function, normal functioning of the nervous system, maintenance of normal mucous membranes, maintenance of normal skin, regulation of hormonal activity, normal function of the heart, and the reduction of tiredness and fatigue.
- Vitamin C is an antioxidant for the maintenance of good health. It contributes to cell protection from free radical damage, helps in the development and maintenance of bones, cartilage, teeth and gums and helps with connective tissue formation.
- Calcium and Vitamin D contribute to the maintenance of normal muscle function and help in the development of healthy bones and teeth.
- Folic Acid contributes to maternal tissue growth during pregnancy and helps to reduce the risk of neural tube defects when taken daily prior to becoming pregnant and during early pregnancy.
- Iron helps with the formation of healthy red blood cells which play a role in oxygen transport in the body.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Brilliant blue (E133), dicalcium phosphate dihydrate, gelatine (bovine), magnesium stearate, sodium lauryl sulfate and titanium dioxide (E171.)

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Keep container tightly closed and protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Plastic containers containing 30 and 90 capsules.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

November 2022