

PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

1 NAME OF THE MEDICINE

PREGVIT MR (tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Per tablet
Calcium (as calcium carbonate)	230 mg
Vitamin C (as calcium ascorbate) Calcium (as calcium ascorbate) 6,58 mg	50 mg
Iron (as iron II bisglycinate 10%)	15 mg
Glycine (as iron II bisglycinate 10%)	5,52 mg
Vitamin B3 (as nicotinamide)	10 mg
Vitamin B1 (as thiamine monohydrate)	3 mg
Vitamin B2 (as riboflavin)	2 mg
Vitamin B6 (as pyridoxine hydrochloride)	1 mg
Potassium (as potassium sulphate)	0,84 mg
Magnesium (as magnesium oxide)	0,5 mg
Copper (as copper glycinate 10%) Glycine (as copper glycinate 10%) 0,053 mg	0,15 mg
Zinc (as zinc oxide)	0,085 mg
Manganese (as manganese bisglycinate 10%) Glycine (as manganese bisglycinate 10%) 18,4 ug	0,05 mg
Molybdenum (as molybdenum bisglycinate 0,2%) Glycine (as molybdenum bisglycinate 0,2%) 5,9 ug	0,025 mg
Vitamin A (as vitamin A acetate)	2 666 IU
Vitamin D3 (as cholecalciferol)	400 IU (10 ug)
Folic acid	500 µg
Vitamin B12 (as cyanocobalamin)	2 µg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oval shaped, pink film coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

PREGVIT MR 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

Swallow one tablet daily with food, as directed by a healthcare provider.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

PREGVIT MR PLUS should be used with caution in patients with hypercalcaemia or renal calculi.

Use in children under the age of 18 years should be under the supervision of a healthcare provider.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on PREGVIT MR. The following interactions are noted in the monographs of the active ingredients:

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

4.6 Fertility, pregnancy and lactation

PREGVIT MR 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

Magnesium stearate, maize starch, polyethylene glycol, povidone, propylene glycol, sodium starch glycolate, stearic acid, talc Coating: Opadry pink, purified water, shellac.
Sugar free.

6.2 Incompatibilities: Unknown

6.3 Shelf life: 2 years

6.4 Special precautions for storage

Store at or below 25 °C. Store blisters in carton to protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Blister packs of 10 tablets each, packed in cartons of 30, 60 or 90 tablets.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd, 15E Riley Road, Bedfordview, 2007
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8 REGISTRATION NUMBER

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

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

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