

## PROFESSIONAL INFORMATION

### SCHEDULING STATUS

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### 1 NAME OF THE MEDICINE

PREGOMEGA PLUS

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Component 1: Multivitamin and mineral tablet contains:

Ingredients	Per tablet
Calcium (Calcium Carbonate)	230 mg
Vitamin C (Calcium Ascorbate)	50 mg
Calcium (Calcium ascorbate)	6,25 mg
Iron (Iron II bisglycinate 20%)	15 mg
Glycine (Iron II bisglycinate 20%)	5,52 mg
Vitamin B3 (Nicotinamide)	10 mg
Vitamin B1 (Thiamine Monohydrate)	3 mg
Vitamin B2 (Riboflavin)	2 mg
Vitamin B6 (Pyridoxine Hydrochloride)	1 mg
Potassium (Potassium Sulphate)	0,84 mg
Folic Acid	500 µg
Magnesium (Magnesium oxide)	0,5 mg
Copper (Copper glycinate 10 %)	0,15 mg
Glycine (Copper glycinate 10 %)	0,053 mg
Zinc (Zinc Oxide)	0,085 mg
Manganese (Manganese bisglycinate 10%)	0,05 mg
Glycine (Manganese bisglycinate 10%)	18,4 µg
Molybdenum (Molybdenum bisglycinate 0,2%)	0,025 mg
Glycine (Molybdenum bisglycinate 0,2%)	5,9 µg
Vitamin A (Vitamin A acetate)	2 666 IU
Vitamin D3	100 IU
Vitamin B12 (Cyanocobalamin)	2 µg

Component 2: Each Calcium combination tablet contains:

Ingredients	Per tablet
Calcium (as Calcium Carbonate)	500 mg
Magnesium (as Magnesium Carbonate)	125 mg
Vitamin D3	400 IU

Component 3: Each Omega-3 soft gel capsule contains:

Ingredients	Per capsule
Total Pharmaceutical Grade Fish oil, from tuna and deep marine fish oil providing:	823 mg
Docosahexaenoic Acid (DHA)	261 mg
Eicosapentaenoic Acid (EPA)	92 mg

Contains sugar: glycerol 0,11 g and sorbitol 0,013 g/capsule.

For full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Multivitamin and Mineral Tablet: Oval, purple/magenta, film-coated tablet.

Calcium Tablet: Oblong, yellow coated tablet.

Omega-3 Soft Gel Capsule: Oblong, clear, yellow soft gel capsule.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indication

All-in-one multivitamin and mineral supplement containing vitamins and minerals your body needs before, during and after pregnancy.

#### 4.2 Posology and method of administration

Take one multivitamin and mineral tablet (purple), one calcium tablet (yellow) and one omega-3 soft gel capsule (clear yellow capsule) daily with food, or as directed by your healthcare provider.

The daily dosage can be taken all at once, or incrementally throughout the day.

The dosage remains the same for multiple (twins, triplets, etc) pregnancies.

#### 4.3 Contraindications

- Patients with hypersensitivity to any of the active or inactive ingredients.
- Patients with hypercalcaemia, hypercalciuria, renal impairment, renal calculi or sarcoidosis.
- Patients with renal osteodystrophy with hyperphosphatemia (a bone disease caused by the incorrect functioning of the kidneys)

#### 4.4 Special warnings and precautions for use

PREGOMEGA PLUS should be used with caution in patients with haemorrhagic disorders or in patients using medication affecting blood coagulation, such as anticoagulants. (see **INTERACTIONS**)

The omega-3 capsules contain small amounts of sorbitol and glycerol which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary condition of sorbitol or glycerol intolerance should not take this medicine.

Use with caution in patients with hypophosphatemia or hyperphosphatemia.

Use with caution in patients with heart disease.

#### 4.5 Interaction with other medicines and other forms of interaction

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

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

**Anticoagulants/Antiplatelets:** there is an increased risk of bleeding with concurrent use of medicines containing omega-3 and/or magnesium.

**Calcium-channel blockers:** calcium supplements should be used with caution due to an antagonistic effect.

Calcium can chelate and prevent the absorption of some medicines such as tetracyclines, quinolones, bisphosphonates, anti-retrovirals, levothyroxine and verapamil. Doses should be separated by at least 4 hours.

**Digoxin:** administration of high doses of calcium increases the risk of cardiac arrhythmias. Magnesium may reduce the absorption of digoxin and thereby reduce its therapeutic effects.

**Estrogen:** concurrent use may cause hypercalcaemia.

**Gabapentin:** concurrent use with magnesium reduces the absorption of gabapentin.

**Levodopa/Carbidopa:** magnesium may reduce the effectiveness of levodopa/carbidopa if taken together.

**Potassium sparing diuretics:** magnesium levels may increase with concurrent use.

**Sulfonylureas:** concomitant administration with magnesium may enhance absorption and effect of sulfonylureas (e.g. glibenclamide)

**Thiazide diuretics:** concurrent use may increase serum calcium levels. Serum calcium levels should be monitored.

**Thyroid medicines:** Calcium can interfere with thyroid hormone replacement treatment. Separate calcium and thyroid medications by at least 4 hours.

#### 4.6 Fertility, pregnancy and lactation

PREGOMEGA PLUS is suitable for use before and 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)
- eructation (belching) associated with a fishy taste in the mouth

#### 4.9 Overdose

Symptoms of overdosage include stomach upset, nausea, diarrhoea or constipation.

Treatment is symptomatic and supportive.

### 5 PHARMACOLOGICAL PROPERTIES

#### 5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: 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.
- Omega-3 contains Eicosapentaenoic Acid (EPA) and Docosahexaenoic Acid (DHA) which help to support cognitive health and brain function.

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Component 1: Multivitamin and mineral tablet: castor oil, croscarmellose sodium, copovidone, flexicoat violet, magnesium stearate, microcrystalline cellulose, shellac and purified water. Sugar free.

Component 2: Calcium tablet: beeswax, colloidal silica, magnesium stearate, maize starch, maltodextrin, opadry yellow, povidone, silicon dioxide, sodium starch glycolate, stearic acid. Sugar free.

Component 3: Omega-3 softgel capsule: alpha-tocopherol (covitol), gelatine (bovine), lemon flavour, simethicone, purified water. Contains sugar: glycerol 0,11 g and sorbitol 0,013 g/capsule.

#### 6.2 Incompatibilities

Unknown

#### 6.3 Shelf life

2 years

#### 6.4 Special precautions for storage

Store at or below 25 °C. Store blister strips in the outer carton to protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

#### 6.5 Nature and contents of container

30-day pack containing 6 blisters with 15 tablets per blister.

Each blister has 5 rows, with each row containing a multivitamin and mineral tablet, an omega-3 capsule and a calcium tablet.

#### 6.6 Special precautions for disposal and other handling

No special requirements

### 7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd,

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### 8 REGISTRATION NUMBER

To be allocated.

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

September 2020