

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

PREGOMEGA

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)	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
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%)	0,0184 mg
Molybdenum (Molybdenum bisglycinate 0,2%)	0,025 mg
Glycine (Molybdenum bisglycinate 0,2%)	5,9 ug
Vitamin A (Vitamin A acetate)	2 666 IU
Vitamin D3 (Cholecalciferol)	400 IU (10 ug)
Folic Acid	500 µg
Vitamin B12 (Cyanocobalamin)	2 µg

Component 2: 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

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Component 1: Multivitamin and Mineral Tablet: Oval, purple/magenta, film-coated tablet.

Component 2: Omega-3 Soft Gel Capsule: Oblong, clear, yellow soft gel capsule.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

PREGOMEGA is a multivitamin, mineral and omega supplement which contains the 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) and one omega-3 soft gel capsule (clear yellow capsule) daily with food, or as directed by a healthcare provider.

The daily dosage can be taken together, or incrementally throughout the day.

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

4.3 Contraindications

Do not take PREGOMEGA:

- if you are hypersensitive to any of the active or inactive ingredients.

4.4 Special warnings and precautions for use

- PREGOMEGA should be used with caution in patients with haemorrhagic disorders or in patients using medication affecting blood coagulation, such as anticoagulants. (see **INTERACTIONS**)
- Use with caution in patients with hypercalcaemia or renal calculi.
- The omega-3 capsules contain small amounts of sorbitol and glycerol which may have an effect on the control of blood sugar in patients with diabetes mellitus. Patients with the rare hereditary condition of sorbitol or glycerol intolerance should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

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

Antacids should be taken at least 2 hours before or after PREGOMEGA, 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.

4.6 Fertility, pregnancy and lactation

PREGOMEGA 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 which 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 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

Component 2: 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 4 blisters: 2 blisters each with 15 multivitamin and mineral tablets per blister, and 2 blisters each with 15 omega-3 softgel capsules per blister.

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