

PROFESSIONAL INFORMATION

D 34.12 Multiple Substance Formulation. Complementary Medicine: Health Supplement.

Health supplements are intended only to complement health or supplement the diet.

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

BIOGEN PREGNANCY PACK (Multivitamin tablet, Calcium tablet, Omega soft-gelatine capsule).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

COMPONENT 1: EACH MULTIVITAMIN AND MINERAL TABLET CONTAINS:

		%NRV*
Vitamin A (from Vitamin A acetate)	2 564,10 IU	86 %
Vitamin B ₁ (as Thiamine hydrochloride)	6,00 mg	500 %
Vitamin B ₂ (as Riboflavin)	2,00 mg	154 %
Vitamin B ₃ (as Nicotinamide)	18,00 mg	113 %
Vitamin B ₅ (as Calcium-D-pantothenate)	6,00 mg	120 %
Vitamin B ₆ (as Pyridoxine hydrochloride)	5,00 mg	294 %
Vitamin B ₁₂ (as Cyanocobalamin)	10,00 µg	417 %
Vitamin C (as Ascorbic Acid)	100,00 mg	100 %
Vitamin E (as α-tocopheryl acetate)	22,35 IU (15,00 mg α-TE)	100 %
Biotin	30,00 µg	100 %
Folic Acid	500,00 µg	125 %
Inositol	100,00 mg	
Iron (from Iron gluconate)	24,00 mg	133 %
Copper (from Copper sulphate anhydrous)	1,30 mg	144 %
Zinc (from Zinc oxide)	5,00 mg	45 %
Choline (as Bitartrate)	100,00 mg	

Contains sugar: Sorbitol 0,070 g per tablet

COMPONENT 2: EACH CALCIUM TABLET CONTAINS:

		%NRV*
Calcium (from Calcium carbonate)	500,00 mg	38 %
Vitamin D ₃ (as Cholecalciferol)	1 000 IU (10,00 mg)	67 %
Magnesium (from Magnesium oxide)	150,00 mg	36 %
Vitamin K ₂	90,00 µg	75 %

[from 45,00 mg K2VITAL® Delta (All-trans micro-encapsulated Vitamin K₂ MK-7)]

Sugar free

COMPONENT 3: EACH OMEGA 3 SOFT GELATINE CAPSULE CONTAINS:

		%NRV*
Fish oil (Engraulidae and Clupeidae)	1 000,00 mg	
Providing Omega 3 fatty acids:		
Eicosapentaenoic acid (EPA)	180,00 mg	
Docosahexaenoic acid (DHA)	120,00 mg	

Sugar free

*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010)

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Multivitamin and Mineral Tablet: Oblong, beige, film-coated tablet.

Calcium Tablet: Oblong, white, film-coated tablet.

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN PREGNANCY PACK, multivitamin and mineral supplement containing vitamins and minerals important for optimal development of the baby before, during and after pregnancy.

4.2 Posology and method of administration

Adults (18 years and older)

Take 1 (one) multivitamin and mineral tablet (beige), 1 (one) calcium tablet (white) and 1 (one) omega-3 soft gelatine capsule (clear-yellow soft gelatine capsule) daily with food, or as recommended 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.

Paediatric/Adolescent population

BIOGEN PREGNANCY PACK is not recommended for use in children or adolescents below 18 years of age.

4.3 Contraindications

- Hypersensitivity to any of the ingredients or excipients listed under section 6.1.
- 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

- Caution is advised in patients with haemorrhagic disorders or in patients using medication affecting blood coagulation, such as anticoagulants.
- Caution is advised in patients with insulin resistance, high blood glucose levels or diabetes. Inositol, sorbitol and glycerol may influence blood glucose.
- 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 specific drug interaction studies have been performed on BIOGEN PREGNANCY PACK as a combination product due to the complexity associated with the number of active ingredients present. However, the known interactions of active ingredient have been summarized.

Interactions with Medicines

- Concomitant use of antacids and vitamins and minerals, as in BIOGEN PREGNANCY PACK, should be taken at least 2 hours before or after taking BIOGEN PREGNANCY PACK, as they may reduce the absorption.
- Anticoagulants / Antiplatelets:* Concomitant use of medicines containing Omega 3 and magnesium should be used with caution as it may increase the risk of bleeding.
- Calcium should be used with caution as it may cause an antagonist 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:* High doses of calcium may increase the risk of cardiac arrhythmias. Magnesium may reduce the absorption of digoxin and thereby reduce its therapeutic effects.
- Concomitant use of estrogen and BIOGEN PREGNANCY PACK may cause hypercalcaemia.
- Concomitant use of Gabapentin with magnesium reduces the absorption of gabapentin.
- Magnesium may reduce the effectiveness of levodopa/carbidopa if taken together.
- Potassium sparing diuretics: magnesium levels may increase with concurrent use.
- Concomitant administration of sulfonyleureas and magnesium may enhance absorption and effect of sulfonyleureas (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.

Interactions with Diseases/Impairments

- The absence of hydrochloric acid in gastric secretions causes decreased stomach acidity, and consequently impaired iron absorption.
- Patients with coronary stents should avoid Folate and Vitamin B₁₂ supplementation, as it may increase the rate of restenosis.
- Vitamin B₁₂ contains cobalamin and cobalt and may cause allergic reactions in patients who are sensitive to both these compounds.
- Vitamin B₁ absorption is decreased in patients receiving haemodialysis.
- Patients with liver disease, such as hepatitis, biliary obstruction, cirrhosis etc., may experience manganese accumulation and toxicity and decreased Vitamin B₉ absorption. Theoretically, chromium might exacerbate liver disease. Vitamin B₉ absorption is decreased in patients with liver disease such as hepatitis, biliary obstruction, and cirrhosis.
- Inositol might interfere with diabetes and may influence insulin resistance or blood glucose levels.

Interactions with Food

There are no known interactions between BIOGEN PREGNANCY PACK, food and drink.

4.6 Fertility, pregnancy and lactation

BIOGEN PREGNANCY PACK is suitable for use before, during and after pregnancy. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before using BIOGEN PREGNANCY PACK.

4.7 Effects on ability to drive and use machines

BIOGEN PREGNANCY PACK may affect the ability to drive or operate machinery, as it may cause headache and somnolence. Please exercise care until you are certain that your ability to perform such activities is not affected.

4.8 Undesirable effects

BIOGEN PREGNANCY PACK can have side effects. Not all side effects reported for BIOGEN PREGNANCY PACK are included in this leaflet. Should your general health worsen or if you experience any effects while taking BIOGEN PREGNANCY PACK, please consult your health care provider for advice.

If any of the following happens, stop taking BIOGEN PREGNANCY PACK and contact your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- Rash or itching;
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to BIOGEN PREGNANCY PACK. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Abdominal cramps, belching, constipation, dizziness, metallic taste, nausea and vomiting;
- Flushing, gastric discomfort, headache and rash;
- Heartburn, somnolence, loss of appetite.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

4.8 a Description of selected adverse reactions

Severity of adverse effects listed above are typically dose dependent.

4.8 b Paediatric Population

The use of BIOGEN PREGNANCY PACK in children and adolescents has not been established due to lack of adequate data.

4.8 c Other special populations

The use of BIOGEN PREGNANCY PACK in special populations has not been established due to lack of adequate data.

4.8 d Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

Insufficient reliable information for BIOGEN PREGNANCY PACK overdose. Side effects listed in section 4.8 can be precipitated and/or be of increased severity.

5. PHARMACOLOGICAL PROPERTIES

- 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.

5.1 Preclinical safety data (Adults)

No data available for BIOGEN PREGNANCY PACK.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Component 1: *Multivitamin and mineral tablet:* Polyvinylpyrrolidone K30, magnesium stearate, microcrystalline cellulose, sorbitol powder. Contains sugar: Sorbitol 0,070 g per tablet.

Component 2: *Calcium tablet:* magnesium stearate. Sugar free.

Component 3: *Omega 3 softgel capsule:* gelatine (bovine), glycerine, mixed tocopherols. Sugar free.

6.2 Incompatibilities

In the absence of compatibility studies, BIOGEN PREGNANCY PACK must not be mixed with other medicines.

6.3 Shelf Life

24 Months.

6.4 Special precautions for storage

- Store in a cool, dry place at or below 25 °C.
- Protect from moisture.
- Keep the container tightly closed.
- KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents

30 day pack containing PVC/foil blister strips of 3 x 10 multivitamin and mineral tablets, 3 x 10 calcium tablets, and 3 x 10 omega-3 softgel capsules, packed into an outer carton.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen.
23 Stag Road,
Glen Austin,
South Africa.
Tel: 0860 347 243.
Email: info@biogen.co.za
Website: www.biogen.co.za

8. REGISTRATION NUMBER


To be allocated.

9. DATE OF FIRST AUTHORISATION

Not Applicable.

10. DATE OF REVISION OF THE TEXT

June 2023.

JOB: 41727_BPS_PREGNANCY PACK	SIZE: 370mm x 190mm
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input type="checkbox"/> Other: <input checked="" type="checkbox"/>	
COLOURS:  K	FINISHING: <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing
PLEASE CHECK CAREFULLY Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.	