

PROFESSIONAL INFORMATION

SCHEDULING STATUS

S0

1 NAME OF THE MEDICINE

ALLVIT+M (Capsules)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ALLVIT+M capsule contains:

Korean Ginseng Root (Panax Ginseng Root powder extract 5:1)	400 mg
Calcium (Calcium phosphate dibasic)	86 mg
Phosphorus (Calcium phosphate dibasic)	67 mg
Vitamin C (Ascorbic acid)	60 mg
Rutin (Rutin)	21,4 mg
Vitamin B3 (Nicotinamide)	15 mg
Iron (Ferrous fumarate)	10 mg
Magnesium (Magnesium oxide)	10 mg
Vitamin B5 (Calcium D-pantothenate)	10 mg
Calcium (Calcium D-pantothenate)	1,28 mg
Potassium (Potassium phosphate dibasic)	8 mg
Phosphorus (Potassium phosphate dibasic)	6 mg
Vitamin B1 (Thiamine mononitrate)	2 mg
Vitamin B2 (Riboflavin)	2 mg
Copper (Copper glycinate 10 %)	1 mg
Glycine	0,354 mg
Manganese (Manganese sulphate monohydrate)	1 mg
Vitamin B6 (Pyridoxine hydrochloride)	1 mg
Zinc (Zinc oxide)	1 mg
Vitamin A (Retinyl Palmitate)	4000 IU 1201 µg
Vitamin D3 (Cholecalciferol)	400 IU
Vitamin E (d-α tocopherol)	10 IU
Folic Acid (Folic acid)	500 µg
Vitamin B12 (Cyanocobalamin)	2 µg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oblong, black-brown gelatin capsule.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

ALLVIT+M is a health supplement that provides the body with vitamins and minerals for the maintenance of good health.

4.2 Posology and method of administration

Adults: Take 1 capsule daily with food, or as recommended by a healthcare provider.

The recommended dose should not be exceeded.

4.3 Contraindications

Do not use ALLVIT+M in patients who are hypersensitive to any of the ingredients, including excipients.

Not for use in children under the age of 18 years.

4.4 Special warnings and precautions for use

- Caution is advised in patients with kidney impairment/insufficiency.
- Panax ginseng has not been studied in people with cardiovascular disease. Use with caution.

- Caution is advised in patients taking other supplements containing Vitamin A or Vitamin D.
- **ALLVIT+M** contain small amounts of sorbitol and glycerol. This may cause an increase in blood sugar levels in patients with Diabetes Mellitus.
- Patients with the rare hereditary condition of sorbitol/glycerol intolerance should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on **ALLVIT+M**, however the below interactions are noted from the literature on the active ingredients:

- Antacids should be taken at least 2 hours before or after ALLVIT+M, as they may reduce the absorption of vitamins and minerals.
- Anticoagulants/Antiplatelet medicines: caution is advised as panax ginseng may decrease platelet aggregation.
- Caffeine containing medicines and food: theoretically, Panax ginseng may have an additive stimulant effect.
- Cytochrome P450 substrates: Panax ginseng may inhibit the CYP450 enzyme. Caution is advised in patients taking other medicines metabolized by this enzyme.
- Oestrogens: Panax ginseng may have estrogenic effects and may therefore interfere with hormone replacement therapy.
- Immunosuppressant medicines: Panax ginseng may possess immune stimulating properties. Theoretically, concurrent use may therefore interfere with immunosuppressive therapy.
- Insulin and antidiabetic medicines: concomitant use may enhance blood glucose lowering effects.
- Monoamine oxidase inhibitors (MAOI's): theoretically, panax ginseng can interfere with MAOI therapy.

4.6 Fertility, pregnancy and lactation

Safety of ALLVIT+M during pregnancy and lactation has not been established.

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 with panax ginseng include insomnia, headache, somnolence, vertigo, euphoria and mania. Allergic reactions and anaphylaxis have been reported with use of Panax ginseng, resulting in skin rash, itching and hypotension.

Other possible side effects include gastrointestinal discomfort (nausea, vomiting, stomach pain, bloating, constipation or diarrhoea).

4.9 Overdose

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Discipline Specific Traditional Claims D 33.7 Combination Product

5.2 PHARMACOLOGICAL ACTION

- **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.
- **Calcium and Vitamin D** contribute to the maintenance of normal muscle function and help in the development of healthy bones and teeth.
- **Copper, Manganese, Vitamin C, Vitamin E, Rutin and Zinc** are antioxidants which contribute to the protection of cells from oxidative stress and to normal function of the immune system.
- **Folic Acid** helps to form red blood cells and contributes to maternal tissue growth during pregnancy.

- **Iron** contributes to normal formation of red blood cells and haemoglobin and their proper function, normal oxygen transport in the body, cognitive function and immune system function.
- **Magnesium** contributes to normal electrolyte balance, muscle function, psychological function, and the reduction of tiredness and fatigue.
- **Panax ginseng** helps reduce mental fatigue.
- **Phosphorus** helps to metabolize carbohydrates, fats and proteins and help in the development of healthy bones and teeth.
- **Potassium** contributes to normal functioning of the nervous system, normal muscle function and maintenance of normal blood pressure.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Beeswax, hardened unsaturated oil, lecithin, sunflower seed oil.

Capsules: gelatine (bovine), iron oxide black (CI77499), iron oxide red (CI 77491), purified water, simethicone. Capsules contain sugar: glycerol 0,103 g and sorbitol 0,012 g per capsule.

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 capsules, packed in cartons with 30 capsules.

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

Tel: (011) 087 0000 www.inovapharma.co.za

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

September 2020