

PROFESSIONAL INFORMATION

Complementary Medicine – Health Supplement

SCHEDULING STATUS

To be assigned

1. NAME OF THE MEDICINE

TRINAMIK™ vegetarian capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Magnesium Oxide providing Magnesium 150 mg	249	mg
Menaquinone-7 providing Vitamin K2 120 µg	60	mg
Cholecalciferol providing Vitamin D3 1 000 IU	10	mg

All minerals are expressed in their elemental and non-elemental forms.

Suitable for use by Vegetarians

Sucrose, Lactose, Gluten and Tartrazine Free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard-gel vegetarian capsules.

Each vegecap has a white body and white cap filled with a light brown powder.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

TRINAMIK™ is a health supplement indicated for use in adults to help maintain:

- Bone support in patients that have high levels of calcium in their blood;
- Bone support in patients prone to the formation of kidney stones;
- Cardiovascular health.

TRINAMIK™ can be used as an absorbable source of Vitamin D in those deficient in this nutrient as well as to aid in Brain function.

4.2 Posology and method of administration

For oral use.

Take one capsule daily with food.

Take 2 hours before or after taking other medications or natural health products.

4.3 Contraindications

Do not use if you have a hypersensitivity to any of the ingredients, including the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

The indicated daily dose should not be exceeded.

Not suitable for children below the age of 18 years (due to the Vitamin K2 content) unless under the direct supervision of a qualified healthcare professional.

4.5 Interactions with other medicines

There are no known interactions with other medicines.

4.6 Fertility, Pregnancy and Breastfeeding

Always check with your doctor or pharmacist before taking any medicines if you are pregnant or breastfeeding.

The active ingredients in this product are commonly included in prenatal products.

4.7 Effects on ability to drive and use of machines

None.

4.8 Undesirable effects

Organ System	Less Frequent
Gastrointestinal discomfort	Nausea, diarrhoea, constipation, indigestion, bloating and flatulence

Reporting of suspected adverse reactions:

If you experience any adverse reactions not mentioned in this leaflet, report it to AnaStellar Brands (Pty) Ltd via pharmacist@anastellar.co.za, (011) 792 4601 or https://anastellar.co.za

4.9 Overdose

Treatment of overdose should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties****Magnesium:** Magnesium is an essential cofactor for enzymes requiring ATP (these are involved in glycolysis, fatty acid oxidation and amino acid metabolism). It is also required for the synthesis of RNA, DNA replication, neuromuscular transmission and calcium metabolism.**Vitamin D:** Essential for promoting the absorption and utilization of calcium and phosphorus. Along with Parathyroid Hormone (PTH) and Calcitonin, it regulates serum calcium concentration by altering calcium and phosphate blood levels as needed. This is done by mobilizing calcium from bone into the circulatory system. It also maintains neuromuscular function and insulin production.**Vitamin K:** Vitamin K is an essential cofactor for the hepatic production of proteins involved in the regulation of blood clotting (e.g., Factor II, Factors VII, IX, X and proteins C, S and Z). Vitamin K2 is responsible for the carboxylation of the bone protein Osteocalcin, into its active form. Osteocalcin regulates the function of calcium in bone turnover and mineralisation. It is also required for the synthesis of other proteins found in the plasma and kidney.**6. PHARMACEUTICAL PARTICULARS****6.1 List of excipients**Magnesium Stearate
Maize Starch
Microcrystalline Cellulose
Pirosil**6.2 Incompatibilities**

None.

6.3 Shelf life

2 years.

6.4 Special precautions for storageStore at or below 25 °C.
Keep in the original container until required for use.
Protect from light and moisture.
Keep out of reach of children.**6.5 Nature and contents of container**10 capsules contained in each of 3 PVC/PVDC/Aluminium blister strips.
3 x Blister strips enclosed within a cardboard carton.**6.6 Special precautions for disposal**

No special requirements.

7. Holder of Certificate of RegistrationAnaStellar Brands (Pty) Ltd
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+27 (0)11 792 4601**8. Registration number**

To be assigned

9. Date of first authorisation

Not applicable

10. Date of revision of the text

July 2021

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