

D 34.11 Vitamins. Complementary Medicine: Health Supplement.

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE  
BIOGEN VITAMIN K2

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:		%NRV*
Vitamin K2	120,00 µg	100 %
[From 60,00 mg K2VITAL® Delta (All-trans micro-encapsulated Vitamin K2 MK-7)]		

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

Contains sucrose, 26,4 mg per capsule.  
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM  
Capsule

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN VITAMIN K2, contributes to the maintenance of normal bones and is a factor in the maintenance of good health.

4.2 Posology and method of administration

*Adults:* Take one (1) capsule daily, with food or as recommended by your healthcare provider.

*Elderly:* No specific studies have been performed in older patients, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, older patients.

*Patient with impaired renal and/or liver function:* In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed (see also section 4.4).

*Children and adolescents:*

Not recommended in children and adolescents below the age of 18 years (see section 4.4).

4.3 Contraindications:

- If you have a hypersensitivity to the ingredients or any of the excipients listed in 6.1.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN VITAMIN K2.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Patients who are taking oral anticoagulants such as warfarin (Coumadin) as vitamin K antagonizes the effects of oral anticoagulants.
- The presence of another joint disease and alternative treatment thereof should be excluded.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

4.5 Interaction with other medicines and other forms of interactions

No specific drug interaction studies have been performed on BIOGEN VITAMIN K2, however, the pharmacokinetic properties of Vitamin K2 have been summarized.

Interactions with Medicines

- Patients who are taking other medication, including complementary or traditional medicines), should consult a healthcare provider prior to use.
- Vitamin K antagonizes the effects of oral anticoagulants such as warfarin (Coumadin). Excessive vitamin K intake from supplements or changes in the diet can reduce the anticoagulant effect

Interactions with Diseases/Impairments

- No specific disease interaction studies have been performed on BIOGEN VITAMIN K2 but the presence of another joint disease and alternative treatment thereof should be excluded.

Interactions with Foods

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN VITAMIN K2.

4.6 Fertility, pregnancy and lactation

The safety and efficacy of BIOGEN VITAMIN K2 in pregnancy and lactation has not been established.

4.7 Undesirable effects

Orally, Vitamin K2 is well-tolerated.

Summary of adverse reactions

Gastrointestinal disorders:

*Less frequent:* Constipation and flatulence.

Metabolism and nutrition disorders:

*Less frequent:* Hypercalcaemia (particularly in patients with renal impairment or after high dosages), alkalosis.

Description of selected adverse reactions

BIOGEN VITAMIN K2 may cause several adverse reactions, such as gastrointestinal disturbances, such as, digestive disorders, and constipation.

Paediatric Population

BIOGEN VITAMIN K2 is not recommended for use by children under 18 years, as insufficient data are available concerning its safety and efficacy.

Other special populations

Patients with Renal Impairment: No clinical data are available on the effects of BIOGEN VITAMIN K2 on other special populations.

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. Health care 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>.

4.8 Overdose

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

Vitamin K2: Side effects which have been reported after overdose include jaundice, hyperbilirubinaemia, increases in liver enzyme values, abdominal pain, constipation, soft stools, malaise, agitation and skin eruptions. Most adverse events were not considered to be serious and resolved without any treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action:

Vitamin K may increase bone formation by regulating the transcription of osteoblast markers involved in bone format.

5.2 Pharmacokinetic properties

No clinical data are available on the effects of BIOGEN VITAMIN K2.

Absorption:

Vitamin K2 (menaquinone) are well absorbed, with peak blood levels occurring 4 hours after intake. Menaquinones MK-7 through MK-10 are synthesized by bacteria in the colon.

Distribution:

Vitamin K2, are transported with both low-density lipoprotein (LDL)- and triacylglycerol-rich fractions of plasma lipoproteins, reaching the liver and many extrahepatic tissues.

Metabolism:

Vitamin K2 is metabolised by the pancreas, testes, and arterial vessel walls.

Excretion:

Vitamin K2 are excreted in both urine and feces and the form and route of excretion may depend on the amount in the diet.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose, Magnesium stearate and Silicon dioxide.

6.2 Shelf Life

24 Months.

6.3 Special precautions for storage

Store in a cool, dry place at or below 25 °C. Do not use after expiry date.

Keep the container tightly closed.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

6.4 Nature and contents

30/60 vegetarian capsules

The container is a 175 mL / 250 mL PET container. The cap is a white plastic cap with a tamper evident seal.

6.5 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen,  
23 Stag Rd,  
Glen Austin,  
South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

August 2022

<b>JOB:</b> BPS_VITAMIN K2_ 30s		<b>SIZE:</b> 210mm x 340mm	
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
<b>COLOURS:</b>		<b>FINISHING:</b>	
<input checked="" type="checkbox"/> K	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Foil / Holographic Foil	<input type="checkbox"/> Matte <input type="checkbox"/> Gloss
<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Spot UV	<input type="checkbox"/> Doming <input type="checkbox"/> Embossing
<b>PLEASE CHECK CAREFULLY</b> Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.			