

PROFESSIONAL INFORMATION

D 34.11 Vitamins. 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:

1. NAME OF THE MEDICINE
BIOGEN VITAMIN E capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains	*%NRV
Vitamin E (α -Tocopheryl acetate)	15,00 mg α -TE 58,75 IU

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

Sugar Free

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

White, size 0 gelatine capsules.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

BIOGEN VITAMIN E, contributes to the protection of cells from oxidative stress. A factor in the maintenance of good health.

4.2 Posology and method of administration

Adults and children >12:

Take 1 capsule daily for health maintenance. This product is best utilized when taken with a fatty meal, since Vitamin E is a fat soluble vitamin.

Take BIOGEN VITAMIN E capsules orally.

Paediatric/Adolescent population

BIOGEN VITAMIN E for use in children below 12 years of age, supplementation should be discussed with their healthcare provider.

4.3 Contraindications

- Hypersensitivity to vitamin E, or other excipients listed under section 6.1.

4.4 Special warnings and precautions for use

- Vitamin E might theoretically increase the risk of bleeding – use with caution in patients with existing bleeding disorders.

4.5 Interaction with other medicines and other forms of interaction**Interactions with Medicines**

- Alkylating agents:** Vitamin E may theoretically reduce the effectiveness of alkylating agents.
- Antibiotics:** Vitamin E may reduce the effectiveness of antitumor antibiotics.
- Anticoagulant/antiplatelet supplements/herbs:** Vitamin E may theoretically increase the risk of bleeding due to its antiplatelet properties – avoid using concomitantly with anticoagulants/antiplatelets.
- Cytochrome substrates:** Vitamin E may decrease the bioavailability of CYP3A4 substrates, by inducing CYP3A4 metabolism.
- Kinase inhibitors:** Selumetinib contains vitamin E and may increase the risk of bleeding when using concomitantly with vitamin E supplements.

Interactions with Diseases/Impairments

- Bleeding disorders:** Vitamin E might theoretically increase the risk of bleeding – use with caution in patients with existing bleeding disorders.
- Stroke:** Vitamin E might theoretically increase the risk of haemorrhagic stroke – use with caution in patients with a history of haemorrhagic stroke.
- Surgical procedures:** Vitamin E might increase the risk of bleeding if used perioperatively - Discontinue use at least 2 weeks prior to elective surgical procedures.

Interactions with Foods

- Alcohol:** Alcohol decreases the conservation of magnesium via the kidneys, thus increasing the risk for magnesium deficiency.

4.6 Fertility, pregnancy and lactation

Vitamin E - possibly safe when used orally and appropriately in pregnant and lactating women at a dosage not exceeding 1000 mg daily.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use machinery have been performed. Patients should exercise caution before driving or use of machinery until they are reasonably certain BIOGEN VITAMIN E does not adversely affect their performance.

4.8 Undesirable effects**4.8 a Summary of safety profile**

When used orally and appropriately, vitamin E is generally well tolerated when using as prescribed.

4.8 b Summary of adverse reactions

Gastrointestinal disorders

Frequent: Abdominal pain, esophagitis, heartburn, constipation, belching, flatulence, gastrointestinal irritation, diarrhoea, nausea, metallic taste in mouth, and vomiting.

Gastrointestinal disorders

Frequency unknown: Dry mouth, and flu-like symptoms.

Dermatological disorders

Frequency unknown: Skin irritation, skin rash pruritus, and urticaria.

4.8 c Description of selected adverse reactions

Severity of adverse effects listed in Section 4.8 b are typically dose dependent.

4.8 d Paediatric Population

BIOGEN VITAMIN E for use in children below 12 years of age, supplementation should be discussed with their healthcare provider.

4.8 e Other special populations

No clinical data are available on the effects of BIOGEN VITAMIN E on other special populations.

4.9 Overdose

Insufficient reliable information for BIOGEN VITAMIN E overdosage. Side effects listed in section 4.8 can be precipitated and/or be of increased severity.

Overdosage of individual ingredients:

Vitamin E - Insufficient reliable information.

Reporting of side effects

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>.

5. PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

D 34.1 Vitamins. Complementary Medicine: Health Supplement.

Mechanism of action:

Vitamin E - May improve glucose disposal in patients with type 2 diabetes.

Pharmacodynamic effects:

Vitamin E - Fat-soluble vitamin, for the maintenance of good health.

5.2 Pharmacokinetic properties

Vitamin E

Absorption: Vitamin E is absorbed in the small intestine through passive diffusion.

Distribution: Hepatic alpha-tocopherol transfer protein (alpha-TTP) is necessary for the distribution of alpha-tocopherol. Alpha-TTP is present in the spleen, lung, brain, kidney, uterus, and placenta.

Metabolism: Unclear. Vitamin E appears to be a substrate of the cytochrome P450 enzyme system, possibly CYP3A4. In addition, Vitamin E also seems to activate a nuclear receptor, pregnane X receptor (PXR), which increases CYP3A4 expression.

Excretion: Vitamin E is primarily excreted via the faeces. The water-soluble metabolites of vitamin E are eliminated in the urine.

5.3 Preclinical safety data (Adults)

Vitamin E - Likely safe when used orally and appropriately. The UL in healthy individuals is 1000 mg daily.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Magnesium stearate.

6.2 Incompatibilities

In the absence of compatibility studies, BIOGEN VITAMIN E 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 of container

30's / 60's: White, size 0 gelatine capsules are available in a white plastic container sealed with a white plastic screw cap. The container contains a non-edible silica gel sachet and a foam insert.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen

23 Stag Road, Glen Austin, South Africa

info@biogen.co.za

www.biogen.co.za

Tel: 0860 347243

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Not Applicable

10. DATE OF REVISION OF THE TEXT

June 2022

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Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

PATIENT INFORMATION LEAFLETSCHEDULING STATUS: S0PRODUCT NAME
BIOGEN VITAMIN E capsules

Vitamin E

Sugar free.

D 34.11 Vitamins. Complementary Medicine: Health Supplement.

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

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

Read all of this leaflet carefully because it contains important information for you.

BIOGEN VITAMIN E is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use BIOGEN VITAMIN E carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN VITAMIN E with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What BIOGEN VITAMIN E is and what is it used for.
2. What you need to know before you take BIOGEN VITAMIN E.
3. How to take BIOGEN VITAMIN E.
4. Possible side effects.
5. How to store BIOGEN VITAMIN E.
6. Contents of the pack and other information.

1. What BIOGEN VITAMIN E is and what is it used for

BIOGEN VITAMIN E, contributes to the protection of cells from oxidative stress. A factor in the maintenance of good health.

2. What you need to know before you take BIOGEN VITAMIN E

Do not take BIOGEN VITAMIN E:

- If you are hypersensitive (allergic) Vitamin E, or any of the other ingredients of BIOGEN VITAMIN E (listed in section 6).

Warnings and precautions

Special care should be taken with BIOGEN VITAMIN E:

- If you suffer from bleeding disorders.
- If you have hemoglobinopathies (abnormal haemoglobin) or other refractory anaemias (lack of blood) incorrectly diagnosed as iron deficiency anaemia, as iron overload is likely to occur.
- If you have a history of haemorrhagic stroke (ruptured blood vessel that causes bleeding inside the brain).
- Discontinue use at least 2 weeks prior to elective surgical procedures.

Children and adolescents

BIOGEN VITAMIN E for use in children under the age of 12 years, supplementation should be discussed with their healthcare provider.

Other medicines and BIOGEN VITAMIN E

Always tell your healthcare provider if you are taking other medicines, including complementary or traditional medicines.

Consult your doctor if you want to take BIOGEN VITAMIN E in combination with medicines or treatments such as:

- Alkylating agents, vitamin E may theoretically reduce the effectiveness of these agents.
- Antibiotics, vitamin E may reduce the effectiveness of antitumor antibiotics.
- Anticoagulant/antiplatelet supplements/herbs, as vitamin E may theoretically increase the risk of bleeding due to its antiplatelet properties.
- Cytochrome substrates, as Vitamin E may decrease the bioavailability of CYP3A4 substrates, by inducing CYP3A4 metabolism.
- Kinase inhibitors, such as selumetinib, as it may increase the risk of bleeding when using concomitantly with vitamin E supplements.

Interactions with Diseases/Impairments

BLEEDING disorders: Magnesium and vitamin E might theoretically increase the risk of bleeding – use with caution if you have an existing bleeding disorder.

STROKE: Vitamin E might theoretically increase the risk of haemorrhagic stroke (ruptured blood vessel that causes bleeding inside the brain) – use with caution if you have a history of haemorrhagic stroke.

SURGICAL procedures: Vitamin E might increase the risk of bleeding if used around the time of surgery - Discontinue use at least 2 weeks prior to elective surgical procedures.

BIOGEN VITAMIN E with food and drink

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

Pregnancy, breastfeeding and fertility

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 provider for advice before taking this medicine.

Driving and using machines

No studies on the effects on the ability to drive or use machinery have been performed. Patients should exercise caution before driving or use of machinery until they are reasonably certain BIOGEN VITAMIN E does not adversely affect their performance.

3. How to take BIOGEN VITAMIN E

Do not share medicines prescribed for you with any other person.

Always take BIOGEN VITAMIN E exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

Adults (12 years and older)

Take one (1) capsule daily with food, or as recommended by your healthcare practitioner.

If you take more BIOGEN VITAMIN E than you should

Insufficient reliable information available. Side effects listed in section 4 can be precipitated and/or be of increased severity.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take BIOGEN VITAMIN E

Always take BIOGEN VITAMIN E as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed doses until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BIOGEN VITAMIN E can have side effects.

Not all side effects reported for BIOGEN VITAMIN E are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN VITAMIN E, please consult your healthcare provider for advice.

Side effects associated with BIOGEN VITAMIN E:

- Abdominal pain, esophagitis, heartburn, constipation, belching, flatulence, gastrointestinal irritation, diarrhoea, nausea, metallic taste in mouth, and vomiting.

Frequency unknown:

- Dry mouth, and flu-like symptoms.
- Skin irritation, skin rash pruritus (itchy skin), and urticaria (hives).

Please report/inform your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

Reporting of side effectsIf you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index.aspx>.

By reporting side effects, you can help provide more information on the safety of BIOGEN VITAMIN E.

5. How to store BIOGEN VITAMIN E

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.

Return all unused BIOGEN VITAMIN E to your pharmacist. Do not dispose of unused BIOGEN VITAMIN E in drains or sewerage systems (e.g., toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What BIOGEN VITAMIN E contains:**The active ingredients per capsule are α -tocopherol acetate (vitamin E) 58,75 IU / 43,20 mg α -TE,

The other ingredient is magnesium stearate.

What BIOGEN VITAMIN E looks like and contents of the pack

30's/60's: White, size 0 gelatine capsules are available in a white plastic container sealed with a white plastic screw cap.

The container contains a non-edible silica gel sachet and a foam insert.

Holder of Certificate of Registration and Manufacturer

Biogen

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This leaflet was last revised in

June 2022

PASIËNTINLIGTINGSBLADSKEDULERINGSTATUS: S0PRODUKNAAM
BIOGEN VITAMIN E kapsules

Vitaminien E

Suikervry.

D 34.11. Vitamenes. Komplementêre Medisyne: Gesondheidsaanvulling.
Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

Hierdie ongerekende medisyne is nie deur die SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

Lees die hele inligtingsblad deeglik, want dit bevat belangrike inligting.

BIOGEN VITAMIN E is beskikbaar sonder 'n dokter se voorskryf om u gesondheid te ondersteun. U moet egter steeds BIOGEN VITAMIN E versigtig gebruik om die beste resultate daarmee te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie BIOGEN VITAMIN E met enige ander persoon deel nie.
- Indien u verdere inligting of advies verlang, vra asseblief u gesondheidsorgwerker of apteker.
- U moet 'n dokter raadpleeg indien u simptome vererger of nie verbeter nie.

Wat is in hierdie voubiljet

1. Wat BIOGEN VITAMIN E is en waarvoor dit gebruik word.
2. Wat u moet weet voor dat u BIOGEN VITAMIN E neem.
3. Hoe om BIOGEN VITAMIN E te neem.
4. Moontlike newe-effekte.
5. Hoe om BIOGEN VITAMIN E te stoor.
6. Inhoud van die verpakking en ander inligting.

1. Wat BIOGEN VITAMIN E is en waarvoor dit gebruik word

BIOGEN VITAMIN E, dra by tot die beskerming van selle teen oksidatiewe stres. 'n Faktor in die handhawing van goeie gesondheid.

2. Wat u moet weet voor dat u BIOGEN VITAMIN E neem:Moenie BIOGEN VITAMIN E neem nie:
• Indien u hipersensitiviteit (allergie) aan vitamien E, of enige van die ander bestanddele in BIOGEN VITAMIN E (gelys in afdeling 6).**Waarskuwings en voorsorgmaatreëls**

Spesiale sorg moet geneem word met BIOGEN VITAMIN E:

- As u aan bloedingsversteerings ly.
- As jy hemoglobinpatieë (abnormale hemoglobien) of ander refraktêre anemieë (gebrek aan bloed) het wat verkeerdelik as ysterlekortanemie versigtig indien die ysterkoerantie gedagoen is, aangesien ysterkoerantie waarskynlik sal voorkom.
- As jy 'n geskiedenis van hemorrhagiese beroerte het (gebarste bloedvat wat bloeding in die brein veroorsaak).
- Staak gebruik ten minste 2 weke voor elektiewe chirurgiese prosedures.

Kinders en adolescentes

BIOGEN VITAMIN E vir gebruik by kinders onder die ouerdom van 12 jaar, moet aanvulling met hul gesondheidsorgverskaffer bespreek word.

Ander medikasie en BIOGEN VITAMIN E

Lig altyd u gesondheidspraktisy in wanneer u medisyne op 'n gereeld basis neem, insluitend komplementêre of tradisionele medisyne.

Raadpleeg u dokter as BIOGEN VITAMIN E in kombinasie met die volgende medisyne wil gebruik:

- Alkielerende middels, omrede vitamien E teorieë die doeltreffendheid van antitumor-antibiotika verminder. Magnesium kan die risiko vir neuromuskulêre swakheid verhoog wanneer dit saam met bakteriële antibioticum gebruik word, soos amikasien, gentamicien, streptomycien, tobramycien en neomycien.
- Antistolmiddels/antiplaasjekruwe, omrede vitamien E teorieë die risiko vir bloeding kan verhoog wanneer dit saam met vitamien E-anvullings gebruik word.
- Sitochroomsubstrate, soos selumetinib, omrede vitamien E teorieë die risiko vir bloeding kan verhoog wanneer dit saam met CYP3A4-metabolisme te induseer.

Interaksies met siektes

Berorte: Vitamien E kan teorieë die risiko van hemorrhagiese beroerte (gebarste bloedvat wat bloeding in die brein veroorsaak) verhoog - gebruik versigtig indien u 'n geskiedenis van hemorrhagiese beroerte het.

Bloedafwykings: Magnesium en vitamien E kan teorieë die risiko van bloeding verhoog - gebruik versigtig indien u 'n bestaande bloedafwyking het.

Chirurgiese prosedures: Vitamien E kan die risiko vir bloeding verhoog indien dit rondom die tyd van 'n operasie gebruik word - Staak gebruik ten minste 2 weke voor elektiewe chirurgiese prosedures.

BIOGEN VITAMIN E met kos en drinkgoed

Vitamien, minerale en voedingstowwe wat van ander bronne verkry word, moet in ag geneem word wanneer voorgeskryf word/ voorstel

Swangerskap en borsvoeding

Indien u swanger is of u baba borsvoeding, dink dat u swanger is, of van plan is om 'n baba te hê, raadpleeg u dokter, apteker of gesondheidsorgverskaffer voordat u hierdie medisyne gebruik.

Bestuur en die gebruik van masjinerie

Geen studies oor die uitwerking op die vermoë om die bestuur van masjinerie te gebruik is uitgevoer nie. Pasiënte moet oefen versigtig wees voor bestuur van masjinerie totdat hulle redelik seker is dat BIOGEN VITAMIN E nie nadelig hul prestasie beïnvloed.

3. Hoe om BIOGEN VITAMIN E te neem

Moenie medisyne wat u voorgeskryf is, met enige ander persoon deel nie.

Neem BIOGEN VITAMIN E soos voorgeskryf in hierdie voubiljet of soos u dokter of apteker u aanbeveel het. Maak asseblief seker by u dokter of apteker indien u onseker is.

Volvassenes (12 jaar en ouer)

Neem een (1) kapsule daagliks saam met kos, soos aanbeveel deur u gesondheidspraktisy.

Indien u meer BIOGEN VITAMIN E geneue het as wat u moes

Geen bekende informasie. Die newe-effekte wat in afdeling 4 gelys word, kan ontstaan en/of die graad daarvan kan toeneem.

In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien u vergeet om BIOGEN VITAMIN E te neem

Neem BIOGEN VITAMIN E altyd soos voorgeskryf. Indien u 'n dosis vergeet het, neem dit so gou as wat u onthou. Indien u egter nie van die volgende dosis onthou voor dat dit tyd is vir die volgende dosis nie, slaan die vergeet dosis oor en keer terug na gewone doseringsskedule. Moenie 'n dubbele dosis neem om te vergoed vir die vergeslae individuele dosis nie.

4. Moontlike newe-effekte

BIOGEN VITAMIN E kan newe-effekte hê.

Nie alle newe-effekte wat aangemeeld is vir BIOGEN VITAMIN E is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid verger, of as u ongewenste gevolge ervaar tydens die gebruik van BIOGEN VITAMIN E, raadpleeg u gesondheidsorgverskaffer vir advies.

Newe-effekte geassosieer met BIOGEN VITAMIN E:

Algemeen:

- Maagpyn, esofagitis, sooibrand, hardlywigheid, windbreuk, winderigheid, gastro-intestinale irritasie, diarree, naardheid, metaelsmaak in die mond, en braking.

Frekvensie onbekend:

- Droog mond en griepsimptome.
- Velirritasie, veluitslag, pruritus (jeukerige vel) en urtikaria (korwe).

Lig asseblief by u dokter of apteker in indien u enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Rapportering van newe-effektePraat met u dokter of apteker as u newe-effekte kry. U kan ook newe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <http://www.sahpra.org.za/Publications/Index.aspx>.

Deur newe-effekte aan te meld, kan u help om meer inligting rakende die veiligheid van BIOGEN VITAMIN E te verskaf.

5. Hoe om BIOGEN VITAMIN E te stoor

Bewaar in 'n koel, droë plek by of benede 25 °C.

Beskerm teen vog.

Hou die houer dig toe.

HOU ALLE MEDISYNE BIJTE DIE BEREIK VAN KINDERS.

Neem alle ongebruikte BIOGEN VITAMIN E na u apteker terug.

Moenie ongebruikte BIOGEN VITAMIN E in afvoerpype of riolsisteme (byvoorbeeld toilette) weggoei nie.

6. Inhoud van die verpakking en ander inligting**Wat BIOGEN VITAMIN E bevat:**Aktiewe bestanddeel per kapsule is α -tokoferielaesataat (vitamien E) 58,75 IU / 43,20 mg α -TE.

Die ander bestanddeel is magnesiumstearaat.