

# KETO LIFE™ KETO BHB GUMMIES

## (PATIENT INFORMATION LEAFLET)

### COMPLEMENTARY MEDICINE

D 33.7 Combination Product. This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

### SCHEDULING STATUS

S0

### KETO LIFE™ KETO BHB GUMMIES

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

**KETO LIFE™ KETO BHB GUMMIES** is available without a doctor's prescription for you to maintain your health. Nevertheless, you still need to take **KETO LIFE™ KETO BHB GUMMIES** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **KETO LIFE™ KETO BHB GUMMIES** with anyone.
- Ask your healthcare provider or pharmacist if you need more information or advice.

### WHAT IS IN THIS LEAFLET

1. What **KETO LIFE™ KETO BHB GUMMIES** is and what it is used for.
2. What you need to know before you take **KETO LIFE™ KETO BHB GUMMIES**.
3. How to take **KETO LIFE™ KETO BHB GUMMIES**.
4. Possible side effects.
5. How to store **KETO LIFE™ KETO BHB GUMMIES**.
6. Contents of the pack and other information.

### 1. WHAT KETO LIFE™ KETO BHB GUMMIES IS AND WHAT IT IS USED FOR

**KETO LIFE™ KETO BHB GUMMIES** is a health supplement to help burn fat for energy and induce ketosis. It is only effective when used in conjunction with an energy-controlled meal plan and an increase in physical activity.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE KETO LIFE™ KETO BHB GUMMIES

Do not take **KETO LIFE™ KETO BHB GUMMIES**:

- If you are hypersensitive (allergic) to any of the ingredients (see **WHAT KETO LIFE™ KETO BHB GUMMIES CONTAINS**).
- If you have higher than normal levels of calcium in your blood (hypercalcaemia).
- If you have very high levels of calcium in your urine (severe hypercalciuria).
- If you have severe kidney failure and not being treated by renal dialysis.
- If you have kidney stones.
- If you have high levels of phosphate in your blood (hyperphosphataemia).
- If you are under the age of 18 years.

### WARNINGS AND PRECAUTIONS

Talk to your doctor or pharmacist before taking **KETO LIFE™ KETO BHB GUMMIES**.

Use **KETO LIFE™ KETO BHB GUMMIES** with caution if you:

- Have a heart condition.
- Have a kidney disease.
- Are taking antacids that contains calcium or magnesium as they may lead to high levels of either calcium or magnesium.

Tell your doctor or pharmacist if you are taking any other medication, even those you may have bought without prescription.

### OTHER MEDICINES AND KETO LIFE™ KETO BHB GUMMIES

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary medicines, health supplements or traditional medicines.)

Do not use **KETO LIFE™ KETO BHB GUMMIES** with:

- Cardiac glycosides (medication used to treat heart problems).
- Thiazide diuretics (medication used to treat high blood pressure).
- Antacids (medication used to treat heartburn).
- Corticosteroids (medication used to treat inflammation).

Do not take the following medicines at the same time as **KETO LIFE™ KETO BHB GUMMIES**.

Allow a period of 2 hours before or 4 hours after taking **KETO LIFE™ KETO BHB GUMMIES**:

- Thyroid hormones (medication used to treat underactive thyroid gland).
- Bisphosphonates (medication used to treat osteoporosis).
- Sodium fluoride (medication used to prevent tooth decay).
- Fluoroquinolone antibiotics (medication used to treat bacterial infection).
- Tetracycline antibiotics (medication used to treat bacterial infections).
- Mineral supplements such as zinc and iron.
- Vitamin supplements such as Vitamin D.

### KETO LIFE™ KETO BHB GUMMIES WITH FOOD, DRINK AND ALCOHOL

**KETO LIFE™ KETO BHB GUMMIES** should not be taken within 2 hours of eating foods rich in oxalic acid (e.g. spinach and rhubarb), phosphate (e.g. bran), or phytic acid (e.g. whole cereals).

### 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 **KETO LIFE™ KETO BHB GUMMIES**. Safety and efficacy of **KETO LIFE™ KETO BHB GUMMIES** during pregnancy and breastfeeding have not been established.

### DRIVING AND USING MACHINERY

**KETO LIFE™ KETO BHB GUMMIES** is not likely to affect your ability in performing tasks requiring your attention.

### 3. HOW TO TAKE KETO LIFE™ KETO BHB GUMMIES

Do not share your medicines with any other person.

Always take **KETO LIFE™ KETO BHB GUMMIES** exactly as described in this leaflet, or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

**The usual dose is:**

**Adults 18 years and older:** Take one (1) gummy once daily, or as prescribed by a healthcare provider. If you feel that the effect of **KETO LIFE™ KETO BHB GUMMIES** is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

**KETO LIFE™ KETO BHB GUMMIES** can be taken with or without food.

**If you take more KETO LIFE™ KETO BHB GUMMIES than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining **KETO LIFE™ KETO BHB GUMMIES** with you so the doctor will know what you have taken.

**If you forget to take KETO LIFE™ KETO BHB GUMMIES**

If you forget to take your **KETO LIFE™ KETO BHB GUMMIES**, take them as soon as you remember and then continue with the next dose as instructed. Do not take a double dose to make up for forgotten individual doses.

### 4. POSSIBLE SIDE EFFECTS

**KETO LIFE™ KETO BHB GUMMIES** can have side effects.

Not all side effects reported for **KETO LIFE™ KETO BHB GUMMIES** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **KETO LIFE™ KETO BHB GUMMIES**, please consult your healthcare provider for advice.

**If any of the following happens, stop taking KETO LIFE™ KETO BHB GUMMIES and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Severe rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **KETO LIFE™ KETO BHB GUMMIES**. You may need urgent medical attention or hospitalisation.

**Tell your doctor if you notice any of the following:**

- **Frequency unknown:** Nausea (feeling nauseous).
- **Frequency unknown:** Bloating, abdominal cramps or stomach pains.
- **Frequency unknown:** Heartburn, dyspepsia, gastritis, stomach upset.
- **Frequency unknown:** Vomiting.
- **Frequency unknown:** Diarrhoea (runny, loose stool), constipation, flatulence.
- **Frequency unknown:** Skin rash.
- **Less frequent:** Muscle weakness, headache, dizziness, light-headedness.
- **Less frequent:** Low blood pressure, irregular heartbeat.

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

### Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects 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>. By reporting side effects, you can help provide more information on the safety of **KETO LIFE™ KETO BHB GUMMIES**.

### 5. HOW TO STORE KETO LIFE™ KETO BHB GUMMIES

- Store all medicines out of reach of children.
- Store in a cool, dry place at or below 25°C.
- Store in the original container.
- Keep the container tightly closed after use.
- Protect from light and moisture.
- Do not store in the bathroom.
- Do not use after the expiry date stated on the label or container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### WHAT KETO LIFE™ KETO BHB GUMMIES CONTAINS

Each gummy contains:

The active substances are:

<i>Malus pumila mill</i> (Apple Cider Vinegar) [Fruit].....	300 mg
Calcium Beta-Hydroxybutyrate.....	75 mg
Providing Calcium (elemental).....	12.23 mg
Magnesium Beta-Hydroxybutyrate.....	37.5 mg
Providing Magnesium (elemental).....	3.96 mg
Sodium Beta-Hydroxybutyrate.....	37.5 mg
Providing Sodium (elemental).....	6.84 mg
Beta-Hydroxybutyrate.....	121.80 mg
(from Calcium BHB, Magnesium BHB and Sodium BHB)	
Fructooligosaccharide.....	2.1 g

The other ingredients are purified water, pectin (E440), citric acid (E330), 3H oil (FF140), carnauba wax (E903), trisodium citrate (E331), flavour, colourant, sodium chloride.

#### WHAT KETO LIFE™ KETO BHB GUMMIES LOOKS LIKE AND CONTENTS OF THE PACK

Green, apple flavoured individually wrapped gummies.

**KETO LIFE™ KETO BHB GUMMIES** is packed inside a clear PET plastic bottle with a white tamper-resistant cap.

Pack Size: 30 Gummies.

#### HOLDER OF CERTIFICATE OF REGISTRATION

Vita-Aid (Pty) Ltd  
111 Central Street  
Houghton Estate  
Johannesburg  
2198  
South Africa  
info@vita-aid.co.za

#### THIS LEAFLET WAS LAST REVISED IN

August 2023.

#### REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

#### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

The Professional Information for **KETO LIFE™ KETO BHB GUMMIES** is available on <https://www.vita-aid.co.za/ketolife-keto-bhb/> or can be requested from the contact details above.

# KETO LIFE™ KETO BHB GUMMIES

## (PROFESSIONAL INFORMATION)

### COMPLEMENTARY MEDICINE

D 33.7 Combination Product. This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

### SCHEDULING STATUS

S0

### 1 NAME OF MEDICINE

**KETO LIFE™ KETO BHB GUMMIES**

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each gummy contains:

<i>Malus pumila mill</i> (Apple Cider Vinegar) [Fruit].....	300 mg
Calcium Beta-Hydroxybutyrate.....	75 mg
Providing Calcium (elemental).....	12.23 mg
Magnesium Beta-Hydroxybutyrate.....	37.5 mg
Providing Magnesium (elemental).....	3.96 mg
Sodium Beta-Hydroxybutyrate.....	37.5 mg
Providing Sodium (elemental).....	6.84 mg
Beta-Hydroxybutyrate.....	121.80 mg
(from Calcium BHB, Magnesium BHB and Sodium BHB)	
Fructooligosaccharide.....	2.1 g

### Excipients with known effects:

Sodium 7.84 mg

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Gummies.  
Green, apple flavoured gummies.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

**KETO LIFE™ KETO BHB GUMMIES** is a health supplement to help burn fat for energy and induce ketosis. It is only effective when used in conjunction with an energy-controlled meal plan and an increase in physical activity.

#### 4.2 Posology and method of administration

##### Posology

**Adults 18 years and older:** Take one (1) gummy once a day.

##### Method of administration

Oral.  
The gummy should be chewed and not swallowed whole.

#### 4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients.
- Patients suffering from disturbances of calcium metabolism such as hypercalcaemia.
- Patients suffering from severe renal impairment, calcium renal calculi or history of renal calculi.
- Patients suffering from hyperphosphataemia.
- Pregnancy and breastfeeding mothers.

#### 4.4 Special warnings and precautions for use

Do not exceed the recommended daily dosage.  
This product is not suitable for use in adolescents and children below the age of 18 years.

This product should be used with caution:

- Patients with heart diseases.
- Patients with renal insufficiency.
- Patients taking antacids containing calcium or magnesium salts.

Vitamins and minerals obtained from other sources should be taken into consideration when prescribing or suggesting **KETO LIFE™ KETO BHB GUMMIES**.

#### Sodium

This product contains less than 1mmol sodium (23mg) per gummy. That is safe to regard it as "sodium-free". However this should be considered in patients on a controlled sodium diet.

#### 4.5 Interaction with other medicines and other forms of interaction

##### Thyroid hormones

Concomitant use of **KETO LIFE™ KETO BHB GUMMIES** with thyroid hormones may reduce the absorption and efficacy of thyroid hormones. Caution is advised in patients taking thyroid hormones, and it is recommended that **KETO LIFE™ KETO BHB GUMMIES** be taken at least 2 hours before or after taking thyroid hormones.

##### Bisphosphonates

Concomitant use of **KETO LIFE™ KETO BHB GUMMIES** with bisphosphonates may reduce the absorption and efficacy of bisphosphonates. Caution is advised in patients taking bisphosphonates, and it is recommended that **KETO LIFE™ KETO BHB GUMMIES** be taken at least 2 hours before or 4 hours after taking bisphosphonates.

##### Sodium fluoride

Concomitant use of **KETO LIFE™ KETO BHB GUMMIES** with sodium fluoride may reduce the absorption and efficacy of sodium fluoride. Caution is advised in patients taking sodium fluoride, and it is recommended that **KETO LIFE™ KETO BHB GUMMIES** be taken at least 2 hours before or 4 hours after taking sodium fluoride.

##### Fluoroquinolone Antibiotics

Concomitant use of **KETO LIFE™ KETO BHB GUMMIES** with fluoroquinolones may reduce the absorption and efficacy of fluoroquinolones. Caution is advised in patients taking fluoroquinolones, and it is recommended that **KETO LIFE™ KETO BHB GUMMIES** be taken at least 2 hours before or 4 hours after taking fluoroquinolones.

##### Tetracycline Antibiotics

Concomitant use of **KETO LIFE™ KETO BHB GUMMIES** with tetracyclines may reduce the absorption and efficacy of tetracyclines. Caution is advised in patients taking tetracyclines, and it is recommended that **KETO LIFE™ KETO BHB GUMMIES** be taken at least 2 hours before or 4 hours after taking tetracyclines.

##### Iron

Concomitant use of **KETO LIFE™ KETO BHB GUMMIES** with iron may reduce the absorption and efficacy of iron. Caution is advised in patients taking iron, and it is recommended that **KETO LIFE™ KETO BHB GUMMIES** be taken at least 2 hours before or 4 hours after taking iron.

##### Corticosteroids

Concomitant use of **KETO LIFE™ KETO BHB GUMMIES** with systemic corticosteroid therapy may reduce absorption of calcium in **KETO LIFE™ KETO BHB GUMMIES**. Avoid use in patients undergoing systemic corticosteroid therapy.

##### Thiazide diuretics

Concomitant use of **KETO LIFE™ KETO BHB GUMMIES** with thiazide diuretics may reduce the elimination of calcium resulting in an increased risk of developing hypercalcaemia. Avoid use in patients taking thiazide diuretics.

##### Cardiac glycosides

Concomitant use of **KETO LIFE™ KETO BHB GUMMIES** with cardiac glycosides may increase the effects and side effects of cardiac glycosides. Avoid use in patients taking cardiac glycosides.

##### Vitamin D

Concomitant use of **KETO LIFE™ KETO BHB GUMMIES** with Vitamin D may increase the absorption of calcium resulting in increased risk of hypercalcaemia. Caution is advised in patients taking Vitamin D.

#### 4.6 Fertility, pregnancy and lactation

**KETO LIFE™ KETO BHB GUMMIES** should not be used during pregnancy or while breastfeeding as safety has not been established.

#### 4.7 Effects on ability to drive and use machines

**KETO LIFE™ KETO BHB GUMMIES** should not affect the ability to drive and/or operate machinery. However patients should exercise caution before driving and/or operating machinery until they are definitely certain **KETO LIFE™ KETO BHB GUMMIES** does not affect their performance.

#### 4.8 Undesirable effects

##### Gastrointestinal Disorders:

Mild gastrointestinal events such as flatulence, nausea, vomiting, diarrhoea, and abdominal pain. Frequency not known.

##### Immune System Disorders:

Allergic and anaphylactic reactions, with symptoms of pruritus, urticaria, itching, hives, angioedema, abdominal pain, respiratory distress, tachycardia, palpitations, and shock. Frequency not known.

##### Metabolism and Nutrition Disorders

Hypercalcaemia, hypercalciuria, Frequency not known.

#### 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>.

#### 4.9 Overdose

Excessive doses of **KETO LIFE™ KETO BHB GUMMIES** may increase the risk of experiencing side effects (see "Undesirable Effects"). Treatment of overdose is symptomatic and supportive. Activated charcoal may be administered but the use of emetics or gastric lavage should be avoided.

### 5 PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic properties

Not applicable.

#### 5.2 Pharmacokinetic properties

Not Applicable.

#### 5.3 Preclinical safety data

Not applicable.

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Purified Water  
Pectin (E440)  
Citric Acid (E330)  
3H Oil (FF140)  
Carnauba Wax (E903)  
Trisodium Citrate (E331)  
Flavour  
Colourant  
Sodium Chloride

#### 6.2 Incompatibilities

Not Applicable.

#### 6.3 Shelf life

24 Months.

#### 6.4 Special precautions for storage

Store in a cool, dry place at or below 25°C.  
Do not use after expiry date as written on the label or container.  
Keep the container tightly closed.  
Protect from light and moisture.  
Keep out of reach of children.

#### 6.5 Nature and contents of container

Green, apple flavoured, individually wrapped gummies.  
**KETO LIFE™ KETO BHB GUMMIES** is packed inside a clear PET plastic bottle with a white tamper-resistant cap.  
Pack size: 30 Gummies.

#### 6.6 Special precautions for disposal <and other handling>

No special requirements.

### 7 HOLDER OF CERTIFICATE OF REGISTRATION

Vita-Aid (Pty) Ltd  
111 Central Street, Houghton Estate, Johannesburg, South Africa, 2198.

### 8 REGISTRATION NUMBER(S)

To be allocated by SAHPRA upon registration.

### 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated by SAHPRA upon registration.

### 10 DATE OF REVISION OF THE TEXT

August 2023.

# KETO LIFE™ KETO BHB GOMMETJIES

## (PROFESIONELE INLIGTING)

### KOMPLEMENTÊRE MEDISYNE

D 33.7 Kombinasieprodukt. Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir die kwaliteit, veiligheid of beoogde gebruik daarvan.

### SKEDULERINGSSTATUS

50

### 1 NAAM VAN MEDISYNE

**KETO LIFE™ KETO BHB GOMMETJIES**

### 2 KWALITATIEWE EN KWANTITATIEWE SAMESTELLINGS

Elke gometjie bevat:

Die aktiewe stowwe is:

<i>Malus pumila mill</i> (Appleasyn) [Vrug].....	300 mg
Kalsium Beta-hidroksibutiraat.....	75 mg
Verskaf kalsium (elementêr).....	12,23 mg
Magnesium Beta-hidroksibutiraat.....	37,5 mg
Verskaf magnesium (elementêr).....	3,96 mg
Natrium Beta-hidroksibutiraat.....	37,5 mg
Verskaf natrium (elementêr).....	6,84 mg
Beta-hidroksibutiraat.....	121,80 mg
(van kalsium BHB, Magnesium BHB en Natrium BHB)	
Fruktooligosakkariede.....	2.1 g

*Hulpstowwe met bekende effekte:*

Natrium 7,84 mg.

Vir die volledige lys van hulpstowwe, sien afdeling 6.1.

### 3 FARMASEUTIESE VORM

Gometjies.

Groen, appelgeurde gometjies.

### 4 KLINIESE BESONDERHEDE

#### 4.1 Terapeutiese Indikasies

**KETO LIFE™ KETO BHB GOMMETJIES** is 'n gesondheidsaanvulling om vet te help verbrand vir energie en induseer ketose. Dit is slegs effektief wanneer dit saam met 'n energiebeheerde maalydplan gebruik word en 'n toename in fisiese aktiwiteit.

#### 4.2 Dosering en Metode van Administrasie

##### Posologie

**Volwasse nes 18 jaar en ouer:** Neem een (1) gometjie een keer per dag.

##### Metode van administrasie

Mondelings.

Die gometjie moet gekou word en nie heel ingesluk word nie.

#### 4.3 Kontraindikasies

• Hipersensitiwiteit vir enige van die aktiewe bestanddele of vir enige van die hulpstowwe.

• Pasiënte wat ly aan verstourings van kalsiummetabolisme soos hiperkalsemie.

• Pasiënte wat ly aan ernstige nierversaking, kalsium nierstene of geskiedenis van nierstene.

• Pasiënte wat aan hiperfosfatemie ly.

• Swangerskap en borsvoedende moeders.

#### 4.4 Spesiale Waarskuwings en Voorsorgmaatreëls vir gebruik.

Moenie die aanbevole daaglikse dosis oorskry nie.

Hierdie produk is nie geskik vir gebruik by adolessente en kinders onder die ouderdom van 18 jaar nie.

Hierdie produk moet met omsigtigheid gebruik word in:

• Pasiënte met hartsiektes.

• Pasiënte met nierversaking.

• Pasiënte wat teensuurmiddels gebruik wat kalsium- of magnesiumsoute bevat.

Vitamiene en minerale verkry uit ander bronne moet in ag geneem word wanneer **KETO LIFE™ KETO BHB GOMMETJIES** voorgeskryf of voorgestel word.

#### Natrium

Hierdie produk bevat minder as 1mmol natrium (23mg) per gometjie. Dit is veilig om dit as "natriumvry" te beskou. Dit moet egter oorweeg word by pasiënte op 'n beheerde natrium dieet.

#### 4.5 Interaksie met ander medisyne en ander vorme van interaksie

##### Skildklierhormone

Gelyktydige gebruik van **KETO LIFE™ KETO BHB GOMMETJIES** met tiroïedhormone kan die absorpsie en doeltreffendheid van tiroïedhormone verminder. Pasiënte wat tiroïedhormone neem, word aangeraai om versigtig te wees, en dit word aanbeveel dat **KETO LIFE™ KETO BHB GOMMETJIES** ten minste 2 ure voor of na tiroïedhormone geneem word.

##### Bisfosfonate

Gelyktydige gebruik van **KETO LIFE™ KETO BHB GOMMETJIES** met bisfosfonate kan die absorpsie en doeltreffendheid van bisfosfonate verminder. Omsigtigheid word aangeraai by pasiënte wat bisfosfonate neem en dit word aanbeveel dat **KETO LIFE™ KETO BHB GOMMETJIES** ten minste 2 ure voor of 4 ure na bisfosfonate geneem word.

##### Natriumfluoried

Gelyktydige gebruik van **KETO LIFE™ KETO BHB GOMMETJIES** met natriumfluoried kan die absorpsie en doeltreffendheid van natriumfluoried verminder. Omsigtigheid word aangeraai by pasiënte wat natriumfluoried neem, en dit word aanbeveel dat **KETO LIFE™ KETO BHB GOMMETJIES** ten minste 2 ure voor of 4 ure na natriumfluoried geneem word.

##### Fluorokinoloon antibiotika

Gelyktydige gebruik van **KETO LIFE™ KETO BHB GOMMETJIES** met fluorokinolone kan die absorpsie en doeltreffendheid van fluorokinolone verminder. Omsigtigheid word aangeraai by pasiënte wat fluorokinolone neem, en dit word aanbeveel dat **KETO LIFE™ KETO BHB GOMMETJIES** ten minste 2 ure voor of 4 ure na fluorokinolone geneem word.

##### Tetrasiklien antibiotika

Gelyktydige gebruik van **KETO LIFE™ KETO BHB GOMMETJIES** met tetrasikliene kan die absorpsie en doeltreffendheid van tetrasikliene verminder. Omsigtigheid word aangeraai by pasiënte wat tetrasikliene gebruik, en dit is aanbeveel dat **KETO LIFE™ KETO BHB GOMMETJIES** ten minste 2 ure voor of 4 ure na tetrasikliene geneem word.

##### Yster

Gelyktydige gebruik van **KETO LIFE™ KETO BHB GOMMETJIES** met yster kan die absorpsie en doeltreffendheid van yster verminder. Pasiënte wat yster neem, word aangeraai om versigtig te wees, en dit word aanbeveel dat **KETO LIFE™ KETO BHB GOMMETJIES** ten minste 2 ure voor of 4 ure na yster geneem word.

##### Kortikosteroïede

Gelyktydige gebruik van **KETO LIFE™ KETO BHB GOMMETJIES** met sistemiese kortikosteroïedterapie kan kalsium absorpsie in **KETO LIFE™ KETO BHB GOMMETJIES** verminder. Vermyn gebruik by pasiënte wat sistemiese kortikosteroïedterapie ondergaan.

##### Tiasied diuretika

Gelyktydige gebruik van **KETO LIFE™ KETO BHB GOMMETJIES** met tiasied diuretika kan die eliminasië van kalsium verminder wat lei tot 'n verhoogde risiko om hiperkalsemie te ontwikkel. Vermyn gebruik in pasiënte wat tiasied diuretika gebruik.

##### Hartglikosiede

Gelyktydige gebruik van **KETO LIFE™ KETO BHB GOMMETJIES** met hartglikosiede kan die effekte en nwe-effekte van hartglikosiede verhoog. Vermyn gebruik by pasiënte wat hartglikosiede neem.

##### Vitamiën D

Gelyktydige gebruik van **KETO LIFE™ KETO BHB GOMMETJIES** met Vitamiën D kan die absorpsie van kalsium verhoog wat lei tot verhoogde risiko van hiperkalsemie. Pasiënte wat Vitamiën D neem word aangeraai om versigtig te wees.

#### 4.6 Vruggaardheid, swangerskap en laktasie

**KETO LIFE™ KETO BHB GOMMETJIES** moet nie tydens swangerskap of borsvoeding gebruik word nie, aangesien veiligheid nie vasgestel is nie.

#### 4.7 Effekte op die vermoë om te bestuur en masjiene te gebruik

**KETO LIFE™ KETO BHB GOMMETJIES** behoort nie die vermoë om te bestuur en/of masjinerie te bestuur, te beïnvloed nie. Pasiënte moet egter versigtig wees voordat hulle bestuur en/of masjinerie gebruik totdat hulle heeltemal verseker is dat **KETO LIFE™ KETO BHB GOMMETJIES** nie hul werkverrigting beïnvloed nie.

#### 4.8 Ongewenste effekte

##### Gastroïntestinale afwykings:

Ligte gastroïntestinale gebeure soos winderigheid, naarheid, braking, diarree en buikpyn.

Frekwensie nie bekend nie.

##### Immuunstelselafwykings:

Allergiese en anafalaktiese reaksies, met simptome van prurietes, urtikarie, jeuk, korwe, angioedeem, abdominale pyn, respiratoriese nood, tagikardie, hartkloppings en skok. Frekwensie nie bekend nie.

##### Metabolisme en Voedingsverstourings

Hiperkalsemie, hiperkalsurie, Frekwensie nie bekend nie.

##### Rapportering van vermoedelike nadelige reaksies

Dit is belangrik om vermoedelike nadelige reaksies aan te meld na goedkeuring van die medisyne.

Dit laat toe voortgesette monitoring van die voordeel/risiko-balans van die medisyne.

Gesondheidsorgverskaffers word gevra om enige vermoedelike nadelige reaksies aan SAHPRA via die "6.04 Adverse Drug Reactions Reporting Form", aanlyn gevind onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>, te rapporteer.

#### 4.9 Oordosering

Oormatige dosisse **KETO LIFE™ KETO BHB GOMMETJIES** kan die risiko verhoog om nwe-effekte te ervaar (sien "Ongewenste effekte"). Behandeling van oordosis is simptome en ondersteunend. Geaktiveerde houtskool mag toegedien word, maar die gebruik van braakmiddels of maagspoeling moet vermy word.

### 5 FARMAKOLOGIESE EIENSKAPPE

#### 5.1 Farmakodinamiese eienskappe

Nie van toepassing nie.

#### 5.2 Farmakokinetiese eienskappe

Nie van toepassing nie.

#### 5.3 Prekliniese veiligheidsdata

Nie van toepassing nie.

### 6 FARMASEUTIESE BESONDERHEDE

#### 6.1 Lys van hulpstowwe

Gesuiwerde water

Pektien (E440)

Sitroensuur (E330)

3H-olie (FF140)

Karnaubawas (E903)

Trinatriumsitraat (E331)

Geurmiddel

Kleurstof

Natriumchloried.

#### 6.2 Onverenigbaarheid

Nie van toepassing nie.

#### 6.3 Raklewe

24 Maande.

#### 6.4 Spesiale voorsorgmaatreëls vir berging

Berg in 'n koel, droë plek by of onder 25°C.

Moet nie na die vervaldatum gebruik soos op die etiket of houer geskryf is nie.

Hou die houer dig toe.

Beskerm teen lig en vog.

Hou buite bereik van kinders.

#### 6.5 Aard en inhoud van houer

Groen, appelgeurde, individueel toegedraaide gometjies.

**KETO LIFE™ KETO BHB GOMMETJIES** is verpak in 'n deursigtige PET plastiekbottel met 'n wit peuterbestande afskroefdeksel.

Pakgrootte: 30 Gometjies.

#### 6.6 Spesiale voorsorgmaatreëls vir wegdoening <en ander hantering>

Geen spesiale vereistes nie.

### 7 HOUER VAN SERTIFIKAAT VAN REGISTRASIE

Vita-Aid (Edms.) Bpk

Central Straat 111, Houghton Estate, Johannesburg, Suid-Afrika, 2198.

### 8 REGISTRASIE NOMMER(S)

Word by registrasie deur SAHPRA toegeken.

### 9 DATUM VAN EERSTE Magting/HERNUWING VAN DIE Magting

Word by registrasie deur SAHPRA toegeken.

### 10 DATUM VAN HERSIENING VAN DIE TEKS

V01.08.23.KLBACVGP1



# KETO LIFE™ KETO BHB GOMMETJIES

## (PATIËNTINLIGTINGSBLAD)

### KOMPLEMENTÊRE MEDISYNE.

D 33.7 Kombinasieprodukt. Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir die gehalte, veiligheid of beoogde gebruik daarvan nie.

### SKEDULERINGSSTATUS

50

### KETO LIFE™ KETO BHB GOMMETJIES

Lees die hele inligtingsblad noukeurig deur, want dit bevat belangrike inligting vir jou. Keto Life™ Keto BHB is beskikbaar sonder 'n dokter se voorskrif vir jou om jou gesondheid te handhaaf.

Nietemin moet jy steeds **KETO LIFE™ KETO BHB GOMMETJIES** versigtig neem om die beste resultate daaruit te kry.

- Bewaar hierdie inligtingsblad. Jy sal dit dalk weer moet lees.
- Moenie **KETO LIFE™ KETO BHB GOMMETJIES** met enigiemand anders deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies benodig.

### WAT IS IN HIERDIE INLIGTINGSBLAD

1. Wat **KETO LIFE™ KETO BHB GOMMETJIES** is en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy **KETO LIFE™ KETO BHB GOMMETJIES** neem.
3. Hoe om **KETO LIFE™ KETO BHB GOMMETJIES** te neem.
4. Moontlike nuwe-effekte.
5. Hoe om **KETO LIFE™ KETO BHB GOMMETJIES** te bêre.
6. Inhoud van die pakkie en ander inligting.

### 1. WAT KETO LIFE™ KETO BHB IS EN WAARVOOR DIT GEBRUIK WORD.

**Keto Life™ Keto BHB** is 'n gesondheidsaanvulling om vet te help verbrand vir energie en induseer ketose. Dit is slegs effektief wanneer dit saam met 'n energiebeheerde maaltydplan gebruik word en 'n toename in fisiese aktiwiteit.

### 2. WAT JY MOET WEET VOORDAT JY KETO LIFE™ KETO BHB GOMMETJIES NEEM.

**Moenie KETO LIFE™ KETO BHB GOMMETJIES neem nie:**

- As jy hipersensitief (allergies) is vir enige van die bestanddele (sien **WAT KETO LIFE™ KETO BHB BEVAT**).
- As jy hoër as normale vlakke van kalsium in jou bloed het (hiperkalsemie).
- As jy baie hoër vlakke van kalsium in jou urine het (ernstige hiperkalsurie).
- As u ernstige nierversaking het en nie deur nierdialise behandeling word nie.
- As jy nierstene het.
- As jy hoër vlakke van fosfaat in jou bloed het (hiperfosfatemie).
- As jy onder die ouderdom van 18 jaar is.

### WAARSKUWINGS EN VOORSORGMATREËLS

Moenie die aanbevole daaglikse dosis oorskry nie.

Praat met jou dokter of apteker voordat jy **KETO LIFE™ KETO BHB GOMMETJIES** neem.

Gebruik **KETO LIFE™ KETO BHB GOMMETJIES** met omsigtigheid as jy:

- 'n Hart toestand het.
- 'n Nier siekte het.
- Teensuurmiddels neem wat kalsium of magnesium bevat want dit mag tot hoër vlakke van kalsium en magnesium lei.

Vertel jou dokter of apteker as jy enige ander medikasie gebruik, selfs dié wat jy dalk gekoop het sonder voorskrif.

### ANDER MEDISYNE EN KETO LIFE™ KETO BHB GOMMETJIES

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne ook gebruik.

(Dit sluit alle aanvullende medisyne, gesondheidsaanvullings of tradisionele medisyne in.)

Moenie **KETO LIFE™ KETO BHB GOMMETJIES** gebruik saam met:

- Hartglikosiede (medikasie wat gebruik word om hartprobleme te behandel).
- Tiasied diuretika (medikasie wat gebruik word om hoër bloeddruk te behandel).
- Teensuurmiddels (medikasie wat gebruik word om sooibrand te behandel).
- Kortikosteroïede (medikasie wat gebruik word om inflammasie te behandel).

Moenie die volgende medisyne gelyktydig met **KETO LIFE™ KETO BHB GOMMETJIES** neem nie.

- Laat 'n tydperk van 2 ure toe voor, of 4 ure nadat **KETO LIFE™ KETO BHB GOMMETJIES** geneem is:
- Skildklierhormone (medikasie wat gebruik word om onderaktiewe skildklier te behandel)
- Bisfosfonate (medikasie wat gebruik word om osteoporose te behandel).
- Natriumfluoried (medikasie wat gebruik word om tandbederf te voorkom).
- Fluorokinoloon-antibiotika (medikasie wat gebruik word om bakteriële infeksie te behandel).
- Tetrasiklien-antibiotika (medikasie wat gebruik word om bakteriële infeksies te behandel).
- Minerale aanvullings soos sink en yster.
- Vitamien aanvullings soos Vitamien D.

### KETO LIFE™ KETO BHB MET KOS, DRANK EN ALKOHOL

**KETO LIFE™ KETO BHB GOMMETJIES** moet nie geneem word binne 2 ure nadat u voedsel wat ryk is aan oksaalsuur geëet het nie (bv. spinasie en rabarber), fosfaat (bv. semels), of fitiensuur (bv. volgraan).

### SWANGERSKAP, BORSVOEDING EN VRUGBAARHEID

As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u **KETO LIFE™ KETO BHB GOMMETJIES** neem. Veiligheid en doeltreffendheid van **KETO LIFE™ KETO BHB GOMMETJIES** tydens swangerskap en borsvoeding is nie vasgestel nie.

### BESTUUR EN GEBRUIK VAN MASJINERIE

Keto Life™ Keto BHB sal waarskynlik nie jou vermoë beïnvloed om take uit te voer wat jou aandag vereis nie.

### 3. HOE OM KETO LIFE™ KETO BHB TE NEEM.

Moenie jou medisyne met enige ander persoon deel nie.

Neem altyd **KETO LIFE™ KETO BHB GOMMETJIES** presies soos beskryf in hierdie pamflet, of soos jou dokter of apteker jou aangeraai het. Bevestig met jou dokter of apteker as jy nie seker is nie.

#### Die gewone dosis is:

**Volwassenes 18 jaar en ouer:** Neem een (1) gometjie een keer per dag, of soos voorgeskryf deur 'n gesondheidsorg verskaffer. As jy voel dat die effek van **KETO LIFE™ KETO BHB GOMMETJIES** te sterk of te swak is, vertel jou dokter of apteker.

#### Moenie die aanbevole dosis oorskry nie.

**KETO LIFE™ KETO BHB GOMMETJIES** kan met of sonder kos geneem word.

As jy meer **KETO LIFE™ KETO BHB GOMMETJIES** neem as wat jy moet.

In die geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gif kontaksentrum. Neem hierdie pamflet en die res van **KETO LIFE™ KETO BHB GOMMETJIES** saam sodat die dokter sal weet wat jy geneem het.

#### As jy vergeet om KETO LIFE™ KETO BHB GOMMETJIES te neem

As jy vergeet om jou **KETO LIFE™ KETO BHB GOMMETJIES** te neem, neem dit so gou as wat jy onthou en gaan dan voort met die volgende dosis soos aangedui. Moenie 'n dubbele dosis neem om op te maak van vergete individuele dosisse nie.

### 4. MOONTLIKE NUWE-EFFEKTE

**KETO LIFE™ KETO BHB GOMMETJIES** kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir **KETO LIFE™ KETO BHB GOMMETJIES** aangemeld is, is in hierdie pamflet ingesluit nie. Moet jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar terwyl jy **KETO LIFE™ KETO BHB GOMMETJIES** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

#### As enige van die volgende gebeur, hou op om KETO LIFE™ KETO BHB GOMMETJIES te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak in sluk of asemhaling.
- Erge uitslag of jeuk.

Dit is alles baie ernstige nuwe-effekte. As jy hulle het, het jy dalk 'n ernstige allergiese reaksie gehad op **KETO LIFE™ KETO BHB GOMMETJIES**. Jy benodig dalk dringende mediese aandag of hospitalisasie.

#### Vertel jou dokter as jy enige van die volgende opmerk:

- **Frekwensie onbekend:** Naarheid (voel naar).
- **Frekwensie onbekend:** Opblaas, buikkrampe of maagpyn.
- **Frekwensie onbekend:** Sooibrand, dispepsie, gastritis, maagversteuring.
- **Frekwensie onbekend:** Braking.
- **Frekwensie onbekend:** Diarree (loperig, los stoelgang), hardlywigheid, winderigheid.
- **Frekwensie onbekend:** Veluitslag.
- **Minder gereeld:** Spierswakheid, hoofpyn, duiseligheid, lighoofdigheid.
- **Minder gereeld:** Lae bloeddruk, onreëlmate hartklop.

Indien u enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

#### Aanmelding van nuwe-effekte

As jy nuwe-effekte kry, brespreek dit met jou dokter of apteker. Jy kan ook nuwe-effekte by SAHPRA rapporteer via die "**6.04 Adverse Drug Reactions Reporting Form**", aanlyn gevind onder SAHPRA's se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van **KETO LIFE™ KETO BHB GOMMETJIES** te verskaf.

### 5. HOE OM KETO LIFE™ KETO BHB GOMMETJIES TE BÊRE.

- Bêre alle medisyne buite bereik van kinders.
- Bêre in 'n koel, droë plek by of onder 25°C.
- Bêre in die oorspronklike houer.
- Hou die houer dig toe na gebruik.
- Beskerm teen lig en vog.
- Moenie in die badkamer bêre nie.
- Moet nie na die vervaldatum, soos op die etiket of houer aangedui is, gebruik word nie.
- Gee alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

### 6. INHOUD VAN DIE PAKKIE EN ANDER INLIGTING.

#### WAT KETO LIFE™ KETO BHB GOMMETJIES BEVAT

Elke gometjie bevat:

Die aktiewe stowwe is:	
<i>Malus pumila mill</i> (Appleasyn) [Vrug].....	300 mg
Kalsium Beta-hidroksibutiraat.....	75 mg
Verskaf kalsium (elementêr).....	12,23 mg
Magnesium Beta-hidroksibutiraat.....	37,5 mg
Verskaf magnesium (elementêr).....	3,96 mg
Natrium Beta-hidroksibutiraat.....	37,5 mg
Verskaf natrium (elementêr).....	6,84 mg
Beta-hidroksibutiraat.....	121,80 mg
(van kalsium BHB, Magnesium BHB en Natrium BHB)	
Fruktooligosakkariede.....	2.1 g

Die ander bestanddele is gesuiwerde water, pektien (E440), sitroensuur (E330), 3H-olie (FF140), karnauba (E903), trinatriumsitraat (E331), geurmiddel, kleurstof, natriumchloried.

#### HOE LYK KETO LIFE™ KETO BHB GOMMETJIES EN INHOUD VAN DIE PAK

Groen, appelgeurde individueel toegedraaide gometjies.

**KETO LIFE™ KETO BHB GOMMETJIES** word in 'n deursigtige PET-plastiekbottel met 'n wit peuteurbestande afskroefdeksel verpak.

Pakgrootte: 30 Gometjies.

#### HOUER VAN SERTIFIKAAT VAN REGISTRASIE

Vita-Aid (Edms.) Bpk  
Central Straat 111  
Houghton Estate  
Johannesburg  
2198  
Suid-Afrika  
info@vita-aid.co.za

#### HIERDIE PAMFLET IS LAAS IN HERSIEN

Augustus 2023.

#### REGISTRASIENOMMER

Word by registrasie deur SAHPRA toegeken.

#### TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING

Die professionele inligting vir **KETO LIFE™ KETO BHB GOMMETJIES** is beskikbaar op <https://www.vita-aid.co.za/keto-life-keto-bhb/> of kan aangevra word by die kontakbesonderhede hierbo.