

## 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 THE MEDICINE

VIKELEKA HERBAL IMMUNIZER™ Softgel Capsules

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| Each Softgel Capsule contains:                 |          | % RDA |
|--|----------|-------|
| <i>Hypoxis hemerocallidea</i> (African Potato) | 150 mg   | -     |
| <i>Aloe barbadensis</i> (Aloe Vera)            | 10 mg    | -     |
| Vitamin A                                      | 834 IU   | 25    |
| Thiamine (Vitamin B1)                          | 8,34 mg  | 596   |
| Riboflavin (Vitamin B2)                        | 4,15 mg  | 260   |
| Ascorbic Acid (Vitamin C)                      | 100 mg   | 167   |
| Nicotinamide (Vitamin B3)                      | 12,5 mg  | 69    |
| Pantothenic acid (Vitamin B5)                  | 12,5 mg  | 208.5 |
| Pyridoxine (Vitamin B6)                        | 4,15 mg  | 207   |
| Folic acid (Vitamin B9)                        | 92 mcg   | 46    |
| Cyanocobalamin (Vitamin B12)                   | 8,3 mcg  | 830   |
| Calciferol (Vitamin D)                         | 17 IU    | 8.5   |
| Tocopherol (Vitamin E)                         | 15 IU    | 100   |
| Boron  | 167 mcg  | -     |
| Calcium  | 41,7 mg  | -     |
| Chromium                                       | 17 mcg   | -     |
| Copper   | 170 mcg  | -     |
| Iodine   | 12,5 mcg | -     |
| Iron   | 1,65 mg  | 12    |
| Magnesium                                      | 41,7 mg  | 14    |
| Manganese                                      | 1,65 mg  | -     |
| Molybdenum                                     | 12,5 mcg | -     |
| Potassium                                      | 8,25 mg  | -     |
| Selenium                                       | 17 mcg   | -     |
| Zinc   | 2,5 mg   | 16    |
| Histidine                                      | 3,55 mg  | -     |
| Isoleucine                                     | 11,5 mg  | -     |

|               |          |   |
|---------------|----------|---|
| Leucine       | 17,35 mg | - |
| Lysine        | 3,45 mg  | - |
| Phenylalanine | 3,9 mg   | - |
| Threonine     | 5,85 mg  | - |
| Valine        | 14,25 mg | - |
| Cysteine      | 26,05 mg | - |

% Recommended daily allowance per capsule

Sugar free.

For a full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Softgel capsules.

Reddish brown, oblong, softgel capsules.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

VIKELEKA HERBAL IMMUNIZER is a nutritional and immune system supplement for adults.

#### **4.2 Posology and method of administration**

##### **Posology**

Adults: One capsule to be taken twice daily with a meal, or as directed by a health care professional.

##### **Method of administration**

For oral use.

#### **4.3 Contraindications**

- Hypersensitivity to any of the ingredients contained in VIKELEKA HERBAL IMMUNIZER (see section 6.1).

#### **4.4 Special warnings and precautions for use**

- VIKELEKA HERBAL IMMUNIZER should be used with caution in the presence of a cardiovascular disorder, disorders of the gastro-intestinal tract, diabetes mellitus, liver impairment, renal function impairment and mental disorders. In the presence of such conditions, a healthcare professional should be consulted before taking VIKELEKA HERBAL IMMUNIZER.
- VIKELEKA HERBAL IMMUNIZER contains phenylalanine which may be harmful for people with phenylketonuria.
- VIKELEKA HERBAL IMMUNIZER is not suitable for use by vegetarians.

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

Supplementation with VIKELEKA HERBAL IMMUNIZER should be done under the close supervision of a healthcare professional in patients receiving the following medicines:

- Anti-diabetic medicines as VIKELEKA HERBAL IMMUNIZER may lower blood sugar levels. Serum glucose levels should be carefully monitored by a healthcare professional when taking VIKELEKA HERBAL IMMUNIZER.
- Phenytoin (anti-epileptic) and levodopa (anti-parkinsons) as the effect of both may be reduced.
- Retinoids such as isotretinoin indicated for the treatment of acne. There is concern of Vitamin A toxicity where Vitamin A containing supplements and retinoids are used concomitantly.
- Anticoagulants e.g. warfarin. There have been reports of an increased risk of bleeding in patients taking Vitamin E and warfarin concomitantly. This effect is more likely to occur with larger doses of Vitamin E (> 800 IU).
- Anti-infectives (e.g. tetracyclines and fluoroquinolones), bisphosphonates and levothyroxine as their absorption and efficacy may be reduced when used concomitantly with supplements containing calcium and magnesium.

Caution should be exercised when supplementing with VIKELEKA HERBAL IMMUNIZER in patients receiving the following medicines: Angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, digoxin, diuretics, corticosteroids, indomethacin and levothyroxine.

#### **4.6 Fertility, pregnancy and lactation**

VIKELEKA HERBAL IMMUNIZER is not recommended for pregnant and lactating women.

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

VIKELEKA HERBAL IMMUNIZER can cause drowsiness or dizziness. You should be aware of how you react to VIKELEKA HERBAL IMMUNIZER before you drive or use machinery.

#### **4.8 Undesirable effects**

The following side effects have been reported when supplementing with *Hypoxis hemerocallidea* (African potato), *Aloe barbadensis* (Aloe Vera), vitamins, minerals and amino acids. The frequency is unknown.

##### *Gastrointestinal disorders:*

Nausea, vomiting, diarrhoea, constipation, abdominal cramps, indigestion.

##### *Nervous system disorders:*

Dizziness, irritability, headaches, insomnia, drowsiness, depression, hallucination and loss of concentration.

##### *Skin and subcutaneous tissue disorders:*

Dermatitis, skin rash, dryness of the skin and itchiness.

#### *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 & Quality Problem Reporting Form**”, found online under SAHPRA’s publications:

[https://sahpra.org.za/wp-content/uploads/2020/01/6.04\\_ARF1\\_v5.1\\_27Jan2020.pdf](https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf)

#### **4.9 Overdose**

The symptoms of overdosage can be any of those described under section 4.8 above. The treatment of overdosage is symptomatic and supportive.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Complementary Medicine

D 33.7 Combination Product

VIKELEKA HERBAL IMMUNIZER is a nutritional and immune system supplement for adults. It contains a combination of herbal medicines, vitamins, minerals and amino acids all of which support the body’s immune system and have been attributed with the following activity.

|   |  |
|---|--|
| <i>Hypoxis hemerocallidea</i><br>(African Potato) and<br><i>Aloe barbadensis</i> (Aloe<br>Vera) | Provide a rich source of sterols and sterolins that have been attributed to supporting a healthy immune system.  |
| Vitamin A   | For the maintenance of good vision and healthy skin, nails and hair.   |
| Thiamine<br>(Vitamin B1)  | Required for the release of energy from glucose, and for the transformation of carbohydrates to fat. Maintains healthy nerve function.   |
| Riboflavin<br>(Vitamin B2)  | For the production of energy from protein, fat and carbohydrate.<br>Helps maintain healthy skin.   |
| Ascorbic Acid<br>(Vitamin C)  | Plays a role in maintaining healthy gums, skin and connective tissue.<br>Helps with the absorption of iron from food. Functions as a tissue antioxidant thereby keeping cells healthy. |
| Nicotinamide<br>(Vitamin B3)  | Helps the body in protein metabolism and the conversion of fats and carbohydrates into energy.   |
| Pantothenic acid<br>(Vitamin B5)  | Plays a role in the metabolism of fatty acids, glucose and proteins for energy production. Helps maintain healthy skin and mucous membranes.   |
| Pyridoxine<br>(Vitamin B6)  | For energy release from protein, carbohydrates and fat. Plays a role in amino acid metabolism. Helps maintain healthy skin.  |
| Folic acid<br>(Vitamin B9)  | Plays a role in the metabolism of cell division and in the regeneration of blood and cells.  |

|                              |  |
|------------------------------|--|
| Cyanocobalamin (Vitamin B12) | Contributes to the health of the nervous system and is involved in the manufacture of red blood cells.   |
| Calciferol (Vitamin D)       | For the maintenance of healthy bones and teeth. Helps the body utilise calcium which is necessary for the normal development and maintenance of strong bones and teeth.  |
| Tocopherol (Vitamin E)       | Functions as a tissue antioxidant thereby keeping cells healthy. Protects unsaturated fatty acids and vitamin A against oxidation in the body (natural antioxidant).   |
| Boron                        | Plays a role in mineral metabolism and membrane function.  |
| Calcium                      | Helps maintain healthy bones and teeth.  |
| Chromium                     | Helps regulate blood sugar levels.   |
| Copper                       | Plays a role in the absorption of iron in the body.  |
| Iodine                       | Essential component of important hormones (thyroid).   |
| Iron                         | Helps maintain healthy red blood cells, which play a role in oxygen transportation.  |
| Magnesium                    | Helps in the utilisation of proteins. Helps and maintains healthy nervous system metabolism.   |
| Manganese                    | Helps maintain healthy skin, bone and cartilage.   |
| Molybdenum                   | Contributes to the functioning of certain enzyme dependant processes including the metabolism of iron.   |
| Potassium                    | Plays a role in fluid balance, acid-base balance, various chemical reactions in the body, transmission of nerve signals, the break down and use of carbohydrates, building protein and muscle, muscle contractions and normal body growth. |
| Selenium                     | Helps the body with the production of antioxidant enzymes which play a role in preventing cell damage  |
| Zinc                         | Plays a vital role in growth and maintenance of the human body; it plays a role in cell division, reproductive health, the immune system, wound healing, taste, smell and appetite, skin, hair, nails, vision and thyroid function.        |

The following are essential amino acids the body cannot make (enough of) and can be obtained only from diet. Supplementation can assist in providing the requirements.

|                            |  |
|----------------------------|--|
| Histidine (semi-essential) | Required for growth and for the repair of tissues. It is also required for the maintenance of a healthy nervous system and for manufacture of both red and white blood cells. It assists the body against damage caused by radiation and in removing heavy metals from the body. |
| Isoleucine                 | Plays a role in muscle recovery after physical exercise and it is needed for the formation of haemoglobin as well as assisting with regulation of blood sugar levels as well as energy levels. It is also involved in blood-clot formation.                                      |
| Leucine                    | Plays a role in the regulation of blood-sugar levels, growth and repair of muscle tissue (bones, skin and muscles), growth hormone   |

|               |  |
|---------------|--|
|               | production, wound healing and energy regulation.   |
| Lysine        | Required for muscle growth and bone development. It assists in calcium absorption and maintaining the correct nitrogen balance in the body and maintaining lean body mass. |
| Phenylalanine | Helps to elevate the mood since it is so closely involved with the nervous system. It also helps with memory and learning.   |
| Threonine     | Helps maintain a proper protein balance in the body, as well as assist in the formation of collagen and elastin in the skin.   |
| Valine        | Needed for muscle metabolism, repair and growth of tissue and maintaining the nitrogen balance in the body.  |
| Cysteine      | Required for the maintenance of healthy skin, hair and nails. It assists with the detoxification of the body. It assists in skin elasticity and texture.                   |

## 5.2 Pharmacokinetic properties

No information is available.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Gelatin wet solution

Iron oxide red

Lecithin 450-M

Purified water

Sunflower oil

Wax mixture

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

24 months.

### 6.4 Special precautions for storage

Store in a cool dry place below 25 °C. Keep well closed in the original container.

Keep out of reach of children.

### 6.5 Nature and contents of container

Soft-Gel Capsules in white HDPE plastic containers of 30's and 60's.

VIKELEKA HERBAL IMMUNIZER is Halaal certified with the NIHT(National independent Halaal Trust)

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 HOLDER OF CERTIFICATE OF REGISTRATION**

Vikeleka Herbal Pharmaceuticals CC

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031 2073007

[customerservices@vikeleka.com](mailto:customerservices@vikeleka.com)

[www.vikeleka.com](http://www.vikeleka.com)

## **8 REGISTRATION NUMBER**

To be allocated

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

Date of publication: October 2020

## **10 DATE OF REVISION OF THE TEXT**

January 2021

***Scroll down for Immunizer Professional Information (Afrikaans)***

## PROFESSIONELE INLIGTING

Komplementêre medisyne

D 33.7 Kombinasie Produk

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer in terme van kwaliteit, veiligheid of die beoogde gebruik nie.

### SKEDULERINGSSTATUS

S0

#### 1 NAAM VAN DIE MEDISYNE

**VIKELEKA HERBAL IMMUNIZER™ Sagtejelkapsules**

#### 2 KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

| Elke sagtejelkapsule bevat:                      |          | % ADT |
|--|----------|-------|
| <i>Hypoxis hemerocallidea</i> (Afrika-aartappel) | 150 mg   | -     |
| <i>Aloe barbadensis</i> (Aloe Vera)              | 10 mg    | -     |
| Vitamien A                                       | 834 IU   | 25    |
| Tiamien (Vitamien B1)                            | 8,34 mg  | 596   |
| Riboflaviën (Vitamien B2)                        | 4,15 mg  | 260   |
| Askorbiensuur (Vitamien C)                       | 100 mg   | 167   |
| Nikotinamied (Vitamien B3)                       | 12,5 mg  | 69    |
| Pantoteensuur (Vitamien B5)                      | 12,5 mg  | 208.5 |
| Piridoksien (Vitamien B6)                        | 4,15 mg  | 207   |
| Foliensuur (Vitamien B9)                         | 92 mcg   | 46    |
| Sianokobalamien (Vitamien B12)                   | 8,3 mcg  | 830   |
| Kalsiferol (Vitamien D)                          | 17 IU    | 8.5   |
| Tokoferol (Vitamien E)                           | 15 IU    | 100   |
| Boron  | 167 mcg  | -     |
| Kalsium  | 41,7 mg  | -     |
| Chroom   | 17 mcg   | -     |
| Koper  | 170 mcg  | -     |
| Jodium   | 12,5 mcg | -     |
| Yster  | 1,65 mg  | 12    |
| Magnesium  | 41,7 mg  | 14    |
| Mangaan  | 1,65 mg  | -     |



|               |          |    |
|---------------|----------|----|
| Molibdeen     | 12,5 mcg | -  |
| Kalium        | 8,25 mg  | -  |
| Selenium      | 17 mcg   | -  |
| Sink          | 2,5 mg   | 16 |
| Histidien     | 3,55 mg  | -  |
| Isoleusien    | 11,5 mg  | -  |
| Leusien       | 17,35 mg | -  |
| Lisien        | 3,45 mg  | -  |
| Fenielalanien | 3,9 mg   | -  |
| Treonien      | 5,85 mg  | -  |
| Valien        | 14,25 mg | -  |
| Sistien       | 26,05 mg | -  |

% Aanbevole daaglikse toelaag per kapsule

Suikervry.

Vir 'n volledige lys van onaktiewe stowwe, sien afdeling 6.1

VIKELEKA HERBAL IMMUNIZER is halaal gesertifiseerd deur NIHT.

### **3 FARMASEUTIESE VORM**

Sagtejelkapsules.

Rooibruin, langwerpige, sagtejelkapsules.

### **4 KLINIESE BESONDERHEDE**

#### **4.1 Terapeutiese indikasies**

VIKELEKA HERBAL IMMUNIZER is 'n voedings- en immuunstelselaanvulling vir volwassenes.

#### **4.2 Posologie en metode van toediening**

##### **Posologie**

Volwassenes: Een kapsule twee keer per dag saam met 'n maaltyd, of soos deur 'n gesondheidsorgkundige aangedui.

##### **Metode van toediening**

Vir orale gebruik.

#### **4.3 Kontraindikasies**

- Hipersensitiwiteit vir enige van die bestanddele wat in die produk voorkom (sien afdeling 6.1).

#### **4.4 Spesiale waarskuwings en voorsorgmaatreëls vir gebruik**

- VIKELEKA HERBAL IMMUNIZER moet met versigtigheid gebruik word in die geval van enige kardiovaskulêre versteuring, versteurings van die spysverteringskanaal, diabetes

miëlitis, lewerskade, gebrekkige nierfunksie en geestesiektes. Waar sulke toestande voorkom, moet 'n gesondheidsorgwerker geraadpleeg word voordat VIKELEKA HERBAL VIKELEKA HERBAL IMMUNIZER gebruik word.

- VIKELEKA HERBAL IMMUNIZER bevat fenielalanien wat skadelik kan wees vir persone met fenielketonurie.

#### **4.5 Interaksie met ander medisyne en ander vorms van interaksie**

Aanvulling met VIKELEKA HERBAL IMMUNIZER moet onder noukeurige toesig van 'n gesondheidsorgwerker gebruik word deur pasiënte wat die volgende medikasie gebruik:

- Antidiabetiese medikasie - VIKELEKA HERBAL IMMUNIZER kan bloedsuikervlakke verlaag. Bloedglukosevlakke moet noukeurig deur 'n gesondheidspraktisyn gemoniteer word as VIKELEKA HERBAL IMMUNIZER gebruik word.
- Fenitoïen (anti-epilepties) en levodopa (teen Parkinson se siekte) omdat die uitwerking van albei verminder kan word.
- Retinoïede soos isotretinoïen wat vir die behandeling van aknee gebruik word. Daar bestaan kommer oor vitamien A-toksiteit indien aanvullings wat vitamien A bevat en retinoïede saamlopend gebruik word.
- Antistolmiddels bv. warfarien. Aanmeldings van 'n verhoogde risiko van bloeding in pasiënte wat vitamien E en warfarien saam gebruik, kom voor. Daar is 'n groter moontlikheid dat hierdie effek sal voorkom by groter dosisse van vitamien E (>800 IU).
- Disinfeksiemiddels (bv. tetrasiklien en fluorkinolone), bisfosfonate en levotiroksien omdat die absorpsie en doeltreffendheid daarvan verminder kan word indien dit saam met aanvullings wat kalsium en magnesium bevat, gebruik word.

Omsigtigheid moet aan die dag gelê word wanneer VIKELEKA HERBAL IMMUNIZER as aanvulling gebruik word vir pasiënte wat die volgende medikasie ontvang: Angiotensien-omskakelende ensiem-inhibeerders of angiotensienreseptorblokkeerders, digoksien, diuretika, kortikosteroïede, indometasien en levotiroksien.

#### **4.6 Fertiliteit, swangerskap en laktasie**

VIKELEKA HERBAL IMMUNIZER word nie vir swanger en borsvoedende vrouens aanbeveel nie.

#### **4.7 Effekte op die vermoë om te bestuur en gebruik van masjinerie**

VIKELEKA HERBAL IMMUNIZER kan lomerigheid of duiseligheid veroorsaak. Jy moet seker maak dat jy nie betrokke raak in die bogenoemde aktiwiteite nie, totdat jy bewus is tot en met watter mate VIKELEKA HERBAL IMMUNIZER jou affekteer nie.

#### **4.8 Ongewenste effekte**

Die volgende newe-effekte is aangemeld met die gebruik van aanvullings wat *Hypoxis hemerocallidea* (Afrika-aartappel), *Aloe barbadensis* (Aloe Vera), vitamien, minerale en aminosure bevat. Die voorkoms van die newe-effekte is onbekend.

*Spysverteringsongesteldhede:*

Naarheid, vomering, diarree, hardlywigheid, maagkrampe, slegte spysvertering.

*Ongesteldhede van die senuweestelsel:*

Duiseligheid, geïrriteerdheid, hoofpyn, slapeloosheid, lomerigheid, depressie, hallusinasies en verlies aan konsentrasie.

*Vel- en onderhuidse aandoenings:*

Dermatitis, veluitslag, droogheid van die vel, jeukerigheid.

#### **Anmelding van vermoedelike ongewenste reaksies**

Anmelding van vermoedelike ongewenste reaksies na goedkeuring van die medisyne is belangrik. Dit laat volgehoue monitoring van die voordeel/risiko balans van die medisyne toe. Gesondheidsorgwerkers word versoek om enige vermoedeilike ongewenste reaksies by SAHPRA aan te meld via die “**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**”, wat aanlyn gevind kan word onder SAHPRA se publikasies:

[https://sahpra.org.za/wp-content/uploads/2020/01/6.04\\_ARF1\\_v5.1\\_27Jan2020.pdf](https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf).

#### **4.9 Oordosering**

Die simptome van oordosering kan enige van dié wees wat onder afdeling 4.8 hierbo beskryf is.

Die behandeling van oordosering is simptomaties en ondersteunend.

### **5 FARMAKOLOGIESE EIENSKAPPE**

#### **5.1 Farmakodinamiese eienskappe**

Komplementêre medisyne

Kombinasie Produk

D 33.7 Kombinasie Produk

VIKELEKA HERBAL IMMUNIZER is 'n voedings- en immuunstelselaanvuller vir volwassenes. Dit bevat 'n kombinasie van kruiegeneesmiddels, vitamien, minerale en aminosure wat almal die liggaam se immuunstelsel ondersteun en waaraan die volgende werking toegeskryf word:

|   |  |
|---|--|
| <i>Hypoxis hemerocallidea</i> (Afrika-aartappel) en <i>Aloe barbadensis</i> (Aloe Vera) | Verskaf 'n ryk bron van sterol en sterolien wat help met die ondersteuning van 'n gesonde immuunstelsel. |
| Vitamien A  | Vir die handhawing van goeie sig en gesonde vel, naels en hare.  |
| Tiamien   | Noodsaaklik vir die vrystelling van energie uit glukose, en vir die verandering van                      |

|                                   |   |
|-----------------------------------|---|
| (Vitamien B1)                     | koolhidrate in vet. Handhaaf gesonde senuweefunksie.  |
| Riboflaven<br>(Vitamien B2)       | Vir die vervaardiging van energie uit proteïne, vet en koolhidrate. Help om die vel gesond te hou.  |
| Askorbiensuur (Vitamien C)        | Speel 'n rol in die instandhouding van gesonde tandvleis, vel en bindweefsel. Help met die absorpsie van yster uit voedsel. Funksioneer as 'n weefsel-antioksidant waardeur selle gesond gehou word.  |
| Nikotinamied (Vitamien B3)        | Help die liggaam met die metabolisme van proteïne en die omskakeling van vette en koolhidrate na energie.   |
| Pantoteensuur<br>(Vitamien B5)    | Speel 'n rol in die metabolisme van vetsure, glukose en proteïne vir die verskaffing van energie. Help om die vel en slymvliese gesond te hou.  |
| Piridoksien<br>(Vitamien B6)      | Vir die vrystelling van energie uit proteïne, koolhidrate en vette. Speel 'n rol in die metabolisme van aminosure. Help om die vel gesond te hou.   |
| Foliensuur<br>(Vitamien B9)       | Speel 'n rol in die metabolisme van seldeling en in die vernuwing van bloed en selle.   |
| Sianokobalamien<br>(Vitamien B12) | Dra by tot die gesondheid van die senuweestelsel en is betrokke by die vervaardiging van rooibloedselle.  |
| Kalsiferol<br>(Vitamien D)        | Vir die instandhouding van gesonde bene en tande. Help die liggaam om kalsium te benut, wat nodig is vir die normale ontwikkeling en instandhouding van sterk bene en tande.  |
| Tokoferol<br>(Vitamien E)         | Funksioneer as 'n weefsel-antioksidant waardeur selle gesond gehou word. Beskerm onversadigde vetsure en vitamien A teen oksidasie in die liggaam ('n natuurlike antioksidant).   |
| Boron                             | Speel 'n rol in die metabolisme van minerale asook in die werking van membrane.   |
| Kalsium                           | Help om bene en tande gesond te hou.  |
| Chroom                            | Help om bloedsuikervlakke te reguleer.  |
| Koper                             | Speel 'n rol in die absorpsie van yster in die liggaam.   |
| Jodium                            | Noodsaaklike komponent van belangrike hormone (skildklier).   |
| Yster                             | Help om rooibloedselle gesond te hou, wat 'n belangrike rol speel in die vervoer van suurstof.  |
| Magnesium                         | Help met die benutting van proteïne. Help om metabolisme van die senuweestelsel gesond te hou.  |
| Mangaan                           | Help om vel, been en kraakbeen gesond te hou.   |
| Molibdeen                         | Dra by tot die werking van sekere ensiemafhanklike prosesse insluitende die metabolisme van yster.  |
| Kalium                            | Speel 'n rol in vloeistofbalans, suurbasisbalans, verskeie chemiese reaksies in die liggaam, oordrag van senuweeseine, die afbreek en gebruik van koolhidrate, die ontwikkeling van proteïne en spiere, spiersametrekking en normale liggaamsgroei. |
| Selenium                          | Help die liggaam met die vervaardiging van antioksiderende ensieme wat 'n rol speel in die voorkoming van skade aan selle.  |
| Sink                              | Speel 'n noodsaaklike rol in groei en instandhouding van die menslike liggaam; dit is betrokke by seldeling, voortplantingsgesondheid, die immuunstelsel, genesing van wonde, smaak, reuk en aptyt, vel, hare, naels, visie (sig) en                |

|  |                    |
|--|--------------------|
|  | skildklierfunksie. |
|--|--------------------|

Die volgende is noodsaaklike aminosure wat nie (voldoende) deur die liggaam gemaak kan word nie en net deur dieet aangevul kan word. Aanvulling kan help om die vereiste hoeveelheid te voorsien.

|                                  |   |
|----------------------------------|---|
| Histidien<br>(deels noodsaaklik) | Dit word vereis vir groei en vir die herstel van weefsel. Dit is ook nodig om die senuweestelsel gesond te hou en vir die vervaardiging van beide rooi- en witbloedselle. Dit help om die liggaam te beskerm teen skade wat deur bestraling veroorsaak word en om swaar metale uit die liggaam te verwyder. |
| Isoleusien                       | Speel 'n rol in die herstel van spiere na liggaamlike oefening en is op sigself nodig vir die vorming van hemoglobien asook om te help met die regulering van bloedsuikervlakke en energievlakke. Dit is ook by bloedstolling betrokke.   |
| Leusien                          | Speel 'n rol in die regulering van bloedsuikervlakke, die groei en herstel van spierweefsel (been, vel en spiere), die vervaardiging van groeihormone, wondgenesing en energieregulering.   |
| Lisien                           | Vereis vir spiergroei en beenontwikkeling. Dit help met kalsiumabsorpsie en hou die stikstofbalans in die liggaam korrek, en sorg vir slanke liggaamsmassa.   |
| Sistien                          | Sistien word benodig om die vel, hare en naels gesond te hou. Dit help met die ontgifting van die liggaam. Dit lewer 'n bydrae tot die elastisiteit en tekstuur van die vel.  |
| Fenielalanien                    | Help om die gemoed goed te laat voel omdat dit so nou by die senuweestelsel betrokke is. Dit help ook met geheue en studie.   |
| Treonien                         | Help om die regte proteïenbalans in die liggaam in stand te hou, en help ook met die vorming van kollageen en elastien in die vel.  |
| Valien                           | Is nodig vir spiermetabolisme, herstel en groei van weefsel, en hou die stikstofbalans in die liggaam in stand.   |

## 5.2 Farmakokinetiese eienskappe

Geen inligting is beskikbaar nie.

## 6 FARMASEUTIESE EIENSKAPPE

### 6.1 Lys van onaktiewe bestanddele

Gelatien in vogtige oplossing

Lesitien 450-M

Rooi ysteroksied

Sonneblomolie

Wasmengsel

Water, gesuiwer

### 6.2 Onverenigbaarhede

Nie van toepassing nie.

### **6.3 Rakleef tyd**

24 maande.

### **6.4 Spesiale voorsorgmaatreëls vir berging**

Bewaar by of benede 25 °C in die oorspronklike houer. Hou dig toe.

Hou beite bereik van kinders.

### **6.5 Aard en inhoud van houer**

Sagtejelkapsules in wit HDPE plastiekhouders van 30's en 60's.

VIKELEKA HERBAL IMMUNIZER is Halaal gesertifiseer deur NIHT(National Independent Halaal Trust)

### **6.6 Spesiale voorsorgmaatreëls vir vernietiging en ander hantering**

Geen spesiale voorsorgmaatreëls vir vernietiging is nodig nie.

## **7 HOUER VAN REGISTRASIESERTIFIKAAT**

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## **8 REGISTRASIENOMMER**

Sal toegeken word

## **9 DATUM VAN EERSTE GOEDKEURING/HERNUWING VAN DIE GOEDKEURING**

Datum van publikasie: Oktober 2020

## **10 DATUM VAN HERSIENING VAN DIE TEKS**

Januarie 2021