

PROFESSIONAL INFORMATION
VITILIFT
Multivitamin Kids (syrup) agera™

SCHEDULING STATUS: **S2**

PROPRIETARY NAME AND DOSAGE FORM:
VITILIFT Multivitamin Kids (syrup).

COMPOSITION:
Active substances per 5 ml syrup:

		% DR1* (L3/Vitara)	% DR1* (L4/Vitara)
Vitamin A (Retinol)	999 IU	100 %	150 %
Vitamin D3 (Cholecalciferol)	100 IU	80 %	160 %
Vitamin B1 (Thiamine)	0,5 mg	100 %	166,67 %
Vitamin B2 (Riboflavin)	0,5 mg	100 %	166,67 %
Vitamin B3 (Nicotinamide)	6,0 mg	100 %	150 %
Vitamin B6 (Pyridoxine)	0,5 mg	100 %	166,67 %
Vitamin B12 (Cyanocobalamin)	0,9 µg	100 %	150 %
Vitamin E (Tocopherol)	6 IU	67,12 %	115,06 %
Vitamin C (Ascorbic acid)	20 mg	133,33 %	160 %

*DR1: Dietary Reference Intake.
Inactive ingredients: Flavoxing (mint, tulle-fuñ), glycerine, maltodextrin, microcrystalline cellulose, croscarmellose sodium and water.
Contains preservatives: potassium sorbate (0,035 % w/v) and sodium benzoate (0,045 % w/v).
Contains sorbitol (2-31 g/ml).
Contains sweetener: CSA 80 10 mg % ml (cesulfaline potassium, sodium cyclamate and sodium saccharin).

Alcohol, sugar, lactose and tartaric acid free.

CATEGORY AND CLASS:
D. 31.11 Vitamins
Complementary Medicines, Health Supplement.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

VITILIFT Multivitamin Kids is a multivitamin syrup for the maintenance of good health in children.

Pharmacokinetic properties:
The active ingredients in this formulation are well known. Pharmacokinetic studies have not been conducted on **VITILIFT Multivitamin Kids**.

INDICATIONS:

VITILIFT Multivitamin Kids is a multivitamin health supplement for maintenance of good health and to support your child's general wellbeing.

CONTRAINDICATIONS:

VITILIFT Multivitamin Kids is contra-indicated in patients hypersensitive to any of the ingredients. Not intended for patients where specific vitamin deficiency exists.

WARNINGS AND SPECIAL PRECAUTIONS:
Health supplements are intended only to complement health or supplement the diet. A nutritional supplement should not replace a balanced diet.

- Contains sorbitol and may have a laxative effect. Patients with the rare hereditary condition of sorbitol intolerance should not take **VITILIFT Multivitamin Kids**.
- Carbon dioxide is used in patients with chronic liver disease.
- Vitamin D should be used with caution in patients with hypercalcaemia.
- Increased sensitivity to vitamin D is observed in patients with renal impairment and having an abnormal calcium/phosphorus ratio.

Women who are or might become pregnant should avoid taking daily supplements containing more than 500 IU vitamin A, without consulting a medical practitioner.
The safe dosage may be exceeded when medicines and/or health products containing vitamin A are taken together with a high dietary intake of vitamin A.

Effects on the ability to drive and use machinery:
No studies on the effect of **VITILIFT Multivitamin Kids** on the ability to drive or operate machines were performed. It is unlikely that **VITILIFT Multivitamin Kids** would affect the ability to drive or operate machines.

INTERACTIONS:

- Vitamin A might affect the efficiency of the measles vaccine. Advise patients not to use this product when receiving the vaccine.
- The effects of vitamin D may be reduced in patients taking barbiturates or anti-convulsants.
- Pyridoxine (vitamin B6) can reduce the effects of levodopa.

HUMAN REPRODUCTION:

Pregnancy and lactation:
Not recommended during pregnancy or lactation due to lack of data.

INDICATOR AND DIRECTIONS FOR USE:

Children aged 1 to 3 years old: Give 5 ml per day or as directed by your healthcare professional.
Children aged 4 to 6 years old: Give 10 ml per day or as directed by your healthcare professional.
Do not exceed the recommended dose.
SHAKE THE BOTTLE WELL BEFORE EACH USE.

SIDE EFFECTS:

Gastrointestinal disorders: Diarrhoea, epigastric discomfort, nausea or vomiting, and dyspepsia, constipation (*frequency*).

Respiratory, dermatic and infectious disorders: Dryness (*frequency*), wheezing.

Skin and subcutaneous tissue disorders: Urticaria, skin rash (*less frequency*).

General disorders and administrative site conditions: Allergic reactions (*very frequency*).

Investigations: Bright yellow urine: discoloration has been reported with riboflavin usage (*frequency*).

Patients with liver disease might be more susceptible to these side effects.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
High doses of individual components of this product have been associated with exanthematous and exfoliative skin lesions, fatigue and nausea.

In higher treatments to doses, liver damage, gout and ulcer formation have been noted.
High doses of vitamin A can lead to hypoxaemia, anaemia, myopia, tinnitus, bone pain, thrombocytopenia, epistaxis, anaemia, increased administration rate, and accelerated reabsorption of tubular and cortical bone.

Long term administration of vitamin A >10 000 IU daily may cause chronic hyperparathyroidism A. Symptoms of chronic intoxication are as follows: headache, vertigo, hyperreflexia, changes in skin and mucous membranes, tenderness and pain in the bone and joints, fever, increased serum cholesterol and serum triglyceride concentration, increased hyperparathyroidism, hyperparathyroidism, hypercalcaemia, increased diurnal phosphate, hypoparathyroidism, hypocalcaemia, low serum inorganic acid decreased protein content of the coagulation fluid, elevated serum hydroxyproline and hydroxylysine, polyuria, increased frequency of micturition, urinary incontinence, emesis and acute renal failure due to tubular necrosis, papilloedema, dysuria, haematuria and oedema of the legs, yellow to yellow-orange discoloration of the skin, decreased tolerance to sunlight, changes in pigmentation, hair loss and brittle nails, spike anginae and oedema.

Initial symptoms of vitamin D overdose are usually comprised of weakness, lassitude, headache, nausea, vomiting and diarrhoea. Renal function can be impaired at an early stage with polyuria, polydipsia, nocturia, decreased urinary concentrating ability and polyuria.

Characteristic features of chronic vitamin D intoxication include hypercalcaemia and deposition of calcium salts in various tissues. Occasionally, mental disturbances, cerebellar ataxia, peripheral blood pancytopenia, apathy and lack of interest have been reported.

L symptoms of overdose are: Ataxic gait, use of the medicine. Treatment is symptomatic and supportive.

IDENTIFICATION:

VITILIFT Multivitamin Kids is a yellow syrup with a tulle-fuñ flavor.

PRESENTATION:

VITILIFT Multivitamin Kids is supplied in a 200 ml amber plastic bottle with a white plastic safety cap and cap.

STORAGE INSTRUCTIONS:

Store at or below 25°C.
Keep the container tightly closed.
Protect from light.

KEEP OUT OF REACH AND REACH OF CHILDREN.

REGISTRATION NUMBER: To be allocated.

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

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Agera Health (Pty) Ltd
6A Boleyn Road
Brynville 7530
Cape Town

info@agerapharma.co.za

www.agerahealth.co.za

DATE OF PUBLICATION OF THE PACKAGE INSERT:

January 2019.



PATIENT INFORMATION LEAFLET

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority (SAHPRA) for its quality, safety or its intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.

Complementary Medicine, Health Supplement.

SCHEDULING STATUS: **S2**

PROPRIETARY NAME (and dosage form):
VITILIFT Multivitamin Kids (syrup).

Read all of this leaflet carefully, because it contains important information for you.
• **VITILIFT Multivitamin Kids** is available without a doctor's prescription, for you to treat you in the maintenance of good health and to support your child's general wellbeing. Nevertheless, you still need to use **VITILIFT Multivitamin Kids** carefully to get the best results from it.
• Keep this leaflet. You may need to read it again.
• Do not share **VITILIFT Multivitamin Kids** with any other person.
• Ask your Doctor or Pharmacist if you need more information or advice.
• You must see a doctor if your symptoms worsen or do not improve.

1. WHAT VITILIFT Multivitamin Kids CONTAINS:
The active ingredients in each 5 ml:

		% DR1* (L3/Vitara)	% DR1* (L4/Vitara)
Vitamin A (Retinol)	999 IU	100 %	150 %
Vitamin D3 (Cholecalciferol)	100 IU	80 %	160 %
Vitamin B1 (Thiamine)	0,5 mg	100 %	166,67 %
Vitamin B2 (Riboflavin)	0,5 mg	100 %	166,67 %
Vitamin B3 (Nicotinamide)	6,0 mg	100 %	150 %
Vitamin B6 (Pyridoxine)	0,5 mg	100 %	166,67 %
Vitamin B12 (Cyanocobalamin)	0,9 µg	100 %	150 %
Vitamin E (Tocopherol)	6 IU	67,12 %	115,06 %
Vitamin C (Ascorbic acid)	20 mg	133,33 %	160 %

*DR1: Dietary Reference Intake.
Inactive ingredients: Flavoxing (mint, tulle-fuñ), glycerine, maltodextrin, microcrystalline cellulose, croscarmellose sodium and water.
Contains preservatives: potassium sorbate (0,035 % w/v) and sodium benzoate (0,045 % w/v).
Contains sorbitol (2-31 g/ml).
Contains sweetener: CSA 80 10 mg % ml (cesulfaline potassium, sodium cyclamate and sodium saccharin).

Alcohol, sugar, lactose and tartaric acid free.

2. WHAT IS VITILIFT Multivitamin Kids USED FOR:

VITILIFT Multivitamin Kids is a multivitamin health supplement for maintenance of good health and to support your child's general wellbeing.

3. BEFORE YOU USE VITILIFT Multivitamin Kids:

Do not use VITILIFT Multivitamin Kids

- If you are hypersensitive (allergic) to any of the listed ingredients.
- If you have chronic liver disease, hypercalcaemia (high blood levels of calcium) or renal disease or have had in the past. Consult your Doctor if you are unsure.

• If you have a specific vitamin deficiency.

Please consult your doctor or pharmacist prior to use if you:

Taking VITILIFT Multivitamin Kids with food and drink:
There are no known side effects to taking **VITILIFT Multivitamin Kids** with food and drink.

Pregnancy or breastfeeding:
Do not use **VITILIFT Multivitamin Kids** during pregnancy or while you are breastfeeding your baby, as well as if you are still breastfeeding your child. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **VITILIFT Multivitamin Kids**.

Women who are or might become pregnant should avoid taking daily supplements containing more than 500 IU vitamin A, without consulting a medical practitioner.
The safe dosage may be exceeded when medicines and/or health products containing vitamin A are taken together with a high dietary intake of vitamin A.

Driving and using machinery:
No studies on the effect on the ability to drive or use machinery have been performed. It is unlikely that **VITILIFT Multivitamin Kids** would affect your ability to drive or use machinery.

Important information about some of the ingredients of VITILIFT Multivitamin Kids:
This medicine contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Sorbitol may have a laxative effect or cause diarrhoea. Do not exceed the recommended dosage.

Using other medicines with VITILIFT Multivitamin Kids

- Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).
- Vitamin A might affect the efficiency of the measles vaccine.
- The effects of vitamin D may be reduced in patients taking barbiturates or anti-convulsants.
- Pyridoxine (vitamin B6) can reduce the effects of levodopa.

Health supplements are intended only to complement health or supplement the diet. A nutritional supplement should not replace a balanced diet.

4. HOW TO USE VITILIFT Multivitamin Kids
For oral use only.
Always use **VITILIFT Multivitamin Kids** exactly as per dosage instructions or as directed by your Doctor or Pharmacist.
Do not exceed the recommended dose.

Shake the bottle well each time before use.

The usual dose is:
Children aged 1 to 3 years old Give 5 ml (one medicine measure) daily or as directed by your healthcare professional.
Children aged 4 to 8 years old Give 10 ml (two medicine measures) daily or as directed by your healthcare professional.

If you use more VITLIFT Multivitamin Kids than you should:
If you experience weakness, vomiting, headaches, nausea, vomiting, dizziness, excessive urination (especially at night), very concentrated urine and thirst after using too much VITLIFT Multivitamin Kids, consult your doctor or pharmacist. If the thirst is not relieved, contact the nearest hospital or poison control centre.

If you experience overdose or, discuss the use of the medicine. Treatment is symptomatic and supportive.

High doses of individual ingredients of this product have been associated with acne-like and erythema skin lesions, exhaustion and sleeplessness.
With high vitamin E3 doses, liver disease, goiter and slow formation have been noted.
High doses of vitamin A can lead to blurry vision, swelling of the bone or bone pain, poor appetite and sensitive to sunlight.
Symptoms of vitamin D3 overdose may lead to the development of hypercalcemia or hypernatremia (elevated phosphate and/or calcium levels). Occasionally, mental disturbances, cerebellar ataxia (inability to co-ordinate balance, gait, extremity and eye movements), peripheral facial paresthesia (muscle weakness or partial paralysis), spally and lack of interest have been reported.

If you forget to take VITLIFT Multivitamin Kids:
Always take VITLIFT Multivitamin Kids as prescribed. If you miss a dose, take it as soon as you remember. If it is almost time for the next dose, skip the missed dose and take the next dose at the usual time. Do not take two doses at once. Do not take more than the advised dose and do not take more than the advised dose and do not take more than the advised dose and do not take more than the advised dose.

If you have any questions or if you are unsure of anything, please consult your doctor, pharmacist or healthcare practitioner.

5. POSSIBLE SIDE-EFFECTS:
Like all medicines, this product may have side effects, although not everybody gets them. They are listed below.

If any of the following happens, stop using VITLIFT Multivitamin Kids and tell your doctor immediately or go to the nearby department of your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing (angioedema).
- Rash or itching.
- The individual ingredients of this product have been associated with side-effects such as:
 - Abdominal pain and cramps, diarrhoea and constipation (*opspaan*).
 - Heartburn, vomiting, nausea and loss of appetite (*opspaan*).
 - Allergic reactions, including skin rash and irritation (*oos opspaan*).
 - Single yellow urine discoloration has been reported with vitamin B2 usage (*opspaan*).

Patients with liver disease might be more susceptible to these side effects.
Not all side effects reported for VITLIFT Multivitamin Kids are included in this leaflet. Should you experience any side effects, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORAGE AND DISPOSING OF VITLIFT Multivitamin Kids:

- Store at or below 25 °C.
- Store away from light.
- Store in the place.
- Store in the original container.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the label.
- Return all unused medicine or contents to your Pharmacist.
- Do not dispose of unused medicine or medicines in drains or sewerage systems (e.g. toilets).

KEEP OUT OF REACH OF CHILDREN

7. PRESENTATION OF VITLIFT Multivitamin Kids:
250 ml amber plastic bottle with white plastic tamper evident cap.

8. IDENTIFICATION OF VITLIFT Multivitamin Kids:
Yellow syrup with a turn-of-mouth flavor.

9. REGISTRATION NUMBER/REFERENCE NUMBER:
To be allocated.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:
Agera Health (Pty) Ltd
6A Breda Road, Tienie Meyer Drive
Bathville 7530, Cape Town
South Africa
info@agerapharma.co.za
www.agerahealth.co.za

11. DATE OF PUBLICATION:
January 2019

VS200PIL102018v1

PASIENTINLIGTINGSBLAAD

Hierdie inligtingsblad is bedoel om u te help om die SAHPK-gebruik van die geneesmiddel, versigtig te gebruik te gebruik.

Komplekse Mediese Oorsig/Handreiking

SKEDULEERINGSSTATUS [2]

BEWAKINGSMAATREKELING:
VITLIFT Multivitamin Kids (stroop).

Lees hierdie hele voorskrif noukeurig deur aangesien dit belangrike inligting vir u bevat.

- Hierdie medisyne is beskikbaar sonder voorskrif, alhoewel u steeds VITLIFT Multivitamin Kids moet gebruik, soos aangedui op die beste resultate te sien.
- Moenie VITLIFT Multivitamin Kids nie enige vorm van alkohol gebruik.
- Van dokter of apoteker indien u meer inligting of advies benodig.
- U moet u dokter raadpleeg indien u enige ander siekte het.

1. WAT VITLIFT Multivitamin Kids BEVAAT:

Die volgende bestanddele is in die oos:

	% ADH* (1-3 Jaar)	% ADH* (4-8 Jaar)
Vitamin A (Retinol)	999 IU	100%
Vitamin B1 (Thiamine)	160 IU	80%
Vitamin B2 (Riboflavin)	0.5 mg	100%
Vitamin B3 (Nicotinamide)	6.0 mg	100%
Vitamin B6 (Pyridoxine)	0.5 mg	100%
Vitamin B12 (Cyanocobalamin)	0.9 µg	100%
Vitamin E (Tokoferol)	4 IU	67.12%
Vitamin C (Ascorbyl)	20 mg	133.33%

*Lêerwêreld daaglikse hoeveelheid.
Die ander bestanddele is: geur (suur, tart-suiw), gliserien, methylsilaan, mikrokristalliese selulose, karboloom suur en water.

Bewaringsdata: kaliumasfaat (0.035 % w/v), natriumbisfaat (0.045 % w/v).

Bevat ook: 0.31 g 5 ml.

Bevat versueter (S.A. 50 10 mg/ml) (aantal kalium, natrium, kalium en natriumchloried).

Wanneer gebruik, maak seker dat u dit gebruik.

2. WAARVOOR WORD VITLIFT Multivitamin Kids GEBRUIK:

VITLIFT Multivitamin Kids is 'n multivitaminiese geneesmiddel/voedingstof vir die behandeling van gesondheidsprobleme en om kind te help om te groei.

3. VOOR U VITLIFT Multivitamin Kids NEEM:

Moenie VITLIFT Multivitamin Kids neem as:

- Indien u hipertensie (hoë bloeddruk) het.
- Indien u ernstige lewer-, nier-, of hartprobleme het.
- Indien u 'n spesifieke vitamien tekort het.

Raadpleeg ook altyd u dokter of apoteker voor gebruik indien u:

- Teer of ontsteking in die maag het.

Neem van VITLIFT Multivitamin Kids nie met kos en drinkgoed.

Daar is geen bekende wese-wese-effekte van VITLIFT Multivitamin Kids op ander geneesmiddels nie.

Swagereik op beroving:
Moenie VITLIFT Multivitamin Kids neem terwyl u swanger is of van u baba bevoerd raak, aangesien die veiligheid daarvan nie bekend is nie.

Indien u swanger is of bevoerd raak, moet u altyd u dokter raadpleeg vir advies.

Swagereik op beroving:
Moenie VITLIFT Multivitamin Kids neem terwyl u swanger is of van u baba bevoerd raak, aangesien die veiligheid daarvan nie bekend is nie.

Indien u swanger is of bevoerd raak, moet u altyd u dokter raadpleeg vir advies.

Voer wat swanger is of kan word, moet vermy om daaglikse aanvallings te drink wat meer as 500 mg vitamien A bevat omdat dit 'n mediese praktyk is.

Die volgende dose kan oorstryk word wanneer mediese of geneesmiddelproduksie met vitamien A betrek, soos in 'n mediese praktyk.

Bestuur om die gebruik van medisyne:
Geen monitiesing is nodig vir die gebruik van hierdie produk in 'n mediese praktyk.

Indien u swanger is of bevoerd raak, moet u altyd u dokter raadpleeg vir advies.

Belangrike inligting met betrekking tot die bestanddele in VITLIFT Multivitamin Kids:

Hierdie medisyne bevat ook: Indien u dokter gebruik het dat u 'n intoleransie het tot sekere suikers, raadpleeg u dokter voor u hierdie medisyne neem. Seëlfout mag 'n bekende effek lê op die geneesmiddel.

Gebruik van VITLIFT Multivitamin Kids met ander medisyne:

- U moet u dokter raadpleeg indien u enige ander medisyne gebruik, insluitend komplemente of tradisionele medisyne.
- Vitamien A kan die effektiwiteit van die medikasie verminder.
- Die effek van vitamien D kan vermindert word indien dit saam met kalium of natrium gebruik word.
- Pindakosin (Vitamin B6) kan die effek van lewopropyl verhoog.
- Geneesmiddelinteraksie is slegs bekend om gesondheidsprobleme te veroorsaak as gevolg van 'n wisselwerking met 'n geneesmiddel wat verhoog is.

4. HOE OM VITLIFT Multivitamin Kids TE NEEM:

Vit. 100 mg, 100 mg.

VITLIFT Multivitamin Kids moet altyd presies gebruik word soos per aanwysings.

Moenie die aanwysings oorskry nie.

Skud die fleske deeglik elke keer voor gebruik.

Die geneesmiddel is:

Kinderen 1 tot 3 jaar oud: 5 ml (een medisyne) daaglik of soos deur u geneesmiddelpraktisyn aangedui.

Kinderen 4 tot 8 jaar oud: 10 ml (twee medisyne) daaglik of soos deur u geneesmiddelpraktisyn aangedui.

Indien u meer VITLIFT Multivitamin Kids neem as wat u moet:

Indien u swaak, moeg, hoofpyn, maagpyn, braken, diarree, ontsteking, ontsteking (soos), baie gekontreëerde urine en doer die gebruik van te veel VITLIFT Multivitamin Kids, moet u altyd u dokter raadpleeg vir advies.

Indien u swaak, moeg, hoofpyn, maagpyn, braken, diarree, ontsteking, ontsteking (soos), baie gekontreëerde urine en doer die gebruik van te veel VITLIFT Multivitamin Kids, moet u altyd u dokter raadpleeg vir advies.

Indien u swaak, moeg, hoofpyn, maagpyn, braken, diarree, ontsteking, ontsteking (soos), baie gekontreëerde urine en doer die gebruik van te veel VITLIFT Multivitamin Kids, moet u altyd u dokter raadpleeg vir advies.

Indien u swaak, moeg, hoofpyn, maagpyn, braken, diarree, ontsteking, ontsteking (soos), baie gekontreëerde urine en doer die gebruik van te veel VITLIFT Multivitamin Kids, moet u altyd u dokter raadpleeg vir advies.

Indien u swaak, moeg, hoofpyn, maagpyn, braken, diarree, ontsteking, ontsteking (soos), baie gekontreëerde urine en doer die gebruik van te veel VITLIFT Multivitamin Kids, moet u altyd u dokter raadpleeg vir advies.

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Indien u swaak, moeg, hoofpyn, maagpyn, braken, diarree, ontsteking, ontsteking (soos), baie gekontreëerde urine en doer die gebruik van te veel VITLIFT Multivitamin Kids, moet u altyd u dokter raadpleeg vir advies.

Indien u swaak, moeg, hoofpyn, maagpyn, braken, diarree, ontsteking, ontsteking (soos), baie gekontreëerde urine en doer die gebruik van te veel VITLIFT Multivitamin Kids, moet u altyd u dokter raadpleeg vir advies.

Indien u swaak, moeg, hoofpyn, maagpyn, braken, diarree, ontsteking, ontsteking (soos), baie gekontreëerde urine en doer die gebruik van te veel VITLIFT Multivitamin Kids, moet u altyd u dokter raadpleeg vir advies.

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