

PROFESSIONAL INFORMATION  
**VITILIFT**  
**Multivitamin Baby (drops) agera™**



SCHEDULING STATUS: **50**  
 This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or therapeutic benefit.

**PROPRIETARY NAME AND DOSAGE FORM:**  
**VITILIFT Multivitamin Baby (drops)**

**COMPOSITION:**  
 Active substances per 1 ml of drops

	%DR*	%DR*	
(1-Year)	(4-Year)		
Vitamin A (Retinol)	1665 IU	75 %	100 %
Vitamin D3 (Cholecalciferol)	200 IU	100 %	
Vitamin B1 (Thiamine)	0.3 mg	99 %	100 %
Vitamin B3 (Niacinamide)	0.4 mg	89 %	100 %
Vitamin B6 (Pyridoxine)	0.33 mg	100 %	83.33 %
Vitamin B8 (Pantothenic acid)	0.167 mg	100 %	55.67 %
Vitamin C (Ascorbic acid, calcium ascorbate)	50 mg	75 %	100 %

\*DR = Dietary Reference Intake  
 The offered ingredients set: flavouring, glycerine, malodectin, microcrystalline cellulose, potassium bicarbonate, calcium carbonate and water.  
 Contains preservatives (0.035% w/v) and sodium benzoate (0.045% w/v).  
 Contains sorbital (0.42 g/ml).

**CATEGORIES AND CLASS:**  
 D 34.1 VITAMIN  
 Conglutinatory Medicines Health Supplement

**PHARMACOLOGICAL ACTION:**  
**Pharmacodynamic properties:**  
 VITILIFT Multivitamin Baby is a multivitamin for the maintenance of good health in babies and children.

**Pharmacokinetic properties:**  
 The pharmacokinetic properties of the formulation are well known. Pharmacokinetic studies have not been conducted on VITILIFT Multivitamin Baby.

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

**CONTRAINDICATIONS:**  
 VITILIFT Multivitamin Baby is contraindicated in patients who are hypersensitive to any of the ingredients. Not intended for patients where specific vitamin deficiency exists.

**WARNINGS AND SPECIAL PRECAUTIONS:**  
 • Do not exceed the recommended dose. Do not use as a replacement for a balanced diet.  
 • Contains sorbital (0.42 g/ml) which may cause diarrhoea in some individuals with the rare hereditary condition of sorbital intolerance. Should not be taken VITILIFT Multivitamin Baby.  
 • Sorbitol should be used in patients with normal liver function.  
 • Patients with diabetes should take care in monitoring blood glucose levels.  
 • Increased sensitivity to vitamin D is observed in patients with renal impairment and having increased serum calcium levels.

**Women who are or might become pregnant should avoid taking daily supplements containing more than 5 000 IU vitamin A, without consulting a medical practitioner. The risk of birth defects is increased when mothers take daily supplements containing Vitamin A are taken together with a high dietary intake of Vitamin A.**

**EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES:**  
 No adverse effects on the ability to drive or operate machinery were performed. It is unlikely that VITILIFT Multivitamin Baby would affect the ability to drive or operate machinery.

**INTERACTIONS:**  
 • Vitamin A might affect the efficacy of the measles vaccine. Advise patients not to use this product during vaccination.

• The effects of vitamin D may be reduced in patients taking barbiturates or carbamazepine.

• Pyridoxine (vitamin B6) can interfere with the effects of levodopa.

**HUMAN REPRODUCTION:**  
**Pregnancy:**  
 Not recommended during pregnancy, as a caution, due to lack of data.

**Pregnancy Category:** **D** (Teratogenicity not confirmed)

**VITILIFT Multivitamin Baby will not cause milk and may be added to infants' feeds or may be mixed with cereal or fruit juice if any taste is disliked.**

**Babies aged 0 to 6 months old:** Give 0.6 ml per day or as directed by your healthcare professional.

**Children aged 6 to 12 months old:** Give 1.2 ml per day or as directed by your healthcare professional.

**Children aged 1 to 3 years old:** Give 1 ml per day or as directed by your healthcare professional.

**SIDE EFFECTS:**  
**General and systemic disorders:** Diarrhoea, dyspepsia, epigastric discomfort, nausea or vomiting, constipation (rarely).

**Metabolic and nutritional disorders:** Urticaria, skin rash (rarely reported).

**General disorders and administrative site condition:** Hypersensitivity reactions (rarely reported).

**Investigations:** Bright yellow urine discolouration has been reported with riboflavin usage (rarely).

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

**KNOWLEDGE OF OVERDOSE AND PARTICULARS OF ITS TREATMENT:**

High doses of individual components of this product have been associated with cataracts and conjunctival haemorrhage.

In larger macromolecular doses, liver damage, pain and ulcer formation have been noted.

Significant doses of riboflavin (D) may cause reversible photophobia, eye irritation, conjunctivitis, thrombocytopenia, aplastic anaemia, increased sedimentation rate, and accelerated reabsorption of trabecular meshwork and cornea.

Long term intake of vitamin A >10 000 IU daily may cause chronic hypervitaminosis A. Symptoms of chronic intoxication are as follows: headache, vertigo, hypertension, tachycardia, arrhythmia, abdominal pain, constipation, dry mouth and eyes, fever, increased serum cholesterol and serum triglyceride concentration, intracranial hypertension, hypotension, hypoglycaemia, low serum sodium and decreased protein content of the cerebrospinal fluid, elevated urinary hydroxyconjugated and hydroxylated bilirubin, increased excretion of calcium, sulphur, uric acid, citrate, citrate, and oxalate, tubular necrosis, papillitis, dryness, haemorrhages and fissures of the lips, yellow to yellow-orange discoloration of the skin, hair, nails, teeth, mucous membranes, conjunctiva, and organs, hair loss and brittle nails, spider angiomas and oedema.

Characteristic features of chronic vitamin A intoxication include hypocalcaemia and depression of the immune system. Cataract, convulsions, mental disturbances and depression of peripheral facial paresis, spasticity and stiffness have been reported.

Significant doses of riboflavin (D) may cause reversible photophobia, eye irritation, conjunctivitis, headache, nausea, vomiting and diarrhoea. Renal function can be impaired at an early stage with polyuria, polydipsia, nocturia, decreased urinary concentrating ability and proteinuria.

If there is overdose, rinse, discontinue use of the medicine. Treatment is symptomatic and supportive.

**IDENTIFICATION:**  
**VITILIFT Multivitamin Baby** is a yellow liquid with a sweet vanilla odor and flavor.

**PRESENTATION:**  
**VITILIFT Multivitamin Baby** is packed in a 30 ml amber glass bottle with a black plastic tamper evident cap and graduated glass pipette.

**STORAGE INSTRUCTIONS:**  
 Store in a cool place.  
 Keep the container tightly closed.  
 Protect from light.

**EXPOSURE TO SIGHT AND REACH OF CHILDREN:**  
 No.

**REGISTRATION NUMBER:** No.

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**  
 Agera Africa (Pty) Ltd  
 64 Boulevard Park  
 1011 Meyer Drive  
 Bryanston  
 Bryanston  
 South Africa  
 info@agerapharma.co.za  
 www.agerapharma.co.za

**DATE OF PUBLICATION OF THE PACKAGE INSERT:**  
 January 2019.

agera™

**PATIENT INFORMATION LEAFLET**

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

Conglutinatory Medicines Health Supplement.

**SCIENTIFIC NAME:** No.

**PROPRIETARY NAME and dosage form:**  
**VITILIFT Multivitamin Baby (drops)**

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

• VITILIFT Multivitamin Baby is available without a doctor's prescription to assist you in the treatment of your disease or symptom. You may self-medicate. Nevertheless, you still need to read the VITILIFT Multivitamin Baby carefully to get the most out of it. Keep this leaflet to read it again.

• Never share VITILIFT Multivitamin Baby with any other person.

• Ask your Doctor or Pharmacist if you need more information or advice.

If your symptoms worsen or do not improve.

1. **WHAT VITILIFT Multivitamin Baby CONTAIN:**  
 Each 1 ml contains:

	%DR*	%DR*	
(1-Year)	(4-Year)		
Vitamin A (Retinol)	1665 IU	75 %	100 %
Vitamin D3 (Cholecalciferol)	200 IU	100 %	
Vitamin B1 (Thiamine)	0.3 mg	99 %	100 %
Vitamin B3 (Niacinamide)	0.4 mg	89 %	100 %
Vitamin B5 (Biotin)	0.33 mg	100 %	83.33 %
Vitamin B6 (Pyridoxine)	0.167 mg	100 %	55.67 %
Vitamin C (Ascorbic acid, calcium ascorbate)	50 mg	75 %	100 %

\*DR = Dietary Reference Intake

The offered ingredients set: flavouring, glycerine, malodectin, microcrystalline cellulose,

potassium bicarbonate, calcium carbonate and water.

Contains preservatives: potassium sorbate (0.035% w/v) and sodium benzoate (0.045% w/v).

Contains sorbital (0.42 g/ml).

Recent research has shown that VITILIFT Multivitamin Baby is safe to drink with food and drink.

There are no known side effects to taking VITILIFT Multivitamin Baby with food and drink.

Do not use VITILIFT Multivitamin Baby during pregnancy or while you are breastfeeding.

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare professional for advice before taking VITILIFT Multivitamin Baby.

The safe dose may be exceeded when medicines and/or health products containing VITILIFT Multivitamin Baby are taken together.

Driving and using machinery:  
 No studies have been done to show that VITILIFT Multivitamin Baby affects driving or using machinery.

Important information about some of the ingredients of VITILIFT Multivitamin Baby:

• If you are hypersensitive (allergic) to any of the listed ingredients.

• If you have a history of kidney or liver disease, or if you have high blood levels of calcium or renin deplexe or have had in the past. Consult your Doctor if you are unsure.

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

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Do not use VITILIFT Multivitamin Baby during pregnancy or while you are breastfeeding.

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare professional for advice before taking VITILIFT Multivitamin Baby.

The safe dose may be exceeded when medicines and/or health products containing VITILIFT Multivitamin Baby are taken together.

Driving and using machinery:  
 No studies have been done to show that VITILIFT Multivitamin Baby affects driving or using machinery.

Important information about some of the ingredients of VITILIFT Multivitamin Baby:

• Always tell your healthcare professional if you are taking any other medicine, including herbal remedies, or dietary supplements.

• Vitamin A might affect the effectiveness of the measles vaccine.

• The effects of vitamin D may be reduced in patients taking barbiturates or carbamazepine.

• Pyridoxine (vitamin B6) can reduce the effects of levodopa.

• Pyridoxine (vitamin B6) can reduce the effects of levodopa.

A multivitamin supplement does not replace a balanced diet.

Shake the bottle well each time before use.

For oral use only.

Always use VITILIFT Multivitamin Baby exactly as dosage instructions or as directed by your healthcare professional.

Do not exceed the recommended dose.

Shake the bottle well each time before use.

