COMPLEMENTARY MEDICINE

Health Supplement

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

SUPAVITE®, syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL syrup contains:

Vitamin A	333 IU (99,9 µg RAE*)
Vitamin D (cholecalciferol)	67 IU (1,675 µg)
Vitamin C (ascorbic acid)	50 mg
Vitamin B_1 (thiamine HCl)	1 mg
Vitamin B_2 (riboflavin)	1 mg
Vitamin B_3 (nicotinamide)	7 mg
Vitamin B_6 (pyridoxine HCl)	250 µg
Vitamin B_{12} (cyanocobalamin)	1 µg

* RAE (Retinol Activity Equivalent)

Contains sugar as

Sucrose	3,00 g per 5 mL

Contains sugar-alcohol as

Sorbitol (70 %)	1,40 g per 5 mL

Preservatives

Methyl hydroxybenzoate 0,1 % *m/v*

Propyl hydroxybenzoate 0,25 % *m/v*

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup

A yellowish liquid, free from any particulate matter with an orange fruity flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SUPAVITE® is indicated in children aged 1 year and older.

SUPAVITE® is a multivitamin supplement that assists with general well-being and maintenance of good health in children.

SUPAVITE® contributes to

- The maintenance of eyesight, skin, membranes and immune function.
- The development and maintenance of night vision.
- The metabolism (energy production) of carbohydrates, fats and proteins.

- The development and maintenance of bones, cartilage, teeth and gums.
- The formation of connective tissue.
- Normal growth and development.
- The formation of normal red blood cells.

4.2 Posology and method of administration

Posology

Children 1 – 3 years: 2,5 mL once to twice daily.

Children 3 years and older: 5 mL once to twice daily.

Paediatric population

The safety and efficacy of SUPAVITE® in children under 1 year has not yet been established.

Method of administration

For oral use only.

SUPAVITE® can be taken with or without food. Taking it with food may reduce the likelihood of stomach upset, nausea, or gastrointestinal discomfort.

Shake the bottle before use.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Pre-existing hypervitaminosis A or D.
- Severe hypercalcaemia, hypercalciuria or any treatment, disease and/or disorder that can result in severe hypercalcaemia and/or hypercalciuria (e.g. tumours, skeletal metastases, primary hyperparathyroidism, granulomatosis).

4.4 Special warnings and precautions for use

Hypervitaminosis

SUPAVITE® should be used with caution in patients receiving other vitamin-containing preparations, particularly those containing vitamins A or D, as excessive intake may result in cumulative toxicity.

Vitamin D

SUPAVITE® should be used with caution in patients with renal impairment, nephrolithiasis, or conditions associated with altered calcium metabolism. Monitoring of calcium levels may be required during prolonged use.

Severe renal impairment

Patients with severe renal impairment should seek medical advice before using SUPAVITE®.

Laboratory test

The vitamin B_2 (riboflavin) in SUPAVITE® may cause a bright yellow discolouration of the urine that may interfere with certain laboratory tests.

Excipients with known effect

Orange colour might contain Sunset yellow FCF (E 110) and Ponceau 4R/Cochineal red A (E 124): May cause allergic reactions.

Sorbitol (70 %): SUPAVITE® contains 980 mg sorbitol in each 5 mL, which is equivalent to 196 mg/kg/mL. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.

The content of sorbitol in SUPAVITE® may affect the bioavailability of other medicinal products for oral use administered concomitantly (see section 4.5).

Patients with hereditary fructose intolerance (HFI) should not take SUPAVITE®.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Sucrose: SUPAVITE® contains 3 g sucrose per 5 mL. This should be taken into account in patients with diabetes mellitus.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take SUPAVITE®.

It may be harmful to the teeth.

Methyl hydroxybenzoate and propyl hydroxybenzoate: May cause allergic reactions (possibly delayed).

4.5 Interactions with other medicines and other forms of interaction

Concurrent administration with other vitamin-containing products may increase the risk of excessive vitamin intake, particularly vitamins A and D.

- Vitamin A: Concomitant administration with other products containing vitamin A may increase the risk of hypervitaminosis A.
- Concurrent use with retinoids (e.g. bexarotene, acitretin, isotretinoin or tretinoin) may increase the risk of vitamin A toxicity.
- Vitamin D: Concomitant administration with other vitamin D-containing products may increase the risk of hypercalcaemia.

Medicines that decrease vitamin levels include

- Medicines interfering with vitamin D metabolism, including antiepileptics (e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin and primidone), antineoplastics (e.g. anthracyclines, taxanes), rifampicin, glucocorticoids, efavirenz, zidovudine and ketoconazole may increase vitamin D inactivation rate.
- Vitamin B6 (pyridoxine) antagonist including cycloserine, hydralazine, isoniazid, penicillamine, phenelzine and theophylline and certain enzyme-inducing anticonvulsants (e.g. phenytoin or carbamazepine) may increase pyridoxine requirements.
- Ethionamide can cause vitamin B6 (pyridoxine) deficiency.
- Corticosteroids can reduce the effects of vitamin D.
- Absorption of vitamin B12 (cyanocobalamin) from the gastrointestinal tract may be reduced by neomycin, aminosalicylic acid, histamine H2-antagonists, omeprazole, and colchicine.
- Parenteral chloramphenicol may attenuate the effect of vitamin B12 in anaemia.
- Omeprazole may affect the bioavailability of dietary vitamin C.
- Absorption of vitamin A from the gastrointestinal tract may be reduced by the presence of neomycin, cholestyramine or liquid paraffin.

Other medicine interactions when taken with SUPAVITE®

- Vitamin B6 (pyridoxine) reduces the activity of altretamine.
- Vitamin C (ascorbic acid) may have interactions with deferoxamine, hormonal contraceptives, HRT, fluphenazine and warfarin.
- Vitamin C (ascorbic acid) may increase the absorption of iron in iron-deficiency states.
- There is an increased risk of hypercalcaemia if vitamin D is given with thiazide diuretics, calcium, or phosphate. Plasma-calcium concentrations should be monitored in such situations.

Sorbitol in SUPAVITE® can interact with the following medicines when taken concomitantly

- Sodium polystyrene sulfonate: (often prescribed to treat high blood potassium) can lead to severe gastrointestinal complications, including colonic necrosis.
- Lamivudine: Can reduce the absorption of lamivudine, which can lower its effectiveness and lead to viral resistance.
- Other laxatives: Can significantly increases the risk of dehydration and severe electrolyte imbalances.
- Diuretics: Can increase fluid loss, and therefore the risk of dehydration.

4.6 Fertility, pregnancy and lactation

Pregnancy

SUPAVITE® can be taken during pregnancy.

Breastfeeding

SUPAVITE® can be taken during breastfeeding.

Fertility

No data on male and female fertility is available.

4.7 Effects on ability to drive and use machines

SUPAVITE® has no or negligible influence on mental and/or physical ability to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8 Undesirable effect

Tabulated summary of adverse reactions

System Organ Class	**Frequency**	**Adverse reactions**
Immune system disorders	Frequency unknown	Hypersensitivity (see sections 4.3 and 4.4)
Gastrointestinal disorders	Frequency unknown	Nausea, abdominal discomfort, vomiting, diarrhoea
Hepato-biliary disorders	Frequency unknown	Transaminases increased, alanine aminotransferase increased, total bile acids increased, gamma-glutamyl transferase increased, glutamate dehydrogenase increased, blood alkaline phosphatase increased
Skin and subcutaneous tissue disorders	Frequency unknown	Rash, pruritus
Renal and urinary disorders	Less frequent	Bright yellow discoloration of the urine

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 requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

In addition, side-effects can also be reported to info@pharmacorp.co.za.

4.9 Overdose

Symptoms

Most frequent overdoses are associated with nausea, vomiting, and diarrhoea.

The risk of overdose is particularly high if a patient receives vitamins from multiple sources and overall supplementation of a vitamin does not match the patient's individual requirements, and in patients with increased susceptibility to hypervitaminosis (see section 4.4).

Treatment

Treatment of overdosage should be withdrawal of SUPAVITE®, and other measures as clinically indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D.34.11 Vitamins

Mechanism of action

Vitamins are indispensable dietary components because they facilitate basic metabolic processes, support fundamental cellular functions, and boost immune responses.

5.2 Pharmacokinetic properties

The vitamins are absorbed, distributed, metabolised and eliminated in the body in the same manner as vitamins taken with oral food.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate

Orange colour (Sweet Orange No.1 and/or Orange F1617 T/F (Quinoline Yellow (E104), Ponceau 4R, Cochineal red A (E 124), Sunset yellow FCF (E 110))Propyl hydroxybenzoate

Sorbitol solution (70 %)

Sucrose

Sweet orange flavourant

Tutti-frutti flavourants

Water, purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25 °C. Protect from light.

6.5 Nature and contents of container

PVC round amber 100 mL or 200 mL plastic bottle with white snap LDPE cap or a white PP duet screw cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACORP (PTY) LTD

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, RSA

8. REGISTRATION NUMBER

To be allocated

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

To be allocated

10. DATE OF REVISION OF THE TEXT

July 2026

Version number: A/SUP/PIL/03.26