

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

LOCAL HEALTH MULTIVITAMIN tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Calcium (as Tricalcium Phosphate)	243 mg
Phosphorus (as Tricalcium Phosphate)	125 mg
Magnesium (as Magnesium Oxide)	100 mg
Ascorbic Acid (Vitamin C)	60 mg
Niacin (Vitamin B3)	18 mg
d- α -Tocopherol (Vitamin E)	15 IU / 10 mg TE
Iron (as Electrolytic Iron)	10 mg
Pantothenic Acid (Vitamin B5)	6 mg
Zinc (as Zinc Oxide)	5 mg
Pyridoxine (Vitamin B6)	2 mg
Riboflavin (Vitamin B2)	1,6 mg
Thiamine (Vitamin B1)	1,4 mg
Vitamin A (as Vitamin A Palmitate)	4000 IU / 1200 μ g
Manganese (as Manganese Sulphate)	1 mg
Copper (as Copper Sulphate 25%)	0,5 mg
Lutein (<i>Tagetes erecta</i> L. Marigold)	250 μ g
Folic Acid	195 μ g
Biotin (Vitamin H)	100 μ g
Iodine (as Potassium Iodide)	100 μ g
Selenium (as Selenium Amino Acid Chelate 2%)	60 μ g
Molybdenum (as Molybdenum Amino Acid Chelate)	50 μ g
Chromium (as Chromium Amino Acid Chelate 10%)	40 μ g
Menaquinone (Vitamin K2)	30 μ g
Cholecalciferol (Vitamin D3)	200 IU / 5 μ g
Cyanocobalamin (Vitamin B12)	2 μ g

Contains sugar: 88,2 mg isomalt per tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Oval, yellow coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LOCAL HEALTH MULTIVITAMIN is a daily multivitamin supplement that contains a combination of vitamins, minerals, and antioxidants for the maintenance and support of good health.

4.2 Posology and method of administration

Adults 18 years and older: one tablet daily after breakfast.

4.3 Contraindications

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1, including members of the Asteraceae/Compositae plant family (ragweed, chrysanthemums, marigolds, daises, and many other herbs) and iodine.
- Patients with hypercalcaemia, hypercalciuria, or renal impairment.
- Patients with calcium renal calculi or a history of renal calculi.
- Retinoids taken in conjunction with vitamin A containing supplements could have additive toxic effects. Patients should avoid taking vitamin A supplements if they are taking retinoids.
- Patients receiving blood transfusions, parenteral iron therapy, or patients with an anaemia not produced by an iron deficiency, unless iron deficiency is also present, as overdosage may occur.
- Patients with a vitamin B12 deficiency, as folic acid can mask pernicious anaemia by decreasing megaloblastic anaemia. This can prevent appropriate treatment with vitamin B12 and result in neurological damage, such as subacute combined degeneration of the spinal cord.
- Patients with Leber's disease or tobacco amblyopia should not use vitamin B12 as it may cause further degeneration.

4.4 Special warnings and precautions for use

- Vitamin C may increase the risk of hyperoxaluria in patients with chronic kidney dysfunction. Large doses (>2 g daily) have been associated with an increased risk of oxalate kidney stones.
- Large amounts of vitamin C can cause haemolysis in individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency, and can increase the risk of oxalate stone formation in people with a history of oxalate kidney stones. The daily recommended dosage should not be exceeded.
- Patients with iron-storage or iron-absorption diseases such as haemochromatosis or haemoglobinopathies should use iron-containing supplements with caution.
- Patients with gastrointestinal diseases such as inflammatory bowel disease, intestinal strictures or diverticulitis should use iron-containing supplements with caution as iron may cause gastrointestinal irritation and exacerbate these conditions.

4.5 Interaction with other medicines and other forms of interaction

- Retinoids taken in conjunction with vitamin A containing supplements could have additive toxic effects. Patients should avoid taking vitamin A supplements if they are taking retinoids.

- Vitamin A taken concomitantly with warfarin may contribute to increased anticoagulant effects.
- Zinc forms various complexes with antibiotics in the gut, affecting the absorption and effectiveness of antibiotics.
- Iron and zinc may interfere with the absorption and effectiveness of penicillamine.
- Thiazide diuretics reduces the urinary excretion of calcium which may increase the risk of hypercalcaemia and milk-alkali syndrome.
- Iron can form toxic complexes with dimercaprol and these should therefore not be administered together.
- Iron and calcium may interfere with the absorption and effectiveness of bisphosphonates.
- Some anticonvulsants (phenytoin, barbiturates, primidone) may reduce the effect of vitamin D by accelerating its metabolism.
- High doses of vitamin D can cause hypercalcaemia. Hypercalcaemia increases the risk of fatal cardiac arrhythmias with digoxin.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH MULTIVITAMIN does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders

Frequent: gastrointestinal irritation, abdominal pain, nausea, vomiting, diarrhoea, constipation.

Immune system disorders

Frequency unknown: hypersensitivity reactions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity. Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Class and category: D 34.12 Multiple Substance Formulation

5.1 Pharmacodynamic properties

LOCAL HEALTH MULTIVITAMIN is a daily multivitamin containing a combination of vitamins, minerals and antioxidants for the maintenance of good health.

5.2 Pharmacokinetic properties

The active ingredients in this formulation are well known. Pharmacokinetic studies have not been conducted on LOCAL HEALTH MULTIVITAMIN.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate, isomalt, talc, silicon dioxide, polyethylene glycol, yellow coating.

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

White PET plastic container and white screwcap lid.
Pack size: 30 or 75 tablets.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CJ Distribution
23 Stag Road, Glen Austin, Johannesburg, South Africa
careline@cjsa.com
010 589 2729
www.localhealth.com

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

