

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 (Tagetes erecta 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 overdose 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@jds.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.

MULTIVITAMIN TABLETS

MULTIVITAMIN TABLETS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

[S]

LOCAL HEALTH MULTIVITAMIN (tablets)

Complementary Medicine: Multiple Substance Formulation (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.

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

LOCAL HEALTH MULTIVITAMIN is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH MULTIVITAMIN carefully to get the best results from it.

• Keep this leaflet. You may need to read it again.

• Do not share LOCAL HEALTH MULTIVITAMIN with any other person.

• Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet

1. What LOCAL HEALTH MULTIVITAMIN is and what it is used for.

2. What you need to know before you use LOCAL HEALTH MULTIVITAMIN.

3. How to use LOCAL HEALTH MULTIVITAMIN.

4. Possible side effects.

5. How to store LOCAL HEALTH MULTIVITAMIN.

6. Contents of the pack and other information.

1. What LOCAL HEALTH MULTIVITAMIN is and what it is used for

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.

2.What you need to know before you use LOCAL HEALTH MULTIVITAMIN

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

Do not use LOCAL HEALTH MULTIVITAMIN:

- If you are allergic or sensitive to any of the ingredients listed in section 6, including members of the Asteraceae/Compositae plant family (ragweed, chrysanthemums, marigolds, daisies, and many other herbs) and iodine.
- If you have hypercalcaemia, hypercalcuria, or renal impairment.
- If you have calcium renal calculi, or a history of renal calculi.
- If you are taking retinoids.
- If you are receiving blood transfusions, parenteral iron therapy, or if you have an anaemia not produced by iron deficiency.
- If you have a vitamin B12 deficiency, Leber's disease or tobacco amblyopia.

Warnings and precautions

Consult with a healthcare practitioner prior to using LOCAL HEALTH MULTIVITAMIN, especially if you have a medical condition.

Use LOCAL HEALTH MULTIVITAMIN with caution and consult a healthcare practitioner before use:

- If you have hyperoxaluria or G6PD deficiency.
- If you have an iron-storage or iron-absorption disease such as haemochromatosis or haemoglobinopathy.
- If you have an existing gastrointestinal disease such as inflammatory bowel disease, intestinal strictures, or diverticulitis.

Children and adolescents

LOCAL HEALTH MULTIVITAMIN is not recommended for individuals below the age of 18 years. Consult a healthcare practitioner prior to use.

Other medicines and LOCAL HEALTH MULTIVITAMIN

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines can be shown in this leaflet. Consult with a healthcare practitioner prior to use. LOCAL HEALTH MULTIVITAMIN may interact with the following medications: retinoids, anticoagulants, antibiotics, penicillamine, digoxin, thiazide diuretics, anticonvulsants, dimercaprol, bisphosphonates.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before using LOCAL HEALTH MULTIVITAMIN.

Driving and using machinery

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.

3. How to use LOCAL HEALTH MULTIVITAMIN

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH MULTIVITAMIN exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Adults 18 years and older:

One tablet daily after breakfast, or as recommended by a healthcare practitioner.

4. Possible side effects

LOCAL HEALTH MULTIVITAMIN can have side effects. Not all side effects reported for LOCAL HEALTH MULTIVITAMIN are included in this leaflet. Should your general health worsen or if you experience any unwanted effects while taking LOCAL HEALTH MULTIVITAMIN, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH MULTIVITAMIN and tell your doctor or pharmacist immediately, or go to the casualty department at your nearest hospital: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing; rash or itching, fainting. These are very serious side effects. If you have them, you may have had a serious reaction to LOCAL HEALTH MULTIVITAMIN. You may need urgent medical attention or hospitalisation.

- Frequent: gastrointestinal irritation, abdominal pain, nausea, vomiting, diarrhoea, constipation.
- Frequency unknown: hypersensitivity reactions.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you experience side effects, inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form" found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/6>. By reporting side effects, you can help provide more information on the safety of LOCAL HEALTH MULTIVITAMIN.

5. How to store LOCAL HEALTH MULTIVITAMIN

• Protect from moisture and store at or below 25 °C.

• KEEP OUT OF REACH OF CHILDREN.

• Store in the original container and keep the container tightly sealed.

• Do not use after the expiry date stated on the label.

• Return all unused LOCAL HEALTH MULTIVITAMIN to your pharmacist.

• Do not dispose of unused LOCAL HEALTH MULTIVITAMIN in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCAL HEALTH MULTIVITAMIN contains

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
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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 (Tagetes erecta 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
Menadionine (Vitamin K2)	30 μ g
Cholecalciferol (Vitamin D3)	200 IU / 5 μ g
Cyanocobalamin (Vitamin B12)	2 μ g

Other ingredients: magnesium stearate, isomalt, talc, silicon dioxide, polyethylene glycol and yellow coating.

Contains sugar: 88,2 mg isomalt per tablet.

Presentation and identification of LOCAL HEALTH MULTIVITAMIN

Oval, yellow coated tablets packed into a white plastic container with a white plastic screwcap.

Pack size: 30 or 75 tablets.

Holder of Certificate of Registration

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685

Caroline: 010 589 2729; caroline@cjsa.com; www.localhealth.co.za

This pamphlet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS

[S]

LOCAL HEALTH MULTIVITAMIN (tablete)

Komplementêre Medisyne: Meervoudige Bestanddeel Formulasie (Gesondheidsaanvulling)

Hierdie ongeregisterde medisyne is nie deur SAHPRA vir gehalte, veiligheid en gebruik geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.

LOCAL HEALTH MULTIVITAMIN is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH MULTIVITAMIN versigtig gebruik word ten einde die beste resultate te verkry.

• Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.

• Moenie LOCAL HEALTH MULTIVITAMIN met enige ander persoon deel nie.

• Vra u gesondheidsorgpraktisyen of apoteker indien u meer inligting van advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat LOCAL HEALTH MULTIVITAMIN is en waaroor dit gebruik word.

2. Wat u moet weet voor u LOCAL HEALTH MULTIVITAMIN gebruik.

3. Hoe om LOCAL HEALTH MULTIVITAMIN te gebruik.

4. Moontlike newe-effekte.

5. Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH MULTIVITAMIN is en waaroor dit gebruik word

LOCAL HEALTH MULTIVITAMIN is 'n daaglikse multivitaminaanvulling wat 'n kombinasie van vitamiene, minerale en antioksidente bevat vir die handhawing en ondersteuning van goed gesondheid.

2. Wat u moet weet voor u LOCAL HEALTH MULTIVITAMIN gebruik

'n Gevarieerde diët is die doeltreffendste en veiligste manier om goede voeding, gesondheid, liggaamsamestelling, sowel as geestelike en fisiese prestasie te behaal. Moenie nie LOCAL HEALTH MULTIVITAMIN neem nie:

- Indien u allergies of sensitiviteit is vir enige van die bestanddele gelys in afdeling 6, insluitende ledie van die Asteraceae / Composite plantfamilie (dissel, krisante, gousblomme, madeliefies en ander kruie) en jodium.

- Indien u hiperakalserolie: hiperkalserolie of nierontstrekkerheid.

- Indien u retinaoedeem gebruik.

- Indien u bloedortopgrings of parenterale ysterterapie ontvang, asof u anemie het nie deur ysterkort veroorsaak word nie.

- Indien u 'n gastroneurale siekte het, soos inflammatoire dermiese, instestinale vermodings of divertikula.

- Indien u 'n hyperkalsurie of GPD-tektor het.

- Indien u ysteropbergings- of ysterabsorpse-siekte het, soos hemochromatose of hemoglobinoopatie.

- Indien u 'n gastroneurale siekte het, soos inflammatoire dermiese, instestinale vermodings of divertikula.

- Indien u 'n hyperkalsurie of GPD-tektor het.

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