



Professional Information for PHYTOMATRIX®

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT (WESTERN HERBAL MEDICINE / HEALTH SUPPLEMENT)

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

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

PHYTOMATRIX® TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Dicalcium phosphate	340 mg
providing Calcium (elemental)	98,6 mg
<i>Saccharomyces cerevisiae</i> (baker's yeast)	307,18 mg
providing Niacin (Vitamin B ₃)	3,67 mg
Zinc (elemental)	3,51 mg
Iron (elemental)	1,5 mg
Pantothenic acid (Vitamin B ₅)	1,26 mg
Manganese (elemental)	0,6 mg
Pyridoxine (Vitamin B ₆)	0,5 mg
Copper (elemental)	0,4 mg
Riboflavin (Vitamin B ₂)	0,37 mg
Thiamine (Vitamin B ₁)	0,34 mg
Folic acid	91,67 µg
Chromium (elemental)	50 µg
D-calcium pantothenate	40 µg
Biotin (Vitamin B ₇)	34,38 µg
Iodine	26,5 µg
Molybdenum (elemental)	20 µg
Vanadium (elemental)	20 µg
<i>Malpighia glabra</i> L. (Acerola)	115 mg
[fruit, extract standardised to 15 % (15 mg) ascorbic acid (Vitamin C)]	
<i>Lithothamnion</i> spp. (red algae)	100 mg
providing Calcium (elemental)	29 mg
Magnesium (elemental)	2,5 mg

<i>Brassica oleracea</i> L. (Broccoli)	30 mg
[floret, extract standardised to 4 % glucosinolates	
Mixed tocopherols	23,57 mg
providing alpha-tocopherol (Vitamin E)	7,5 IU
<i>Aloe vera</i> (L.) Burm.f. (Aloe)	20 mg
[inner leaf juice powder]	
Rutin	20 mg
<i>Vaccinium oxycoccos</i> L. (Cranberry)	20 mg
[fruit, 12:1 extract providing 240 mg of dried	
herb equivalent]	
<i>Vitis vinifera</i> L. (Grape)	12,5 mg
[skin, extract standardised to 80 % polyphenols]	
Beta-carotene (from <i>Blakeslea trispora</i>)	3,6 mg
providing retinol (Vitamin A)	165 IU
Boron glycinate	2 mg
providing Boron (elemental)	0,2 mg
Glycine	0,6 mg
Ergocalciferol (Vitamin D ₂)	100 IU
Cyanocobalamin (Vitamin B ₁₂)	1,5 µg

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Yellow-brown, oval shaped tablet with a clear coating.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PHYTOMATRIX® is a combination complementary medicine intended to supplement the diet with vitamins, minerals, trace minerals, antioxidants and herbal extracts to assist and support the immune system and general well-being.

4.2 Posology and method of administration

Adults: Take two tablets twice daily with a meal.

Do not exceed the recommended dosage.

Children:

Not suitable for children under the age of 18 years.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 6.1.
- Abnormal constrictions of the gastrointestinal tract, potential or existing intestinal blockage, atonic bowel, appendicitis,

inflammatory colon disease (e.g. Crohn's disease or ulcerative colitis), abdominal pain of unknown origin, undiagnosed rectal bleeding, severe dehydration with depleted water or electrolytes, haemorrhoids or diarrhoea.

- Pregnancy or lactation (see section 4.6).

4.4 Special warnings and precautions for use

Surgery:

PHYTOMATRIX® may cause excessive bleeding or interfere with blood glucose control during and after surgical procedures. Patients should be advised to discontinue PHYTOMATRIX® at least 2 weeks prior to any surgical procedures.

Gastrointestinal conditions:

Patients with faecal impaction or symptoms such as abdominal pain, nausea, vomiting or fever should consult a health care provider prior to use.

If abdominal pain, cramps, spasms and/or diarrhoea is experienced after taking PHYTOMATRIX®, patients should stop taking PHYTOMATRIX® or reduce the dose.

Kidney disorders:

Patients with a kidney disorder or a history of kidney stones should consult a health care provider prior to use.

Diabetes mellitus:

PHYTOMATRIX® may interfere with blood glucose levels and dose adjustment of antidiabetic medicine might be necessary (see section 4.5). Use with caution.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant or antiplatelet medicines:

PHYTOMATRIX® may potentiate the effects of anticoagulant/antiplatelet medicines or herbal supplements with blood thinning effects. Concomitant use may increase the risk of bruising and bleeding.

Antidiabetic medicines:

Concomitant use of PHYTOMATRIX® with antidiabetic medicines or herbal supplements with hypoglycaemic potential may interfere with blood glucose control and caution is advised during concomitant use (see section 4.4).

Antibiotic medicines:

PHYTOMATRIX® may reduce the absorption of antibiotics. Doses should be separated by at least 2 hours prior, or 4 to 6 hours after taking PHYTOMATRIX®.

Cardiac medicines:

Patients taking cardiac medicines (e.g. cardiac glycosides or antidysrhythmic medicines) should consult a health care provider prior to use.

Medicines causing electrolyte imbalances:

Patients taking thiazide diuretics, corticosteroids, liquorice root, or other medicines or health products that may aggravate electrolyte imbalance, should consult with a health care provider prior to use.

Levothyroxine:

PHYTOMATRIX® may reduce levothyroxine absorption. Advise patients to take levothyroxine and PHYTOMATRIX® at least 4 hours apart.

4.6 Fertility, pregnancy and lactation

PHYTOMATRIX® contains aloe vera which is contraindicated during pregnancy and lactation (see section 4.3).

4.7 Effects on ability to drive and use machines

PHYTOMATRIX® may cause side effects such as sleepiness or dizziness and can affect the ability to drive a vehicle and use machines. Caution is advised when driving a vehicle or operating machinery until the effects of PHYTOMATRIX® are known.

4.8 Undesirable effects

PHYTOMATRIX® is generally well tolerated.

Immune system disorders:

Frequency unknown: hypersensitivity and/or allergic reactions.

Metabolism and nutrition disorders:

Frequency unknown: loss of appetite.

Psychiatric disorders:

Frequency unknown: insomnia.

Nervous system disorders:

Frequency unknown: headache, sleepiness, fatigue, dizziness, drowsiness.

Vascular disorders:

Frequency unknown: flushing.

Gastrointestinal disorders:

Frequency unknown: nausea, vomiting, heartburn, abdominal pain or cramps, gastrointestinal irritation, diarrhoea, belching, flatulence, constipation, upset stomach.

Skin and subcutaneous tissue disorders:

Frequency unknown: skin rash or itching.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of PHYTOMATRIX® is important. It allows continued monitoring of the benefit/risk balance of PHYTOMATRIX®. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 33.7 Combination Product.

Calcium contributes to the development and maintenance of bones and teeth and is a factor in the maintenance of good health. Calcium absorption is affected by several factors like age, race, environmental and dietary conditions. Calcium is distributed in the bones and teeth and excreted via the urine and faeces.

Niacin (Vitamin B3) is a water-soluble vitamin that helps to metabolise carbohydrates, fats and proteins and is a factor in the maintenance of good health. It is rapidly absorbed from the gastrointestinal tract and is excreted mainly via urine

Zinc helps to maintain immune function and helps the body to metabolise carbohydrates, fats and proteins. It is absorbed in the small intestines, distributed in the body in skeletal muscle and bone and mainly excreted through the faeces.

Iron helps to form red blood cells and helps in their proper function. Its absorption is variable and is enhanced by the presence of ascorbic acid. Most of the iron absorbed is incorporated into haemoglobin and is mostly excreted in the faeces.

Pantothenic acid (Vitamin B₅) is an essential B vitamin that helps to metabolise carbohydrates, fats and proteins and is a factor in the maintenance of good health. It is the precursor of coenzyme A (CoA) and is excreted in the urine.

Manganese is an essential nutrient that is involved with normal cell growth and generation of the immune response. It is not well absorbed and is cleared hepatically.

Pyridoxine (Vitamin B₆) helps to metabolise carbohydrates, fats and proteins and contributes to tissue formation. It is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.

Copper helps to produce and repair connective tissue and to form red blood cells. It is absorbed primarily from the small intestines, mainly distributed to the skeleton and muscles and excreted in the urine. Riboflavin (Vitamin B₂) helps to metabolise carbohydrates, fats and proteins and contributes to tissue formation. Oral supplementation results in the production of 7-hydroxymethylriboflavin in blood plasma and is excreted in the urine.

Thiamine (Vitamin B₁) is a water-soluble B-vitamin that helps to metabolise carbohydrates, fats and proteins and contributes to normal growth. It is absorbed at the proximal part of the small intestines. It occurs in the body as the metabolically active form, thiamine diphosphate, and is excreted in the urine.

Folic acid is a water-soluble vitamin that helps the body to metabolise proteins and form red blood cells. After absorption, it is reduced to tetrahydrofolate and then converted to L-methylfolate. It is excreted mainly in the urine.

Chromium is a mineral that has antioxidant properties and helps to support healthy glucose metabolism. The small percentage of chromium that is absorbed, approximately 0,5 % to 2 %, is rapidly excreted in the urine and unabsorbed chromium in the faeces.

Selenium is a mineral with antioxidant properties for the maintenance of good health. The kidney accumulates the highest level of selenium and is the major source of plasma glutathione peroxidase. It is excreted mainly in the urine.

Biotin is an essential, water-soluble B vitamin that helps to metabolise carbohydrates, fats and proteins. It is completely absorbed after oral administration. Biotin metabolites are formed by beta-oxidation, sulfur oxidation, or both, and is excreted in the urine.

Iodine contributes to the normal production of the thyroid hormones and normal thyroid function. It is absorbed through the stomach and duodenum and is converted to iodide. Iodine is excreted mainly in the

urine, with small amounts excreted in faeces, sweat and saliva. Molybdenum is an essential trace mineral that helps the body to metabolise proteins. It is readily absorbed from the gastrointestinal tract and is mainly excreted in the urine.

Vanadium is a trace mineral that is factor in the maintenance of good health. Only about 5 % is absorbed with highest concentrations found in the liver, kidneys and bone. Vanadium is excreted primarily in the urine.

Malpighia glabra L. (Acerola) fruit is a rich source of vitamin C. There is some evidence that vitamin C is more bioavailable when ingested in acerola than when taken as an ascorbic acid dietary supplement. Vitamin C is excreted in the urine.

Magnesium, a mineral that contributes to the maintenance of good health, has antioxidant and immune-boosting properties. It is absorbed throughout the gastrointestinal tract, distributed in the skeleton and soft tissue, and excreted primarily via the kidneys.

Brassica oleracea L. (Broccoli) is metabolised into isothiocyanates such as sulforaphane which may have anti-inflammatory and antioxidant properties. Sulforaphane conjugates with glutathione after absorption, is metabolised to N-acetylcysteine and is excreted in the urine. Vitamin E is an antioxidant for the maintenance of good health. It is mostly absorbed in the small intestines by passive diffusion and is excreted mainly unchanged via the faeces.

Aloe vera (L.) Burm.f. (Aloe) has anti-inflammatory, antioxidant, detoxification and immune-boosting properties. Rutin is a flavonoid with antioxidant effects. It is hydrolysed in the gastrointestinal tract to release quercetin.

Vaccinium oxycoccos L. (Cranberry) and its constituents, particularly proanthocyanidins and quercetin, have antioxidant activity. After ingestion, Cranberry compounds are absorbed and excreted in the urine.

Vitis vinifera L. (Grape) extract contains polyphenols which have antioxidant effects. Polyphenols are metabolised to phenolic acids and are excreted in the urine.

Vitamin A is a fat-soluble vitamin that contributes to immune function. It is readily absorbed from the gastrointestinal tract and is excreted primarily in the urine.

Boron is a trace mineral that is a factor in the maintenance of good health. It is well-absorbed from the gastrointestinal tract and is excreted unchanged in the urine, with a half-life of 21 hours.

Glycine is an amino acid involved in muscle protein synthesis. It is rapidly absorbed in the blood and is eliminated within hours after ingestion. Ergocalciferol (Vitamin D₂) is a fat-soluble vitamin that helps in the development and maintenance of bones and teeth and helps with the absorption and use of calcium and phosphorous. It is well absorbed and requires hydroxylation in the body to form the active metabolite, calcitriol.

Cyanocobalamin (Vitamin B₁₂) is an essential water-soluble vitamin that contributes to normal red blood cell formation. It is absorbed in the terminal ileum and has a half-life of about 25 – 30 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose sodium (E468)
Magnesium stearate (E572)
Microcrystalline cellulose (E460)
Opadry® coating [containing vegetable hydroxypropyl methylcellulose (E464) and vegetable glycerin (E422)]
Silicon dioxide (E551)
Stearic acid (E570).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C, in a dry place.
Keep the bottle tightly closed.
Do not use if inner seal is missing or broken.

6.5 Nature and contents of container

HDPE container with a ribbed polypropylene cap containing 120 tablets and a white cotton wad.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Ground Floor, Unit 6
10 Church Street
Durbanville, 7551
South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

October 2021.