



# Professional Information for NUTRIVERUS®

## COMPLEMENTARY MEDICINE: COMBINATION PRODUCT

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

## SCHEDULING STATUS

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### 1. NAME OF THE MEDICINE

NUTRIVERUS® POWDER

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each scoop (approximately 2,7 g) contains:

*Rice bran fibre	1 000 mg
providing Potassium	20,23 mg
Phytosterols	1,5 mg
Calcium (elemental)	1,16 mg
Sodium	0,31 mg
Iron (elemental)	0,199 mg
Vitamin E (as mixed tocotrienols and tocopherols)	0,061 IU
**Rice bran solubles	107,50 mg
providing Potassium	1,46 mg
Phytosterols	0,269 mg
Vitamin E (as mixed tocotrienols and tocopherols)	0,062 IU
Calcium (elemental)	22 µg
Sodium	16 µg
Iron (elemental)	4 µg
<i>Larix laricina</i> (Du Roi) K. Koch or <i>Larix occidentalis</i> Nutt. (Larch Arabinogalactan) [wood]	350 mg
<i>Malpighia glabra</i> L. (Acerola) [fruit, extract providing 15 % (27 mg) ascorbic acid (Vitamin C)]	212,5 mg
Milk calcium complex	208 mg
providing Calcium (elemental)	52 mg
Phosphorus (elemental)	29 mg
Dicalcium phosphate	47 mg
providing Calcium (elemental)	13 mg
D-alpha-tocopheryl acetate	21 mg
providing Vitamin E	13 IU
Ergocalciferol (Vitamin D <sub>2</sub> )	229 IU
Manapol® <i>Aloe vera</i> (L.) Burm.f. (Aloe)	15 mg

[inner leaf gel, 415:1 extract providing 6,2 g dry herb equivalent]	
<i>Astragalus gummifer</i> Labill. (Tragacanth)	12,50 mg
Organic fruit blend	7,5 mg
Organic vegetable blend	7,5 mg
<i>Saccharomyces cerevisiae</i> (baker's yeast)	212,50 mg
providing Niacin (Vitamin B <sub>3</sub> )	5,67 mg
Zinc (elemental)	5,5 mg
Iron (elemental)	2,1 mg
Pantothenic acid (Vitamin B <sub>5</sub> )	1,95 mg
Manganese (elemental)	1,3 mg
Thiamine (Vitamin B <sub>1</sub> )	0,63 mg
Riboflavin (Vitamin B <sub>2</sub> )	0,57 mg
Pyridoxine (Vitamin B <sub>6</sub> )	0,78 mg
Folic acid	141,67 µg
Copper (elemental)	70 µg
Chromium (elemental)	63 µg
Biotin (Vitamin B <sub>7</sub> )	53,13 µg
Iodine	45 µg
Selenium (elemental)	30 µg
<i>Undaria pinnatifida</i> (Wakame)	0,13 mg
[fronds, 5:1 extract, standardised to 75 % fucoidan, providing 0,65 mg dried herb equivalent]	
Mixed carotenoids	17 µg
providing Vitamin A	799 IU
Cyanocobalamin (Vitamin B <sub>12</sub> )	2,7 µg

For the full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

Powder.

Free flowing, yellowish beige to tan powder with dark specks.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

NUTRIVERUS® is a combination complementary medicine containing vitamins, minerals and glyconutrients providing antioxidants and support for the immune system.

#### 4.2 Posology and method of administration

*Adults:*

Take 1 scoop (2,7 grams) with a glass of water or juice, or mixed with food, twice daily. NUTRIVERUS® is designed to mix well with food or drinks.

Do not exceed the recommended dosage.

NUTRIVERUS® should be used in conjunction with a normal, healthy, balanced diet and moderate exercise.

#### 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.
- Hypersensitivity to iodine or seafood allergy.

#### 4.4 Special warnings and precautions for use

##### **Surgery:**

NUTRIVERUS® might cause excessive bleeding and interfere with blood glucose control during and after surgical procedures. Patients should be advised to discontinue NUTRIVERUS® 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 NUTRIVERUS®, patients should stop taking NUTRIVERUS® or reduce the dose.

##### **Kidney disorders:**

Patients with a kidney disorder should consult a health care provider prior to use.

##### **Thyroid conditions:**

NUTRIVERUS® reduces levothyroxine absorption and effectiveness in hypothyroid patients on levothyroxine replacement therapy. Patients taking levothyroxine replacement therapy should separate doses of levothyroxine and NUTRIVERUS® by 4 hours (see section 4.5).

#### 4.5 Interaction with other medicines and other forms of interaction

##### **Anticoagulant or antiplatelet medicines:**

NUTRIVERUS® may potentiate the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects.

##### **Antidiabetic medicines:**

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

**Antibiotics:**

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

**Levothyroxine:**

NUTRIVERUS® reduces levothyroxine absorption. Advise patients to take levothyroxine and NUTRIVERUS® at least 4 hours apart (see section 4.4).

**Medicines causing electrolyte imbalances:**

Patients taking cardiac medicines (e.g. cardiac glycosides or antidysrhythmic medicines), 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.

**4.6 Fertility, pregnancy and lactation**

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

**4.7 Effects on ability to drive and use machines**

NUTRIVERUS® can cause side effects, such as fatigue, sleepiness or drowsiness 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 NUTRIVERUS® are known.

**4.8 Undesirable effects**

**Immune system disorders:**

*Less frequent:* hypersensitivity reactions.

**Metabolism and nutrition disorders:**

*Less frequent:* loss of appetite

**Psychiatric disorders:**

*Frequent:* insomnia.

**Nervous system disorders:**

*Frequent:* headache, sleepiness, fatigue

**Vascular disorders:**

*Frequent:* flushing

**Gastrointestinal disorders:**

*Frequent:* nausea, vomiting, heartburn, abdominal pain or cramps, gastrointestinal obstruction/irritation, diarrhoea, belching, flatulence, constipation, upset stomach

*Less frequent:* bloating

## Skin and subcutaneous tissue disorders:

*Less frequent:* skin rashes or itching, dermatitis, erythema, urticaria.

### Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of NUTRIVERUS® is important. It allows continued monitoring of the benefit/risk balance of NUTRIVERUS®. 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

**Mechanism of action:**

Vitamin A is a fat-soluble vitamin that contributes to immune function.

Vitamin B<sub>1</sub>, B<sub>2</sub>, B<sub>3</sub>, B<sub>5</sub>, B<sub>6</sub> and B<sub>12</sub> are water-soluble vitamins that helps to metabolise carbohydrates, fats and proteins and is a factor in the maintenance of good health.

Vitamin C is a water-soluble vitamin with antioxidant properties. It helps to maintain proper immune function.

Vitamin D is a fat-soluble vitamin that helps with the absorption and use of calcium and phosphorus.

Vitamin E is an antioxidant for the maintenance of good health.

Biotin is an essential, water-soluble B vitamin that is a factor in the maintenance of good health.

Calcium is an element that is a factor in the maintenance of good health.

Chromium is a mineral that has antioxidant properties and helps to support healthy glucose metabolism.

Copper is a mineral that is a factor in the maintenance of good health.

Folic acid is a water-soluble vitamin and a factor in the maintenance of good health.

Iodine is a mineral and factor in the maintenance of good health.

Iron is a mineral and factor in the maintenance of good health.  
Manganese is an essential nutrient that acts as a cofactor in several metabolic and enzymatic reactions.  
Potassium is a mineral and factor in the maintenance of good health.  
Phosphorus is a mineral that contributes to the maintenance of good health.  
Selenium is a mineral supplement with antioxidant properties for the maintenance of good health.  
Wakame is a source of fucoidans which aid in stimulating the immune system.  
Zinc helps to maintain immune function and is a factor in the maintenance of good health.  
Aloe has antioxidant, detoxification and immune-boosting properties.  
Larch arabinogalactan has immune-boosting properties.  
When ingested, the bulk of tragacanth stretches the intestinal wall, increasing peristalsis. It increases stool mass and decreases gastrointestinal (GI) transit time.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Flavourants (natural flavour masking, salt masking and yogurt flavouring).  
Stevia.

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

2 years.

### **6.4 Special precautions for storage**

Store at or below 25 °C, in a dry place.  
Keep in the outer container until required for use.  
Do not use if inner seal is missing or broken.

### **6.5 Nature and contents of container**

HDPE container with a polypropylene cap containing 150 g powder.

### **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**

September 2021.