

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE (HEALTH SUPPLEMENT – MULTIPLE SUBSTANCE FORMULATION)

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. Health Supplements should not be used as a substitute for a varied and balanced diet and healthy lifestyle.

SCHEDULING STATUS S0

1. NAME OF THE MEDICINE

NUTRIPURE ADULT MULTIVITAMIN (multiple substance, gummies)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:

L-Ascorbic Acid (Vitamin C)	40 mg
Nicotinamide (Niacin)	8 mg
DL-alpha-tocopheryl acetate (Vitamin E)	6 mg
Calcium D-Pantothenate (Pantothenic Acid)	6 mg
Zinc Citrate	6,45 mg

providing Zinc (elemental)	1,5 mg
Pyridoxine Hydrochloride (Vitamin B6)	1,4 mg
Retinyl Acetate (Vitamin A)	800 µg
Pteroylmonoglutamic acid (Folic Acid)	100 µg
D-Biotin (Biotin)	50 µg
Potassium Iodide	3,53 mg
providing Iodine (elemental)	22,50 µg
Ergocalciferol (Vitamin D)	5 µg
Cyanocobalamin (Vitamin B12)	1,5 µg

Contains sugar: Glucose syrup (1,07 g); Sucrose (0,90 g)

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gummies

NUTRIPURE ADULT MULTIVITAMIN is a red, conoid-shaped gummy with a red berries flavour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

NUTRIPURE ADULT MULTIVITAMIN is indicated as a complementary medicine that is a factor in the maintenance of good health.

4.2. Posology and method of administration

Posology

Adults: One gummy once daily with meals.

Do not exceed the recommended dose without consulting a relevant health care provider (see **4.4. Special warnings and precautions for use**).

NUTRIPURE ADULT MULTIVITAMIN should not be consumed on an empty stomach, best to be taken with a meal (see **4.4. Special warnings and precautions for use**).

Method of administration

Take orally.

4.3. Contraindications

NUTRIPURE ADULT MULTIVITAMIN should not be used in patients with hypersensitivity to any of the active substances or to any of the excipients listed in **section 6.1**.

The safety and efficacy of **NUTRIPURE ADULT MULTIVITAMIN** in children have not been established. **NUTRIPURE ADULT MULTIVITAMIN** is not recommended for use in children.

4.4. Special warnings and precautions for use

NUTRIPURE ADULT MULTIVITAMIN should not be consumed on an empty stomach, best to be taken with a meal (see **4.2. Posology and method of administration**).

Do not exceed the recommended dose without consulting a relevant health care provider (see **4.2. Posology and method of administration**).

Patients should consult a relevant health care provider before using **NUTRIPURE ADULT MULTIVITAMIN** if they:

- are pregnant or breastfeeding;
- are taking any other medicines, vitamins, minerals or health supplements;
- have thyroid disease or are undergoing investigation or treatment for a thyroid disorder;
- have impaired renal or hepatic function;
- have hypercalcaemia, a history of renal calculi or a condition predisposing to hypercalcaemia;
- have a bleeding disorder or are receiving anticoagulant or antiplatelet treatment; or
- are undergoing treatment for cancer.

The total daily intake of vitamin A, vitamin D, vitamin E, folic acid, iodine and zinc from all dietary and supplemental sources should be considered to avoid excessive cumulative intake.

NUTRIPURE ADULT MULTIVITAMIN contains approximately 1,07 g glucose syrup and 0,90 g sucrose per gummy. This should be considered in patients with diabetes mellitus or patients following a sugar-controlled diet.

Health supplements should not be used as a substitute for a varied and balanced diet and a healthy lifestyle.

4.5. Interactions with other medicines and other forms of interaction

No interaction studies have been performed with **NUTRIPURE ADULT MULTIVITAMIN**.

Clinically significant interactions are not expected when **NUTRIPURE ADULT MULTIVITAMIN** is used at the recommended dose. However, the following interactions have been reported for individual ingredients, particularly at higher supplemental doses:

Retinoids

Concomitant use of vitamin A-containing supplements with systemic retinoids, such as isotretinoin or acitretin, may result in additive vitamin A-related adverse effects.

Concomitant use should be avoided unless advised by a health care provider.

Thyroid medicines, antithyroid medicines, amiodarone and lithium

Iodine may alter thyroid function and may affect or be affected by thyroid hormone replacement therapy and antithyroid medicines. Amiodarone and lithium may increase the risk of iodine-related thyroid dysfunction. Thyroid function should be monitored where clinically indicated.

Tetracycline and quinolone antibiotics

Zinc may reduce the gastrointestinal absorption of tetracycline and quinolone antibiotics through chelation. **NUTRIPURE ADULT MULTIVITAMIN** should be administered separately from these medicines in accordance with the prescribing information of the antibiotic.

Penicillamine

Zinc may reduce the absorption of penicillamine. **NUTRIPURE ADULT MULTIVITAMIN** and penicillamine should be administered separately.

Antiepileptic medicines

High supplemental doses of folic acid may affect serum concentrations or the clinical response to certain antiepileptic medicines.

High doses of vitamin B6 may reduce serum concentrations of phenobarbital or phenytoin. This interaction is unlikely at the amount contained in **NUTRIPURE ADULT MULTIVITAMIN**.

Patients receiving antiepileptic treatment should consult a health care provider before use.

Levodopa

Vitamin B6 may reduce the therapeutic effect of levodopa when levodopa is administered without a peripheral dopa-decarboxylase inhibitor. This interaction does not ordinarily apply to levodopa administered with carbidopa or benserazide.

Methotrexate and folate antagonists

Folic acid may interfere with the therapeutic effect of methotrexate when methotrexate is used for the treatment of malignant disease. Folic acid supplementation during methotrexate treatment should only be used under medical supervision.

Fluoropyrimidines

Folic acid may increase the adverse effects of fluoropyrimidines such as fluorouracil and capecitabine. Medical advice should be obtained before concurrent use.

Anticoagulant and antiplatelet medicines

High doses of vitamin E may increase the risk of bleeding when used with anticoagulant or antiplatelet medicines. This interaction is unlikely at the amount contained in **NUTRIPURE ADULT MULTIVITAMIN** but should be considered where additional vitamin E-containing products are used.

Thiazide diuretics and cardiac glycosides

Excessive vitamin D intake may increase serum calcium concentrations.

Hypercalcaemia may be enhanced by thiazide diuretics and may increase the risk of cardiac arrhythmias in patients receiving cardiac glycosides.

This interaction is unlikely at the recommended dose unless additional vitamin D-containing products are used.

Other vitamins and mineral supplements

Concurrent use with other multivitamins or products containing vitamin A, vitamin D, vitamin E, folic acid, iodine or zinc may increase total daily intake and the risk of dose-related adverse effects.

4.6. Fertility, pregnancy and lactation

Consult a relevant health care provider prior to use if you are pregnant or breastfeeding
(see section **4.4. Special warnings and precautions for use**).

The effect on fertility is unknown.

4.7. Effects on ability to drive and use machines

There is no known effect on the ability to drive and use machines.

4.8. Undesirable effects

NUTRIPURE ADULT MULTIVITAMIN is generally well tolerated when used at the recommended dose.

The following adverse reactions have been reported with the individual ingredients. The frequencies are not known.

Immune system disorders

Hypersensitivity reactions, including rash, pruritus and urticaria.

Nervous system disorders

Headache.

Gastrointestinal disorders

Abdominal discomfort or cramps, nausea, vomiting, diarrhoea, heartburn and dyspepsia.

General disorders

Unpleasant or metallic taste.

Dose-related adverse reactions are more likely when the recommended dose is exceeded or when **NUTRIPURE ADULT MULTIVITAMIN** is taken with other vitamin or mineral supplements.

Large doses of nicotinamide may cause gastrointestinal disturbances, headache, dizziness, drowsiness, pruritus or rash. These effects are unlikely at the 8 mg dose contained in **NUTRIPURE ADULT MULTIVITAMIN**. Nicotinamide does not generally cause the vasodilatation and flushing associated with nicotinic acid.

Excessive or prolonged intake of individual ingredients may result in:

- vitamin A toxicity, including headache, dizziness, dry skin, alopecia, bone or joint pain and hepatic dysfunction;
- vitamin D toxicity and hypercalcaemia;
- iodine-induced hypothyroidism or hyperthyroidism;

- sensory neuropathy associated with prolonged excessive vitamin B6 intake;
- gastrointestinal irritation and copper deficiency associated with excessive zinc intake; and
- an increased bleeding tendency associated with excessive vitamin E intake.

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.

4.9. Overdose

In overdose, the adverse reactions described in section 4.8 may be precipitated or may be of increased severity.

Acute overdose may cause nausea, vomiting, abdominal pain, diarrhoea, headache and dizziness.

Large or prolonged excessive intake may cause:

- vitamin A toxicity, including headache, visual disturbances, dry skin, alopecia, bone or joint pain and hepatic dysfunction;
- vitamin D toxicity and hypercalcaemia, which may present with nausea, vomiting, thirst, polyuria, dehydration, weakness, confusion, nephrolithiasis or renal impairment;
- iodine-induced hypothyroidism or hyperthyroidism;
- sensory neuropathy associated with excessive vitamin B6 intake;
- zinc toxicity, including severe gastrointestinal irritation and renal injury, and with prolonged excessive use, copper deficiency and haematological or neurological abnormalities;
- an increased bleeding tendency associated with excessive vitamin E intake; and
- gastrointestinal disturbances, headache, dizziness, drowsiness, pruritus, rash or altered liver function associated with very high doses of nicotinamide.

There is no specific antidote.

Treatment should be symptomatic and supportive. **NUTRIPURE ADULT MULTIVITAMIN** should be discontinued and the patient medically assessed.

Monitoring of fluid and electrolyte balance, serum calcium, renal function, hepatic function and thyroid function should be considered depending on the quantity ingested, the duration of excessive intake and the clinical presentation.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Complementary Medicine – Health Supplement

D 34.12 Multiple Substance Formulation

Mechanism of action

NUTRIPURE ADULT MULTIVITAMIN contains vitamins and zinc that act as essential nutrients and enzyme cofactors in normal physiological and metabolic processes.

Vitamin C

Vitamin C is a water-soluble antioxidant and a cofactor for several enzymatic reactions. It contributes to collagen synthesis, connective tissue formation, wound healing, immune function and the protection of cellular components against oxidative damage.

Nicotinamide

Nicotinamide is the amide form of vitamin B3 and is a precursor of nicotinamide adenine dinucleotide and nicotinamide adenine dinucleotide phosphate.

These coenzymes participate in oxidation-reduction reactions, cellular energy production and the metabolism of carbohydrates, fats and proteins.

Vitamin E

Vitamin E is a fat-soluble, chain-breaking antioxidant that protects polyunsaturated fatty acids and cellular membranes against oxidative damage.

Pantothenic acid

Pantothenic acid is a precursor of coenzyme A and is required for the metabolism of carbohydrates, proteins and lipids and for the synthesis of fatty acids, sterols, steroid hormones, porphyrins and acetylcholine.

Zinc

Zinc is an essential trace element and acts as a structural, catalytic or regulatory component of numerous enzymes and proteins.

Zinc contributes to DNA, RNA and protein synthesis, immune function, growth and development and tissue repair.

Vitamin B6

Vitamin B6 is converted to pyridoxal phosphate, which acts as a coenzyme in amino acid, carbohydrate and lipid metabolism, neurotransmitter synthesis, haem synthesis and homocysteine metabolism.

Vitamin A

Vitamin A contributes to normal vision, epithelial cell differentiation, immune function, growth and reproduction.

Retinol and its metabolites regulate gene transcription through nuclear retinoid receptors.

Folic acid

Folic acid is converted to biologically active tetrahydrofolate derivatives, which act as coenzymes in one-carbon transfer reactions.

Folate is required for nucleotide synthesis, DNA formation and normal cell division and contributes to normal erythropoiesis and homocysteine metabolism.

Biotin

Biotin acts as a coenzyme for biotin-dependent carboxylases involved in gluconeogenesis, fatty acid synthesis, fatty acid oxidation and amino acid catabolism.

Iodine

Iodine is required for the synthesis of the thyroid hormones thyroxine and triiodothyronine.

Thyroid hormones regulate metabolic activity and contribute to normal growth and development.

Vitamin D

Ergocalciferol is converted to active vitamin D metabolites.

Vitamin D regulates calcium and phosphate homeostasis by increasing intestinal absorption and contributes to the maintenance of normal bone mineralisation and neuromuscular function.

Vitamin B12

Vitamin B12 is converted to active cobalamin coenzymes required for DNA synthesis, normal erythropoiesis, myelin synthesis and the metabolism of methylmalonate and homocysteine.

The combination of vitamins and zinc in **NUTRIPURE ADULT MULTIVITAMIN** provides complementary nutritional support for normal physiological and metabolic processes and contributes as a factor in the maintenance of good health.

5.2. Pharmacokinetic properties

No pharmacokinetic studies have been performed with the finished combination product.

The following information is based on the known pharmacokinetic properties of the individual vitamins and minerals.

Vitamin C

Vitamin C is absorbed from the small intestine by active, saturable transport and passive diffusion.

It is widely distributed in body tissues. Excess vitamin C and its metabolites, including oxalate, are excreted mainly in the urine.

The fractional absorption of vitamin C decreases with increasing oral doses.

Nicotinamide

Nicotinamide is readily absorbed following oral administration and is widely distributed in body tissues.

It is metabolised primarily in the liver by methylation and oxidation. Nicotinamide and its metabolites are excreted predominantly in the urine.

Vitamin E

Vitamin E is absorbed from the gastrointestinal tract in the presence of dietary fat and bile.

It is incorporated into chylomicrons and transported through the lymphatic system to the liver and peripheral tissues.

Vitamin E is metabolised primarily in the liver and is excreted mainly in bile and faeces, with smaller amounts of metabolites excreted in the urine.

Pantothenic acid

Pantothenic acid is absorbed from the gastrointestinal tract and distributed to body tissues as a component of coenzyme A.

It is excreted mainly in the urine.

Zinc

Zinc is absorbed principally in the small intestine. Absorption is regulated according to zinc status and is influenced by dietary constituents, including phytates.

Zinc is distributed in tissues and is bound to proteins. It is eliminated predominantly through the gastrointestinal tract, with smaller amounts excreted in the urine and sweat.

Vitamin B6

Vitamin B6 is absorbed from the upper gastrointestinal tract.

It is converted mainly in the liver to the active coenzyme pyridoxal phosphate. Vitamin B6 metabolites are excreted primarily in the urine.

Vitamin A

Retinyl esters are absorbed in the small intestine in the presence of dietary fat and bile.

They are incorporated into chylomicrons and transported to the liver. Vitamin A is stored mainly in the liver and is released into the circulation bound to retinol-binding protein.

Vitamin A is metabolised to active and inactive metabolites and is eliminated in the urine and faeces.

Folic acid

Folic acid is absorbed mainly from the proximal small intestine after reduction and methylation.

It undergoes hepatic uptake and enterohepatic circulation and is distributed to tissues as reduced folate derivatives.

Excess folate and its metabolites are eliminated mainly in the urine.

Biotin

Biotin is absorbed from the gastrointestinal tract through sodium-dependent transport and, at higher concentrations, passive diffusion.

Peak plasma concentrations occur approximately 1 to 2 hours after oral administration.

Biotin is distributed to the liver and peripheral tissues, metabolised by beta-oxidation and sulfur oxidation and excreted in the urine as unchanged biotin and metabolites.

Iodine

Iodide is rapidly and almost completely absorbed from the gastrointestinal tract.

It is distributed in extracellular fluid and is actively concentrated by the thyroid gland, where it is incorporated into thyroid hormones.

Excess iodide is eliminated predominantly in the urine.

Vitamin D

Ergocalciferol is absorbed from the small intestine with dietary fat and is transported in chylomicrons.

It is hydroxylated in the liver to 25-hydroxyvitamin D and subsequently in the kidneys and other tissues to active metabolites.

Vitamin D and its metabolites circulate bound to vitamin D-binding protein and are stored in adipose tissue and muscle. Elimination occurs mainly through bile and faeces.

Vitamin B12

Cyanocobalamin is absorbed through intrinsic factor-dependent transport in the terminal ileum, with a small proportion absorbed by passive diffusion.

It is converted to active cobalamin coenzymes and is stored mainly in the liver.

Vitamin B12 undergoes enterohepatic circulation. Excess vitamin B12 is excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Water

Fruit juice concentrate

Gelling agent (Pectin)

Acid (Citric acid)

Acidity regulator (Sodium citrate)

Flavouring

Colour (Anthocyanins)

Coconut oil

Glazing agent (Carnauba wax)

6.2. Incompatibilities

None known.

6.3. Shelf life

The shelf life for **NUTRIPURE ADULT MULTIVITAMIN** is two years.

6.4. Special precautions for storage

Store below 25 °C in a cool, dry place.

Keep bottle tightly closed.

6.5. Nature and contents of container

NUTRIPURE ADULT MULTIVITAMIN is supplied in a white 400 ml PET bottle (120's)
with light green CRC cap and silver induction liner.

6.6. Special precautions for disposal and other handling

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

MDI Healthcare cc

P.O. Box 35259, Menlo Park

Pretoria

0102

8. REGISTRATION NUMBER(S):

To be allocated.

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

To be allocated.

10. DATE OF REVISION OF THE TEXT

To be allocated.