PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE (DISCIPLINE-SPECIFIC COMBINATION PRODUCT)

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 MEN'S VITALITY (multiple substance, gummies)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:

Shilajit extract	50 mg
[≥ 50 % Fulvic acid ratio 30:1]	
Zinc citrate	21,51 mg
providing Zinc (elemental)	5 mg
Pyridoxine hydrochloride (Vitamin B6)	1,1807 mg
equivalent to vitamin B6 (as pyridoxine)	0,7 mg

Contains sugar: Glucose syrup (1,10 g); Sucrose (0,93 g)

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gummies

NUTRIPURE MEN'S VITALITY is a red coloured gummy with a berries flavour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

NUTRIPURE MEN'S VITALITY helps to support men's health and vitality, helps the body to metabolise carbohydrates, fats and proteins, maintains immune function and 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 MEN'S VITALITY 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 MEN'S VITALITY should not be used by patients with hypersensitivity to any of the active substances or excipients.

Not recommended during pregnancy and lactation due to insufficient safety data (see **4.6 Fertility, pregnancy and lactation**).

4.4. Special warnings and precautions for use

NUTRIPURE MEN'S VITALITY 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**).

Shilajit may lower blood glucose levels. Caution is advised in patients with diabetes or those taking antidiabetic medicines (see **4.5 Interactions with other medicines and other forms of interaction**).

Discontinue use at least two weeks prior to elective surgical procedures due to potential effects on blood glucose control.

The tolerable upper intake level for zinc in adults is 40 mg per day. Excessive zinc intake over prolonged periods may result in adverse effects including gastrointestinal irritation, copper deficiency and associated anaemia.

This medicine contains sugar and should be used with caution in patients with diabetes mellitus.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5. Interactions with other medicines and other forms of interaction

Shilajit may enhance the glucose-lowering effects of antidiabetic medicines. Concomitant use may increase the risk of hypoglycaemia and blood glucose levels should be monitored.

Zinc may reduce the absorption of certain medicines through chelation or complex formation in the gastrointestinal tract.

Quinolone antibiotics: Take quinolone antibiotics at least 2 hours before or 4–6 hours after zinc.

Penicillamine: Take zinc and penicillamine at least 2 hours apart.

Cephalexin: Zinc may decrease cephalexin levels; to avoid an interaction, take zinc sulfate 3 hours after cephalexin.

Integrase inhibitors: Zinc may reduce the absorption and clinical effectiveness of integrase inhibitors through chelation.

Cisplatin: Zinc might interfere with the therapeutic effects of cisplatin (theoretical).

Ritonavir: Zinc may modestly reduce ritonavir levels.

Certain medicines may reduce vitamin B6 activity or increase its excretion, potentially leading to deficiency with long-term use. Examples include isoniazid, hydralazine, penicillamine, and theophylline. Consider monitoring for deficiency symptoms (e.g., peripheral neuropathy) and supplementing vitamin B6 where clinically appropriate.

4.6. Fertility, pregnancy and lactation

Not recommended during pregnancy and lactation due to insufficient safety data (**see 4.3. Contraindications**).

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

Nervous system disorders

Less frequent: Headache, Sensory neuropathy (with prolonged high-dose vitamin B6 intake), characterised by numbness/tingling of the extremities.

Immune system disorders

Less frequent: Hypersensitivity reactions

Gastrointestinal disorders

Less frequent: Nausea, vomiting, abdominal discomfort, diarrhoea, metallic taste

If adverse effects occur, discontinue use and consult a healthcare professional.

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

There is limited information regarding overdose with this product.

Management of overdose should be symptomatic and supportive.

Excessive intake of zinc may result in adverse effects such as nausea, vomiting, abdominal pain and diarrhoea.

In overdose, side effects can be precipitated and/or be of increased severity (see **section 4.8. Undesirable effects**).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Complementary Medicine Discipline-specific

D 33.7 Combination Products

Shilajit

Shilajit is a natural exudate composed of animal, microbial, mineral and plant material found in high mountain ranges of Asia. It contains various bioactive compounds including fulvic acid, humic substances, dibenzo-alpha-pyrones, minerals, amino acids and organic acids.

Experimental and preliminary clinical studies suggest that shilajit may possess antioxidant and adaptogenic properties. These effects are thought to be related to its humic substances, particularly fulvic acid and dibenzo-alpha-pyrones, which may contribute to improved mitochondrial function and reduced oxidative stress.

Shilajit has also been shown in experimental studies to modulate immune responses and influence metabolic processes including glucose and lipid metabolism.

Zinc

Zinc is an essential trace element involved in numerous biological processes. It functions as a structural, catalytic and regulatory component of many enzymes and proteins involved in cellular metabolism. Zinc plays an important role in immune function, protein synthesis, DNA synthesis and cell division. It also contributes to normal metabolism of carbohydrates, fats and proteins and is required for normal growth and development.

Vitamin B6

Vitamin B6 is a water-soluble vitamin that functions as a coenzyme in numerous enzymatic reactions involved in amino acid, carbohydrate and lipid metabolism. In the body, vitamin B6 is converted to the active coenzyme form pyridoxal-5-phosphate which participates in a wide variety of metabolic processes including neurotransmitter synthesis and haem synthesis.

The combination of shilajit with zinc and vitamin B6 provides complementary nutritional support for metabolic processes, immune function and maintenance of general health.

5.2. Pharmacokinetic properties

Shilajit

Limited pharmacokinetic data are available for shilajit. In humans, administration of processed shilajit for 90 days has been reported to increase semen levels of hydroxylated and conjugated dibenzo-alpha-pyrones, constituents of shilajit.

Zinc

Absorption

Zinc is absorbed primarily in the small intestine via carrier-mediated and passive diffusion mechanisms. Absorption may be influenced by dietary factors. Diets high in phytate may reduce zinc bioavailability.

Distribution

Zinc is widely distributed throughout the body and is present in high concentrations in muscle and bone.

Metabolism

Following oral or intravenous administration, zinc rapidly distributes to the liver and then declines in plasma in a multi-phase pattern.

Elimination

Zinc is excreted primarily via the gastrointestinal tract, with smaller amounts eliminated in urine and sweat.

Vitamin B6

Absorption

Vitamin B6 is rapidly absorbed from the gastrointestinal tract.

Metabolism

It is converted in the liver to the active coenzyme pyridoxal-5-phosphate.

Distribution

Pyridoxal-5-phosphate circulates largely bound to plasma proteins and vitamin B6 is widely distributed in body tissues, with significant storage in muscle.

Elimination

Vitamin B6 is metabolised primarily in the liver and excreted in urine mainly as 4-pyridoxic acid.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Glucose Syrup

Sucrose

Water

Fruit Juice Concentrate

Gelling Agent (Pectin)

Acid (Citric Acid)

Acidity Regulator (Sodium Citrates)

Colour (Anthocyanins)

Flavouring

Coconut Oil

Glazing Agent (Carnauba Wax)

6.2. Incompatibilities

None known.

6.3. Shelf life

The shelf life for NUTRIPURE MEN'S VITALITY is two years.

6.4. Special precautions for storage

Store in a cool dry place below 25 °C.

Keep bottle tightly closed.

6.5. Nature and contents of container

NUTRIPURE MEN'S VITALITY is supplied in a 300ml shiny, white PET bottle with red CRC cap.

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.