

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 TEENS MULTIVITAMIN (multiple substance, gummies)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:

L-Ascorbic Acid (Vitamin C)	40 mg
Nicotinamide (Vitamin B3)	8 mg NE
DL- α Tocopheryl Acetate (Vitamin E)	6 mg α -TE
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
Choline Bitartrate (Choline)	0,02 mg
Myo-Inositol (Inositol)	0,02 mg
Retinyl Acetate (Vitamin A)	400 µg RE
Pteroylmonoglutamic Acid (Folic Acid)	100 µg
D-Biotin (Biotin)	50 µg
Potassium Iodide	3,53 mg
providing Iodine (elemental)	22,5 µg
Ergocalciferol (Vitamin D2)	5 µg
Cyanocobalamin (Vitamin B12)	1,5 µg

Contains sugar: Glucose syrup (1,02 g); Sucrose (0,86 g)

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gummies

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

NUTRIPURE TEENS MULTIVITAMIN is a complementary medicine that is a factor in the maintenance of good health.

4.2. Posology and method of administration

Posology

Ages 13 years and older: Take one gummy daily.

For use by teenagers only under adult supervision (see **4.4. Special warnings and precautions for use**).

Do not give to children under 13 years old (see **4.3. Contraindications**).

Do not exceed daily dosage level without consulting a relevant health care provider (see **4.4. Special warnings and precautions for use**).

Method of administration

Take orally.

4.3. Contraindications

NUTRIPURE TEENS 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**.

Do not give to children under 13 years old.

4.4. Special warnings and precautions for use

Do not exceed daily dosage level without consulting a relevant health care provider (see **section 4.2 Posology and method of administration**).

For use by teenagers only under adult supervision.

Patients should consult a relevant health care provider before using **NUTRIPURE TEENS MULTIVITAMIN** if they are pregnant or breastfeeding.

NUTRIPURE TEENS MULTIVITAMIN contains vitamin A. The recommended dosage should not be exceeded.

Patients with thyroid disorders or those receiving thyroid medication should consult a relevant health care provider before use due to the presence of iodine.

If symptoms worsen, consult a relevant health care provider.

NUTRIPURE TEENS MULTIVITAMIN contains approximately 1,02 g glucose syrup and 0,86 g sucrose per gummy. This should be considered in patients with diabetes mellitus or those 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 clinically significant interactions have been reported when **NUTRIPURE TEENS MULTIVITAMIN** is used at the recommended dosage.

Minerals, including zinc, may reduce the absorption of certain medicines, including tetracycline and quinolone antibiotics. Administration should be separated by at least 2 hours.

Patients receiving thyroid hormone replacement therapy should consult a relevant health care provider before use, as iodine-containing supplements may require monitoring of thyroid function.

Patients taking anticoagulants should consult a relevant health care provider before using supplements containing vitamin E.

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

NUTRIPURE TEENS MULTIVITAMIN is unlikely to affect the ability to drive or operate machinery.

4.8. Undesirable effects

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

Gastrointestinal disorders:

Occasional mild gastrointestinal discomfort, nausea, abdominal discomfort or diarrhoea may occur.

Immune system disorders:

Hypersensitivity reactions may occur in susceptible individuals.

If serious adverse reactions occur, discontinue use and consult a relevant health care provider.

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

No cases of overdose have been reported with **NUTRIPURE TEENS MULTIVITAMIN**.

Overdose may increase the risk of adverse effects associated with the individual vitamins and minerals, particularly fat-soluble vitamins.

In the event of overdose, discontinue use and treat symptomatically. Seek medical attention if necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Complementary Medicine – Health Supplement

D 34.12 Multiple substance formulation

NUTRIPURE TEENS MULTIVITAMIN contains a combination of vitamins and minerals that supplement dietary intake and contribute to the maintenance of good health.

The formulation provides vitamins and minerals that support normal physiological processes, including immune function, normal energy-yielding metabolism, antioxidant protection and normal cellular function.

5.2. Pharmacokinetic properties

The active ingredients of **NUTRIPURE TEENS MULTIVITAMIN** are absorbed from the gastrointestinal tract following oral administration.

Water-soluble vitamins are absorbed and excess amounts are primarily excreted in the urine. Fat-soluble vitamins are absorbed together with dietary lipids and are stored to varying degrees in body tissues. Minerals are absorbed according to physiological

requirements, with absorption influenced by dietary factors and the body's nutritional status.

Pharmacokinetic data are not available for the fixed combination product.

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 TEENS 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 TEENS MULTIVITAMIN is supplied in a clear 300 ml PET bottle (60'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.