

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE (DISCIPLINE-SPECIFIC – COMBINATION PRODUCTS)

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 FOCUS (multiple substance, gummies)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:

L-Ascorbic Acid (Vitamin C)	15 mg
-----------------------------	-------

<i>Bacopa monnieri</i> (Bacopa)	12,5 mg
---------------------------------	---------

[whole herb, extract standardized
to bacosides 50 %]

<i>Helianthus annuus</i> L. (Sunflower Seed)	10 mg
--	-------

[seed, extract standardized to

phosphatidylserine 20 %]

Zinc Citrate	10,8 mg
providing Zinc (elemental)	2,5 mg
Pyridoxine Hydrochloride (Vitamin B6)	0,7 mg
Calcium D-Pantothenate (Pantothenic Acid)	0,5 mg
Ergocalciferol (Vitamin D2)	2,5 µg
Cyanocobalamin (Vitamin B12)	1,25 µg

Contains sugar: Glucose syrup (1,09 g); Sucrose (0,92 g)

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gummies

NUTRIPURE TEENS FOCUS is a red, conoid shaped gummy, cherry flavour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

NUTRIPURE TEENS FOCUS is a complementary medicine formulated to support mental and cognitive performance.

4.2. Posology and method of administration

Posology

Ages 13 years and older: Take two gummies 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 FOCUS 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 FOCUS** if they are pregnant or breastfeeding.

Bacopa should be used with caution in patients with thyroid disorders, pulmonary disorders (including asthma or chronic obstructive pulmonary disease) and urogenital tract obstruction.

If symptoms worsen, consult a relevant health care provider.

NUTRIPURE TEENS FOCUS contains approximately 1,09 g glucose syrup and 0,92 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 interaction studies have been performed with **NUTRIPURE TEENS FOCUS**.

Bacopa and phosphatidylserine may interact with anticholinergic medicines and cholinergic medicines, including acetylcholinesterase inhibitors. Bacopa may also interact with thyroid hormones and medicines affecting thyroid function.

Vitamin B6 may reduce the effects of levodopa when administered without a dopa decarboxylase inhibitor.

Zinc may reduce the absorption and clinical effects of tetracycline and quinolone antibiotics. These antibiotics should be administered at least 2 hours before or 4 to 6 hours after **NUTRIPURE TEENS FOCUS**.

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

Bacopa may cause drowsiness in some patients. Patients should exercise caution when driving, operating machinery or performing activities requiring alertness until they know how **NUTRIPURE TEENS FOCUS** affects them.

4.8. Undesirable effects

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

Gastrointestinal disorders:

Mild gastrointestinal discomfort including nausea, abdominal cramps, diarrhoea, bloating or dry mouth may occur.

Cardiac disorders:

Palpitations have been reported with Bacopa.

Nervous system disorders:

Headache, drowsiness and insomnia may occur.

Immune system disorders:

Hypersensitivity reactions may occur in susceptible individuals.

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 insufficient information available regarding overdose with **NUTRIPURE TEENS FOCUS**. In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Complementary Medicine – Discipline specific

D 33.7 Combination products

NUTRIPURE TEENS FOCUS is a combination complementary medicine containing vitamins, minerals and botanical extracts.

Bacopa monnieri contains pharmacologically active saponin glycosides, including bacosides. Bacopa has demonstrated antioxidant activity, and its potential effects on learning, memory and cognitive performance may involve modulation of cholinergic neurotransmission and other neuronal pathways.

Phosphatidylserine is a phospholipid that is an important structural component of neuronal cell membranes and contributes to normal neuronal membrane function.

Vitamin B6 is involved in amino acid metabolism and the synthesis and metabolism of several neurotransmitters.

Pantothenic acid contributes to normal energy-yielding metabolism.

Vitamin B12 contributes to the normal functioning of the nervous system and normal red blood cell formation.

Vitamin C contributes to the normal functioning of the nervous system and to the protection of cells from oxidative stress.

Vitamin D contributes to normal immune system function.

Zinc contributes to normal cognitive function and protection of cells from oxidative stress.

5.2. Pharmacokinetic properties

Pharmacokinetic data on the combination product are not available.

Bacopa saponin glycosides appear to have limited oral absorption and are primarily excreted in the faeces.

Vitamin B6 is absorbed from the gastrointestinal tract, converted in the liver to pyridoxal phosphate and excreted in the urine.

The remaining active substances are absorbed, distributed, metabolised and eliminated according to their individual physiological pathways.

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 FOCUS** 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 FOCUS 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.