

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 KIDS IMMUNE PLUS (multiple substance, gummies)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:

L-Ascorbic Acid (Vitamin C)	40 mg
<i>Sambucus nigra</i> L. (Elderberry)	25 mg
[fruit, 30:1 extract]	
<i>Apis mellifera</i> L. (Propolis)	3,25 mg
[beehive, extract standardized]	

to flavonoids 5 %]

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 KIDS IMMUNE PLUS is a red, bear-shaped gummy, red berries flavour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

NUTRIPURE KIDS IMMUNE PLUS is a complementary medicine that contains vitamin C, which contributes to the normal function of the immune system, contributes to normal energy-yielding metabolism, and contributes to the reduction of tiredness and fatigue. Propolis and elderberry are traditionally used to support immune health.

4.2. Posology and method of administration

Posology

Ages 3 years and older: Take one gummy once daily.

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

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.

Instruct child to chew each bear carefully and thoroughly.

4.3. Contraindications

NUTRIPURE KIDS IMMUNE PLUS 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**.

Contains bee-derived ingredients (Propolis). Do not use in individuals with known allergy to bee products, pollen or honey.

Do not give to children under 3 years old.

4.4. Special warnings and precautions for use

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

For use by children only under adult supervision.

The safety of prolonged oral use of propolis in children has not been established.
Elevated oestrogen levels have been reported in children following prolonged oral
propolis use.

Patients should consult a relevant health care provider before using **NUTRIPURE KIDS
IMMUNE PLUS** if they:

- are pregnant or breastfeeding;
- have an autoimmune disease.

If symptoms worsen, consult a relevant health care provider.

NUTRIPURE KIDS IMMUNE PLUS 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 KIDS IMMUNE PLUS**.

Elderberry may theoretically interfere with immunosuppressant medicines due to its potential immunostimulant activity. Patients using immunosuppressant medicines should consult a relevant health care provider before use.

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 KIDS IMMUNE PLUS is generally well tolerated when used at the recommended dose.

Hypersensitivity reactions may occur in susceptible individuals.

Gastrointestinal adverse effects, including nausea, abdominal discomfort and diarrhoea, may occur. Headache may occur.

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 available regarding overdose with **NUTRIPURE KIDS IMMUNE PLUS**.

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

Vitamin C contributes to the normal function of the immune system, contributes to normal energy-yielding metabolism, and contributes to the reduction of tiredness and fatigue.

Elderberry is traditionally used to support immune health.

Propolis is traditionally used to support immune health.

5.2. Pharmacokinetic properties

Pharmacokinetic studies have not been conducted with **NUTRIPURE KIDS IMMUNE PLUS**.

Vitamin C is absorbed from the gastrointestinal tract by a saturable transport mechanism. Oral absorption is higher at lower doses and decreases with increasing doses. Most absorbed vitamin C is excreted in the urine.

Elderberry anthocyanidins are detectable in plasma within approximately 30 minutes following oral administration, with peak concentrations occurring after approximately 3 to 4 hours. They are excreted in the urine as conjugated metabolites, with an estimated half-life of 2 to 6 hours.

Pharmacokinetic information for propolis is not available.

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 KIDS IMMUNE PLUS** 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 KIDS IMMUNE PLUS is supplied in a clear 400 ml bottle PET (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.