

## PROFESSIONAL INFORMATION

### COMPLEMENTARY MEDICINE (HEALTH SUPPLEMENT)

D 34.12 Multiple substance formulation

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

#### SCHEDULING STATUS

S0

#### 1. NAME OF THE MEDICINE

**NutriPure Kids Multi-Vit + Iron** (multiple substances, gummies)

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:

L-Ascorbic Acid (Vitamin C)	20 mg
Ferric pyrophosphate providing Iron (elemental)	13,34 mg 4 mg
Nicotinamide (Niacin)	4 mg
Calcium-D-Pantothenate (Pantothenic acid)	3 mg
DL-alpha-tocopheryl acetate (Vitamin E)	3 mg
Zinc citrate providing Zinc (elemental)	5,36 mg 1,5 mg
Pyridoxine hydrochloride (Vitamin B6)	0,7 mg
Retinyl Acetate (Vitamin A)	400 µg
Pteroylmonoglutamic acid (Folic Acid)	50 µg
D-Biotin (Biotin)	25 µg
Potassium Iodide providing Iodine (elemental)	3,26 mg 25 µg
Ergocalciferol (Vitamin D)	2,5 µg
Cyanocobalamin (Vitamin B12)	0,75 µg

Contains sugar: Glucose syrup (0,92 g); Sucrose (0,72 g)

For full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Gummies

NutriPure Kids Multi-Vit + Iron is bear-shaped red gummies with a characteristic berry taste and odour.

## **4. CLINICAL PARTICULARS**

### **4.1. Therapeutic indications**

NutriPure Kids Multi-Vit + Iron Gummies is a health supplement containing vitamins and minerals that:

- contribute to the normal functioning of the immune system,
- contributes to normal growth of children,
- contributes to normal energy-yielding metabolism.

### **4.2. Posology and method of administration**

#### **Posology**

Age 3 years: Give one (1) gummy daily.

Age 4 years & older: Give one (1) to two (2) gummies daily.

Do not give to children under 3 years old (see section **4.3 Contraindications**).

#### **Method of administration**

Take the chewable gummy orally. Instruct the child to chew each bear carefully and thoroughly.

### **4.3. Contraindications**

This product should not be used by patients who have an allergy or are hypersensitive to any of the ingredients.

If symptoms worsen, consult a relevant health care provider.

Not suitable for children under 3 years old.

### **4.4. Special warnings and precautions for use**

For use by children under adult supervision.

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take NutriPure Kids Multi-Vit + Iron Gummies.

Contains glucose syrup and sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Do not exceed the stated recommended daily dose without consulting a relevant health care provider.

Consult a relevant health care provider prior to use if you are pregnant or breastfeeding, as safety has not been established (see section **4.6. Fertility, pregnancy and lactation**).

#### **4.5. Interactions with other medicines and other forms of interaction**

##### **Interaction with Medicines**

**RETINOIDS:** Concomitant use of retinoids with vitamin A supplements might produce suprathereapeutic vitamin A levels.

**WARFARIN:** NutriPure Kids Multi-Vit + Iron Gummies may affect the levels of warfarin. High-dose vitamin C might reduce the levels and effectiveness of warfarin. Using vitamin E and high doses of Vitamin A with warfarin might increase the risk of bleeding.

**ANTICOAGULANT OR ANTIPLATELET MEDICINES:** Niacin and Vitamin E may have additive effects when used with anticoagulant or antiplatelet medicines.

**QUINOLONES ANTIBIOTICS:** Zinc may decrease the levels and clinical effects of quinolones antibiotics. Advise patients to take these medicines at least 2 hours before, or 4 to 6 hours after, zinc supplements.

**TETRACYCLINE ANTIBIOTICS:** Zinc may decrease the levels and clinical effects of tetracycline antibiotics. Advise patients to take these medicines at least 2 hours before, or 4 to 6 hours after, zinc supplements.

**PHENYTOIN:** High doses of vitamin B6 may reduce the levels and clinical effects of phenytoin. Advise people taking phenytoin to avoid high doses of vitamin B6. Folic acid might reduce serum levels of phenytoin in some patients.

**PHENOBARBITAL:** High doses of vitamin B6 may reduce the levels and clinical effects of phenobarbital. Advise people taking phenobarbital to avoid high doses of vitamin B6.

##### **Interaction with Herbs and Supplements**

**ANTICOAGULANT/ANTIPLATELET HERBS AND SUPPLEMENTS:** Niacin and Vitamin E may increase the risk of bleeding in some patients.

##### **Interactions with Foods**

None known.

##### **Interactions with Lab Tests**

None known.

#### **4.6. Fertility, pregnancy and lactation**

Safety in pregnancy and when breastfeeding has not been established, consult a health care provider prior to use (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**

Frequent adverse effects include abdominal cramps, constipation, diarrhoea, gastrointestinal irritation, heartburn, headache, nausea, and vomiting.

Less frequent but serious side effects include hepatotoxicity, myopathy, thrombocytopenia, bleeding, hemorrhagic stroke, cardiovascular complications and vision changes.

If adverse effects do occur, please discontinue use and consult your physician.

#### **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. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**” found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>.

#### **4.9. Overdose**

There is insufficient reliable information available about the presentation or treatment of overdose.

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

Treatment is symptomatic and supportive.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1. Pharmacodynamic properties**

D34.12 Multiple substance formulation

NutriPure Kids Multi-Vit + Iron Gummies contains vitamins and minerals that are factors in the maintenance of good health. Vitamin A, C, D, B6, B12 and Iron contributes to the normal functioning of the immune system. Iodine contributes to the normal growth of children. Niacin contributes to normal growth and development. Biotin, Pantothenic acid, Niacin, B12, B6 & Iron contribute to normal energy-yielding metabolism. Vitamin A, C and D helps in the development and maintenance of bones, cartilage, teeth and gums. Vitamin B12 and Iron helps form red blood cells and helps in their proper function.

#### **5.2. Pharmacokinetic properties**

There is no clinical pharmacokinetic data available on NutriPure Kids Multi-Vit + Iron Gummies to clarify the pharmacokinetic properties.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

Berry aroma,  
carnauba wax,  
citrus pectin,  
citric acid,  
fruit juice concentrate,  
glucose syrup,  
sodium citrate,  
sucrose,  
vegetable oil,  
water,  
E-163 anthocyanins (colourant).

### **6.2. Incompatibilities**

None known.

### **6.3. Shelf life**

The shelf life for NutriPure Kids Multi-Vit + Iron is 24 months.

### **6.4. Special precautions for storage**

Store at or below 25 °C in a cool, dry place.  
KEEP OUT OF REACH OF CHILDREN.

### **6.5. Nature and contents of container**

NutriPure Kids Multi-Vit + Iron container is a white, shiny 300 ml, plastic PET bottle with a green, CRC cap and a silver induction liner containing 60 gummies.

### **6.6. Special precautions for disposal and other handling**

No special requirements.

## **7. HOLDER OF CERTIFICATE OF REGISTRATION**

MDI Healthcare CC  
374 Anderson Street, Menlo Park  
Pretoria  
0081

### **Marketed by:**

NutriPure Healthcare

MDI Healthcare CC  
NutriPure Kids Multi-Vit + Iron Gummies  
Multiple substances

P.O. Box 16645,  
Vlaeberg,  
8018,  
Cape Town.

**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**

August 2024.