

## PROFESSIONAL INFORMATION

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### Category D: Complementary Medicine

#### Health Supplements: 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

**Gummy Vites Multivitamin**

**Multiple Substance Formulation, Gummies**

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<b>Each gummy contains:</b>	
Ascorbic acid (Vitamin C)	15 mg
Niacinamide (Vitamin B <sub>3</sub> )	6 mg
d-Pantothenic acid (Vitamin B <sub>5</sub> )	3 mg
Pyridoxine HCl (Vitamin B <sub>6</sub> )	1,1 mg
Zinc (as Zinc citrate)	500 µg
Riboflavin (Vitamin B <sub>2</sub> )	50 µg
D-Biotin (Vitamin H)	2,5 µg
Cyanocobalamin (Vitamin B <sub>12</sub> )	1,25 µg
All trans Retinyl acetate (Vitamin A)	1100 IU
Cholecalciferol (Vitamin D <sub>3</sub> )	250 IU
DL-alpha tocopheryl acetate (Vitamin E)	5 IU
Magnesium (as Magnesium citrate )	250 µg
Copper (as Copper gluconate )	5 µg

Contains sugar: 0,49 mg from elderberry concentrate and 0,2 mg from black carrot concentrate, Glucose 480 mg and Sucrose 1,36 g per gummy.

For the full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Gummies.

Dark orange coloured, grape flavoured bear-shaped gummies.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

- Contributes to the maintenance of eyesight, skin, membranes and immune function.
- Contributes to development and maintenance of night vision.
- Contributes to the development and maintenance of bones, cartilage, teeth and gums.
- A factor in the maintenance of good health.
- Helps to metabolise carbohydrates, fats and proteins.
- Contributes to tissue formation.
- Multi-vitamin/mineral supplement.
- Helps in wound healing.
- Helps in the absorption and use of calcium and phosphorus.
- Helps to form red blood cells.
- Helps in connective tissue formation.
- Helps to maintain healthy skin.

### 4.2 Posology and method of administration

#### Posology

Children aged 1- 3 years: Chew 1 gummy once daily after food.

Children 4 years and older: Chew 2 gummies once daily after food.

Chew thoroughly before swallowing.

Do not exceed the recommended dosage.

#### Method of administration

For oral use.

### 4.3 Contraindications

Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

- **Gummy Vites Multivitamin** contains:
  - Sucrose 1,36 g. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take **Gummy Vites Multivitamin**.

- Glucose 480 mg. Patients with rare glucose-galactose malabsorption should not take **Gummy Vites Multivitamin**.
- Sucrose and glucose may be harmful to the teeth.
- Less than 1 mmol sodium (23 mg) per gummy, that is to say essentially 'sodium-free'.

#### 4.5 Interaction with other medicines and other forms of interaction

There are no known interactions.

#### 4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

There is no fertility data available.

#### 4.7 Effects on ability to drive and use machines

**Gummy Vites Multivitamin** has no or negligible influence on the ability to drive and use machines.

#### 4.8 Undesirable effects

##### *a) Summary of the safety profile*

**Gummy Vites Multivitamin** is well tolerated.

##### *Reporting of suspected adverse reactions*

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

#### 4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity. Treatment should be symptomatic and supportive.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Category D: Complementary Medicine

Health Supplements: 34.12 Multiple Substance Formulation

ATC code: A11A Multivitamin, combinations

**Gummy Vites Multivitamin** is a multi-vitamin/mineral supplement which helps to metabolise carbohydrates, fats and proteins and is a factor in the maintenance of good health.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Beta-carotene [E160a]

Black carrot concentrate

Citric acid [E330]

Citrus pectin [E440]

Elderberry concentrate

Glucose syrup

Grape flavour

Sucrose

Sucrose syrup

Trisodium citrate [E331]

Water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

2 years.

### 6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light. Keep the container tightly closed.

Keep in the original container until required for use.

### 6.5 Nature and contents of container

A plastic bottle containing 60 or 120 gummies, fitted with a blue lid.

Not all pack sizes may be marketed.

### 6.6 Special warnings and precautions

No special requirements

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand

1685

Customer Care: 0860 ADCOCK/232625

**8. REGISTRATION NUMBER**

To be allocated

**9. DATE OF FIRST AUTHORISATION**

Not applicable.

**10. DATE OF REVISION OF THE TEXT**

4 October 2024

PI 311565 & 311547

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