

## PROFESSIONAL INFORMATION

---

### Category D: Complementary Medicine

#### Health Supplements: 34.11 Vitamins

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 VITAMIN C 60 mg Gummies**

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<b>Each gummy contains:</b>	
L-Ascorbic acid (Vitamin C)	60 mg

Contains sugar: Glucose 240 mg and Sucrose 1,4 g per gummy.

For the full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Gummies.

Yellow to orange coloured and citrus flavoured bear shaped gummies.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

**Gummy Vites Vitamin C** contributes to:

- Iron absorption from food and helps to metabolise fats and proteins.
- Cell protection from free radical damage and helps to maintain the normal function of the immune system.
- Normal collagen formation for the normal function of blood vessels, bones, cartilage, gums, skin, and teeth.
- Normal energy-yielding metabolism and helps protect cells from oxidative stress.
- Reduction of tiredness and fatigue, aids in the regeneration of the reduced form of Vitamin E and helps in connective tissue formation.
- Wound healing, act as an antioxidant for the maintenance of good health. Normal functioning of the nervous system
- Normal psychological function

## 4.2 Posology and method of administration

### Posology

Children aged 1 - 3 years: Chew 1 to 2 gummies twice daily.

Children aged 4 years and older: Chew 2 to 3 gummies twice daily.

Maximum dosage: 8 gummies per day.

Recommended for children over 12 months of age. Also suitable for adults.

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 Vitamin C** contains:

- Sucrose 1,4 g. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take **Gummy Vites Vitamin C**.
- Glucose 240 mg. Patients with rare glucose-galactose malabsorption should not take **Gummy Vites Vitamin C**.
- 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 Vitamin C** 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 Vitamin C** is generally well tolerated.

##### *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 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: 34.11 Vitamins

ATC code: A11GA Ascorbic acid (Vitamin C), plain

**Gummy Vites Vitamin C** contributes to normal psychological function and is a factor for the maintenance of good health.

### **6. PHARMACEUTICAL PARTICULARS**

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

Beta-carotene [E160a]

Burnt sugar

Citric acid [E330]

Citrus pectin [E440]

Glucose syrup

Orange flavour

Rose-hips extract (containing maltodextrin and silicon dioxide)

Sucrose

## PROFESSIONAL INFORMATION

---

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 unit required for use.

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

A plastic bottle containing 60 or 120 gummies, fitted with an orange lid.  
Not all pack sizes may be marketed.

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

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**

01 October 2024

PI 311551 & 311564 11/2024

**adcock ingram** 