

PROFESSIONAL INFORMATION

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

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1. NAME OF THE MEDICINE

**Gummy Vites Select Sugar Free Multivitamin
Multiple Substance Formulation, Gummies**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:	
Ascorbic acid (Vitamin C)	40 mg
dl- α -Tocopheryl Acetate (Vitamin E)	7,5 mg
Niacinamide (Vitamin B ₃)	4 mg
Calcium d-pantothenate (Vitamin B ₅)	2,5 μ g
Zinc (as Zinc citrate)	1 mg
Pyridoxine HCl (Vitamin B ₆)	850 μ g
Folic acid	200 μ g
Retinol Acetate (Vitamin A)	200 μ g
Potassium Iodide (Iodine)	75 μ g
D-Biotin (Vitamin H)	15 μ g
Cyanocobalamin (Vitamin B ₁₂)	1,2 μ g
Cholecalciferol (Vitamin D ₃)	200 IU

Sugar Free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gummies.

Red and purple coloured, grape and strawberry flavoured, bear-shaped gummies.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

A multivitamin and mineral supplement which assists in the:

- Maintenance of good health.
- Development and maintenance of night vision, bones, cartilage, teeth and gums.
- Connective tissue formation.
- Healing of wounds.
- Maintenance of eyesight, skin, membranes and immune function.
- Metabolising of carbohydrates, fats and proteins.

And contributes to:

- Normal growth and development, red blood cell formation, production of the thyroid hormones and normal thyroid function.
- Absorption and use of calcium and phosphorous.
- Reduction of tiredness and fatigue.

4.2 Posology and method of administration

Posology

Children over the age of 3 years: Chew 1 gummy 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 Select Sugar Free Multivitamin** should not be used by persons who are allergic to iodine
- **Gummy Vites Select Sugar Free Multivitamin** contains 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 Select Sugar Free 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 Select Sugar Free 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

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ATC code: A11A Multivitamin, combinations

Gummy Vites Select Sugar Free Multivitamin is a multi-vitamin/mineral supplement which assists in the metabolism of carbohydrates, fats and proteins and is a factor in the maintenance of good health.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Agar [E406]

PROFESSIONAL INFORMATION

Berries (strawberry) flavour (natural)
Carnauba wax [E903]
Chicory root fibre
Black carrot concentrate
Chlorophyll [E140]
Grape flavour (natural)
Pectin [E440]
Tapioca starch [1404]
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, out of direct sunlight.
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 gummies, fitted with a light blue lid.

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

PROFESSIONAL INFORMATION

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Not applicable.

10. DATE OF REVISION OF THE TEXT

25 October 2024

PI 213034 11/2024

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