

APPLICANT: ADCOCK INGRAM LIMITED

Amended:

PROPRIETARY NAME: GUMMY VITES MULTIVITAMIN

17 March 2021

DOSAGE FORM AND STRENGTH: Multicomponent

Line No.	CLEAN PROPOSED PACKAGE INSERT																										
1.																											
2.	SCHEDULING STATUS:																										
3.	S0																										
4.																											
5.	PROPRIETARY NAME AND DOSAGE FORM:																										
6.	GUMMY VITES MULTIVITAMIN (Jelly bear gums)																										
7.																											
8.	COMPOSITION:																										
9.	The active substances are: <table border="1"><thead><tr><th colspan="2">Each 2,5 g jelly bear gum contains:</th></tr></thead><tbody><tr><td>Ascorbic acid (Vitamin C)</td><td>15 mg</td></tr><tr><td>Niacinamide (Vitamin B₃)</td><td>6 mg</td></tr><tr><td>Calcium d-pantothenate (Vitamin B₅)</td><td>3 mg</td></tr><tr><td>Pyridoxine HCl (Vitamin B₆)</td><td>1,1 mg</td></tr><tr><td>Zinc citrate (Zinc)</td><td>500 µg</td></tr><tr><td>Folic acid</td><td>150 µg</td></tr><tr><td>Riboflavin (Vitamin B₂)</td><td>50 µg</td></tr><tr><td>Biotin</td><td>2,5 µg</td></tr><tr><td>Cyanocobalamin (Vitamin B₁₂)</td><td>1,3 µg</td></tr><tr><td>all-trans Retinyl Acetate (Vitamin A)</td><td>1100 IU</td></tr><tr><td>Cholecalciferol (Vitamin D₃)</td><td>250 IU</td></tr><tr><td>DL-alpha Tocopheryl Acetate (Vitamin E)</td><td>5 IU</td></tr></tbody></table>	Each 2,5 g jelly bear gum contains:		Ascorbic acid (Vitamin C)	15 mg	Niacinamide (Vitamin B ₃)	6 mg	Calcium d-pantothenate (Vitamin B ₅)	3 mg	Pyridoxine HCl (Vitamin B ₆)	1,1 mg	Zinc citrate (Zinc)	500 µg	Folic acid	150 µg	Riboflavin (Vitamin B ₂)	50 µg	Biotin	2,5 µg	Cyanocobalamin (Vitamin B ₁₂)	1,3 µg	all-trans Retinyl Acetate (Vitamin A)	1100 IU	Cholecalciferol (Vitamin D ₃)	250 IU	DL-alpha Tocopheryl Acetate (Vitamin E)	5 IU
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10.	Contains Sugar: 1,19 g Sucrose; 0,57 g Glucose and 0,24 g Sucrose Syrup																										

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DATE: 17 MAR 2021

SIGNATURE: 

Module 1.3.1.1
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11.	Excipients: Beta-carotene, black carrot concentrate, citric acid, citrus pectin, copper
12.	gluconate, elderberry concentrate, grape flavour, magnesium citrate, trisodium citrate,
13.	water.
14.	
15.	PHARMACOLOGICAL CLASSIFICATION:
16.	Category D: Complementary Medicine
17.	Discipline 34.12 Health Supplements. Multiple Substance Formulation
18.	This unregistered medicine has not been evaluated by SAHPRA for its quality,
19.	safety or intended use.
20.	
21.	PHARMACOLOGICAL ACTION:
22.	
23.	Pharmacodynamic Properties:
24.	The combination of the active ingredients contained in this formulation contributes to
25.	the maintenance of good health, tissue formation and metabolism of carbohydrates,
26.	fats and proteins.
27.	
28.	Pharmacokinetic Properties:
29.	The active ingredients in this formulation are well known. Pharmacokinetic studies have
30.	not been conducted due to its complex composition and the small quantities of the
31.	active ingredients it contains.
32.	
33.	
34.	INDICATIONS:
35.	<ul style="list-style-type: none">• Contributes to the maintenance of eyesight, skin, membranes and immune
36.	function.

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37.	<ul style="list-style-type: none">Contributes to development and maintenance of night vision.
38.	<ul style="list-style-type: none">Contributes to the development and maintenance of bones, cartilage, teeth and
39.	gums.
40.	<ul style="list-style-type: none">A factor in the maintenance of good health.
41.	<ul style="list-style-type: none">Helps to metabolise carbohydrates, fats and proteins.
42.	<ul style="list-style-type: none">Contributes to tissue formation.
43.	<ul style="list-style-type: none">Multi-vitamin/mineral supplement.
44.	<ul style="list-style-type: none">Helps in wound healing.
45.	<ul style="list-style-type: none">Helps in the absorption and use of calcium and phosphorus.
46.	<ul style="list-style-type: none">Helps to form red blood cells.
47.	<ul style="list-style-type: none">Helps in connective tissue formation
48.	<ul style="list-style-type: none">Helps to maintain healthy skin
49.	
50.	CONTRAINDICATIONS:
51.	GUMMY VITES MULTIVITAMIN Is contraindicated in individuals allergic or sensitive to
52.	any of the listed ingredients. No other contraindications are known.
53.	
54.	WARNINGS AND SPECIAL PRECAUTIONS:
55.	<ul style="list-style-type: none">Do not use this product if you are hypersensitive (allergic) to any of the ingredients.
56.	<ul style="list-style-type: none">Children on medication and pregnant or breastfeeding women must consult a
57.	doctor before use.
58.	<ul style="list-style-type: none">Do not exceed recommended dosages unless on the advice of a healthcare
59.	practitioner.
60.	<ul style="list-style-type: none">GUMMY VITES MULTIVITAMIN contains sucrose, glucose and sucrose syrup
61.	which may have an effect on the glycaemic control of patients with diabetes

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62.	mellitus.
63.	• GUMMY VITES MULTIVITAMIN contains sucrose. Patients with rare hereditary
64.	conditions such as fructose intolerance, glucose-galactose mal-absorption or
65.	sucrase-isomaltase insufficiency should not take GUMMY VITES MULTIVITAMIN.
66.	• If symptoms persist or worsen, consult a health care practitioner.
67.	
68.	INTERACTIONS:
69.	No known interactions have been established. If you suspect any interactions please
70.	consult your healthcare practitioner immediately.
71.	
72.	PREGNANCY AND LACTATION:
73.	Safety for use during pregnancy and lactation has not been established. Pregnant or
74.	breastfeeding women must consult a doctor before use.
75.	
76.	DOSAGE AND DIRECTIONS FOR USE:
77.	Children \geq 3 years: 2 jelly bear gums once daily
78.	Do not exceed the recommended dosage
79.	
80.	SIDE EFFECTS:
81.	GUMMY VITES MULTI VITAMIN is safe when taken in the recommended doses.
82.	Adverse effects are more likely to occur with higher doses. If any side effects occur
83.	please consult your healthcare practitioner immediately.
84.	
85.	KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS
86.	TREATMENT:
87.	Treatment should be symptomatic and supportive. In the case of accidental overdose of

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88.	the product, contact the nearest hospital or poison control centre.
89.	
90.	IDENTIFICATION:
91.	Orange coloured, grape flavoured bear-shaped gums
92.	
93.	PRESENTATION:
94.	GUMMY VITES MULTIVITAMIN are packed in white HDPE bottle with a white PP Lid.
95.	Pack Sizes: 60's, 120's
96.	
97.	STORAGE INSTRUCTIONS:
98.	Store in a cool, dry place at or below 25 °C.
99.	KEEP OUT OF THE REACH OF CHILDREN.
100.	Keep the container tightly closed.
101.	
102.	REGISTRATION NUMBER:
103.	To be allocated.
104.	
105.	NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF
106.	REGISTRATION:
107.	Adcock Ingram Limited
108.	1 New Road,
109.	Erand Gardens,
110.	Midrand,
111.	1685
112.	www.adcock.com
113.	Customer Care: 0860 ADCOCK/232625

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Line No.	CLEAN PROPOSED PACKAGE INSERT
114.	
115.	DATE OF PUBLICATION OF THIS PACKAGE INSERT:
116.	To be allocated.
117.	