

**APPLICANT:** ADCOCK INGRAM LIMITED

**Amended:**

**PROPRIETARY NAME:** GUMMY VITES MULTIVITAMIN

17 March 2021

**DOSAGE FORM AND STRENGTH:** Multicomponent

<b>Line No.</b>	<b>CLEAN PROPOSED PATIENT INFORMATION LEAFLET</b>
1.	
2.	Category D: Complementary Medicine
3.	Discipline 34.12 Health Supplements. Multiple Substance Formulation
4.	This unregistered medicine has not been evaluated by SAHPRA for its quality, safety
5.	or intended use.
6.	
7.	<b>SCHEDULING STATUS:</b>
8.	S0
9.	
10.	<b>PROPRIETARY NAME AND DOSAGE FORM:</b>
11.	GUMMY VITES MULTIVITAMIN (Jelly bear gums)
12.	
13.	<b>Read all of this leaflet carefully because it contains important information for</b>
14.	<b>you:</b>
15.	GUMMY VITES MULTIVITAMIN is available without a doctor's prescription, for you to
16.	maintain your health. Nevertheless, you still need to use GUMMY VITES
17.	MULTIVITAMIN carefully to get the best results from it.
18.	<ul style="list-style-type: none"><li>• Keep this leaflet. You may need to read it again.</li></ul>
19.	<ul style="list-style-type: none"><li>• Do not share GUMMY VITES MULTIVITAMIN with any other person.</li></ul>
20.	<ul style="list-style-type: none"><li>• Ask your pharmacist if you need more information or advice.</li></ul>
21.	You must see a doctor if your symptoms worsen or do not improve.
22.	
23.	<b>1. WHAT GUMMY VITES MULTIVITAMIN CONTAINS:</b>
24.	The active substances are: <div style="border: 1px solid black; padding: 5px; margin-top: 10px;">Each 2,5 g jelly bear gum contains:</div>

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	Ascorbic acid (Vitamin C)	15 mg
	Niacinamide (Vitamin B <sub>3</sub> )	6 mg
	Calcium d-pantothenate (Vitamin B <sub>5</sub> )	3 mg
	Pyridoxine HCl (Vitamin B <sub>6</sub> )	1,1 mg
	Zinc citrate (Zinc)	500 µg
	Folic acid	150 µg
	Riboflavin (Vitamin B <sub>2</sub> )	50 µg
	Biotin	2,5 µg
	Cyanocobalamin (Vitamin B <sub>12</sub> )	1,3 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
25.	Contains Sugar: 1,19 g Sucrose; 0,57 g Glucose and 0,24 g Sucrose Syrup	
26.	The other ingredients are: Beta-carotene, black carrot concentrate, citric acid, citrus	
27.	pectin, copper gluconate, magnesium citrate, elderberry concentrate, grape flavour,	
28.	trisodium citrate, water.	
29.		
30.	<b>2. WHAT GUMMY VITES MULTIVITAMIN IS USED FOR:</b>	
31.	• Contributes to the maintenance of eyesight, skin, membranes and immune	
32.	function.	
33.	• Contributes to development and maintenance of night vision.	
34.	• Contributes to the development and maintenance of bones, cartilage, teeth and	
35.	gums.	

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36.	<ul style="list-style-type: none"><li>• A factor in the maintenance of good health.</li></ul>
37.	<ul style="list-style-type: none"><li>• Helps to metabolise carbohydrates, fats and proteins.</li></ul>
38.	<ul style="list-style-type: none"><li>• Contributes to tissue formation.</li></ul>
39.	<ul style="list-style-type: none"><li>• Multi-vitamin/mineral supplement.</li></ul>
40.	<ul style="list-style-type: none"><li>• Helps in wound healing.</li></ul>
41.	<ul style="list-style-type: none"><li>• Helps in the absorption and use of calcium and phosphorus.</li></ul>
42.	<ul style="list-style-type: none"><li>• Helps to form red blood cells.</li></ul>
43.	<ul style="list-style-type: none"><li>• Helps in connective tissue formation</li></ul>
44.	<ul style="list-style-type: none"><li>• Helps to maintain healthy skin</li></ul>
45.	
46.	<b>3. BEFORE YOU TAKE GUMMY VITES MULTIVITAMIN:</b>
47.	<b>Do not take GUMMY VITES MULTIVITAMIN:</b>
48.	<ul style="list-style-type: none"><li>• If you are hypersensitive (allergic) to the active substances or any of the other</li></ul>
49.	ingredients of GUMMY VITES MULTIVITAMIN.
50.	
51.	<b>Pregnancy and breastfeeding:</b>
52.	Safety during pregnancy and lactation has not been established. If you are pregnant or
53.	breastfeeding your baby, please consult your doctor, pharmacist or other healthcare
54.	professional for advice before taking GUMMY VITES MULTIVITAMIN.
55.	
56.	<b>Taking/ giving/using other medicines with GUMMY VITES MULTIVITAMIN:</b>
57.	Always tell your healthcare professional if you are taking any other medicine.
58.	(This includes complementary or traditional medicines.)
59.	
60.	<b>Important information about some of the ingredients of GUMMY VITES</b>

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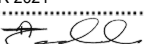
17 March 2021

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61.	<b>MULTIVITAMIN:</b>
62.	• If you have been told by your doctor that you have an intolerance to some sugars,
63.	contact your doctor before taking GUMMY VITES MULTIVITAMIN.
64.	• GUMMY VITES MULTIVITAMIN contains sucrose, glucose and sucrose syrup
65.	which may have an effect on the control of your blood sugar if you have diabetes
66.	mellitus.
67.	
68.	<b>4. HOW TO TAKE GUMMY VITES MULTIVITAMIN:</b>
69.	Do not share medicines prescribed for you with any other person.
70.	
71.	Always take GUMMY VITES MULTIVITAMIN exactly as your doctor has instructed
72.	you. You should check with your doctor or pharmacist if you are unsure.
73.	
74.	The recommended daily dose is:
75.	Children ≥ 3 years: 2 jelly bear gums once daily
76.	Do not exceed the recommended dosage
77.	
78.	<b>If you take GUMMY VITES MULTIVITAMIN more than you should:</b>
79.	In the event of overdosage, consult your doctor or pharmacist. If neither is available,
80.	contact the nearest hospital or poison control centre.
81.	
82.	<b>If you forget to take or missed a dose of GUMMY VITES MULTIVITAMIN:</b>
83.	Do not take a double dose to make up for forgotten individual doses.
84.	
85.	<b>5. POSSIBLE SIDE EFFECTS:</b>

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DATE: 17 MAR 2021  
SIGNATURE: 

Module 1.3.1.1  
Page 4 of 6

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86.	GUMMY VITES MULTIVITAMIN can have side effects.
87.	
88.	GUMMY VITES MULTIVITAMIN is safe when taken in the recommended doses.
89.	Adverse effects are more likely to occur with higher doses. If any side effects occur
90.	please consult your healthcare practitioner immediately.
91.	
92.	Not all side effects reported for GUMMY VITES MULTIVITAMIN are included in this
93.	leaflet.
94.	
95.	Should your general health worsen or if you experience any untoward effects while
96.	taking GUMMY VITES MULTIVITAMIN, please consult your doctor, pharmacist or
97.	other healthcare professional for advice.
98.	
99.	If you notice any side effects not mentioned in this leaflet, please inform your doctor
100.	or pharmacist.
101.	
102.	<b>6. STORING AND DISPOSING OF GUMMY VITES MULTIVITAMIN:</b>
103.	STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
104.	Store in a cool, dry place at or below 25 °C.
105.	Keep the container tightly closed.
106.	Do not store in a bathroom.
107.	Do not use after the expiry date stated on the label / bottle.
108.	Return all unused medicine to your pharmacist.
109.	Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
110.	

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111.	<b>7. PRESENTATION OF GUMMY VITES MULTIVITAMIN:</b>
112.	GUMMY VITES MULTIVITAMIN are packed in white HDPE bottle with a white PP Lid.
113.	Pack Sizes: 60's, 120's
114.	
115.	<b>8. IDENTIFICATION OF GUMMY VITES MULTIVITAMIN</b>
116.	Orange coloured, grape flavoured bear-shaped gums
117.	
118.	<b>9. REGISTRATION NUMBER</b>
119.	To be allocated.
120.	
121.	<b>10. NAME AND ADDRESS OF REGISTRATION HOLDER:</b>
122.	Adcock Ingram Limited
123.	1 New Road
124.	Erand Gardens
125.	Midrand, 1685
126.	<a href="http://www.adcock.com">www.adcock.com</a>
127.	Customer Care: 0860 ADCOCK/232625
128.	
129.	<b>11. DATE OF PUBLICATION:</b>
130.	To be allocated.