

APPLICANT: ADCOCK INGRAM LIMITED

Amended:

28 July

2020

PROPRIETARY NAME: Gummy Vites Omega 3

DOSAGE FORM AND STRENGTH: Each softgel capsule contains Fish Oil 250 mg, Vitamin C 29 mg, Vitamin D 3,3 µg and Vitamin E 2,2 mg

CLEAN PROPOSED PATIENT INFORMATION LEAFLET		
1.		
2.	Category D: Complementary Medicine	
3.	Health supplements. Discipline 34.12: Multiple Substance Formula.	
4.	This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or	
5.	intended use.	
6.		
7.	SCHEDULING STATUS:	
8.	S0	
9.		
10.	PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:	
11.	Gummy Vites Omega 3 (Softgel capsules)	
12.		
13.	Read all of this leaflet carefully because it contains important information for you:	
14.	Gummy Vites Omega 3 is available without a doctor's prescription, for you to treat a	
15.	mild illness. Nevertheless, you still need to use Gummy Vites Omega 3 carefully to get	
16.	the best results from it.	
17.	<ul style="list-style-type: none">• Keep this leaflet. You may need to read it again.	
18.	<ul style="list-style-type: none">• Do not share Gummy Vites Omega 3 with any other person.	
19.	<ul style="list-style-type: none">• Ask your pharmacist if you need more information or advice.	
20.	You must see a doctor if your symptoms worsen or do not improve.	
21.		
22.	1. WHAT Gummy Vites Omega 3 CONTAINS:	
23.	The active substances are:	
24.	<i>Each softgel capsule contains:</i>	
	<table border="1"><tr><td>Fish oil</td><td>250 mg</td></tr></table>	Fish oil
Fish oil	250 mg	

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	<i>Containing:</i>		
	Eicosapentaenoic acid (EPA)	15 mg	
	Docosahexaenoic acid (DHA)	87,5 mg	
	Ascorbic acid (Vitamin C)	29 mg	
	Alpha-tocopheryl acetate (Vitamin E)	2,2 mg	
	Cholecalciferol (Vitamin D)	3,3 µg	
25.	Contains sugar alcohol: Mannitol 207 mg		
26.	Contains Sweeteners: Acesulfame Potassium 1000 mg, Aspartame 1750 mg		
27.	The other ingredients are: Acesulfame potassium, aspartame, citric acid monohydrate,		
28.	flavourant, gelatin, glycerine, hydrogenated soy bean oil, mannitol, titanium dioxide.		
29.			
30.	2. WHAT Gummy Vites Omega 3 IS USED FOR:		
31.	Fish Oils:		
32.	• Source of omega-3 fatty acids for the maintenance of good health.		
33.	• Source of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) for		
34.	the maintenance of good health.		
35.	• Helps support cognitive health and/or brain function*		
36.	Vitamin C:		
37.	• Helps to metabolise fats and proteins		
38.	• Helps in the development and maintenance of bones, cartilage, teeth and gums		
39.	• Helps in connective tissue formation		
40.	• Helps in wound healing		
41.	Vitamin D:		
42.	• Helps in the absorption and use of calcium and phosphorous		
43.	Vitamin E:		
44.	• An antioxidant for the maintenance of good health		

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45.	
46.	3. BEFORE YOU TAKE Gummy Vites Omega 3:
47.	Do not take Gummy Vites Omega 3:
48.	<ul style="list-style-type: none">If you are hypersensitive (allergic) to the active substances or any of the other
49.	ingredients of Gummy Vites Omega 3 .
50.	
51.	Pregnancy and breastfeeding:
52.	If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist
53.	or other healthcare professional for advice before taking Gummy Vites Omega 3 .
54.	
55.	Important information about some of the ingredients of Gummy Vites Omega 3:
56.	Gummy Vites Omega 3 contains mannitol and may have a laxative effect.
57.	
58.	Taking/ giving/using other medicines with Gummy Vites Omega 3:
59.	Always tell your healthcare professional if you are taking any other medicine.
60.	(This includes complementary or traditional medicines.)
61.	<ul style="list-style-type: none">Do not take Gummy Vites Omega 3 with aspirin, anticoagulants or other drugs
62.	affecting coagulation.
63.	<ul style="list-style-type: none">Do not take Gummy Vites Omega 3 with thiazide diuretics, calcium, or phosphate.
64.	<ul style="list-style-type: none">Vitamin C in Gummy Vites Omega 3 may increase the absorption of iron in iron-
65.	deficiency states.
66.	<ul style="list-style-type: none">Omeprazole may affect the bioavailability of dietary Vitamin C in Gummy Vites
67.	Omega 3 .
68.	<ul style="list-style-type: none">Carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, isoniazid and
69.	corticosteroids may decrease Vitamin D levels.
70.	<ul style="list-style-type: none">Colestyramine, colestipol, and orlistat may interfere with the absorption of vitamin E

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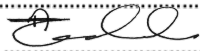
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71.	found in Gummy Vites Omega 3 .
72.	
73.	4. HOW TO TAKE Gummy Vites Omega 3:
74.	Do not share medicines prescribed for you with any other person.
75.	
76.	Always take Gummy Vites Omega 3 exactly as your doctor has instructed you. You
77.	should check with your doctor or pharmacist if you are unsure.
78.	
79.	The usual dose is:
80.	Infants 1 - 2 years: Take 1 capsule daily mixed with cereal or liquids (puncture capsule
81.	and squeeze contents out)
82.	Children 2 - 4 years: Chew 1 - 2 capsules daily
83.	Children 4 years and older: Chew 2 - 3 capsules daily
84.	A varied diet is the most effective and safe way to achieve good nutrition, health, body
85.	composition as well as mental and physical performance.
86.	Do not exceed recommended dosages unless on the advice of a healthcare
87.	practitioner.
88.	If you have the impression that the effect of Gummy Vites Omega 3 is too strong or
89.	too weak, tell your doctor or pharmacist.
90.	
91.	If you take more Gummy Vites Omega 3 than you should:
92.	Treatment should be symptomatic and supportive. In the case of accidental overdose of
93.	the product, contact the nearest hospital or poison control centre.
94.	
95.	If you forget to take Gummy Vites Omega 3:
96.	Do not take a double dose to make up for forgotten individual doses.

RA APPROVED

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DATE: 28 JUL 2020

SIGNATURE: 

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97.	
98.	5. POSSIBLE SIDE EFFECTS:
99.	Gummy Vites Omega 3 can have side effects.
100.	Not all side effects reported for Gummy Vites Omega 3 are included in this leaflet.
101.	Should your general health worsen or if you experience any untoward effects while
102.	taking Gummy Vites Omega 3 , please consult your doctor, pharmacist or other
103.	healthcare professional for advice.
104.	
105.	Tell your doctor if you notice any of the following frequent side effects:
106.	gastrointestinal disturbances, particularly at high doses, including nausea, belching,
107.	vomiting, abdominal distension, diarrhoea, and constipation.
108.	
109.	Tell your doctor if you notice any of the following less frequent side effects:
110.	Hypersensitivity reactions have occurred.
111.	
112.	If you notice any side effects not mentioned in this leaflet, please inform your doctor
113.	or pharmacist.
114.	
115.	6. STORING AND DISPOSING OF Gummy Vites Omega 3:
116.	STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
117.	Store at or below 25 °C.
118.	Store in the original package/container.
119.	Keep the container tightly closed.
120.	Protect from light / moisture.
121.	Do not store in a bathroom.
122.	Do not use after the expiry date stated on the label / carton / bottle.

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123.	Return all unused medicine to your pharmacist.
124.	Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
125.	
126.	7. PRESENTATION OF Gummy Vites Omega 3:
127.	30 Soft gel capsules packed in a white plastic bottle.
128.	60 Soft gel capsules packed in a white plastic bottle.
129.	Not all pack sizes might be marketed simultaneously.
130.	
131.	8. IDENTIFICATION OF Gummy Vites Omega 3:
132.	Oblong shaped golden to beige coloured soft gel capsules.
133.	
134.	9. REGISTRATION NUMBER
135.	To be allocated.
136.	
137.	10. NAME AND ADDRESS OF REGISTRATION HOLDER:
138.	Adcock Ingram Limited
139.	1 New Road
140.	Erand Gardens
141.	Midrand, 1685
142.	Private Bag X69
143.	Bryanston, 2021
144.	www.adcock.com
145.	
146.	11. DATE OF PUBLICATION:
147.	To be allocated.