

APPLICANT: ADCOCK INGRAM LIMITED

Amended:

PROPRIETARY NAME: VIRALGUARD IMMUNE BOOSTER BOX

08 April 2021

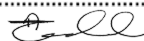
DOSAGE FORM AND STRENGTH: Multicomponent

Line No.	CLEAN PROPOSED PACKAGE INSERT	
1.		
2.	<b>SCHEDULING STATUS:</b>	
3.	S0 ViralGuard Vitamin C 1000 mg	
4.	S0 ViralGuard D <sub>3</sub>	
5.	S0 ViralGuard Zinc	
6.		
7.	<b>PROPRIETARY NAME AND DOSAGE FORM:</b>	
8.	<b>VIRALGUARD IMMUNE BOOSTER BOX</b>	
9.	ViralGuard Vitamin C 1000 mg (effervescent tablet), ViralGuard D <sub>3</sub> (capsule),	
10.	ViralGuard Zinc (capsule)	
11.		
12.	<b>COMPOSITION:</b>	
13.	<b><u>ViralGuard Vitamin C 1000 mg:</u></b>	
14.	<b>Each effervescent tablet contains:</b>	
	Vitamin C	1000 mg
15.	Preservative: Sodium benzoate 0,005 % <i>m/m</i>	
16.	Contains Sugar: Sorbitol 450 mg.	
17.	Contains artificial sweetener: Sucralose 38 mg.	
18.	Excipients: Citric acid anhydrous, colourant, flavourant, polyethylene glycol, povidone,	
19.	simethicone, sodium bicarbonate, sodium lauryl sulphate.	
20.		
21.	<b><u>ViralGuard D<sub>3</sub>:</u></b>	
22.	<b>Each capsule contains:</b>	
	Vitamin D <sub>3</sub>	800 IU
23.	Excipients: Colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose.	

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24.	Sugar free.	
25.		
26.	<b><u>ViralGuard Zinc:</u></b>	
27.	<b>Each capsule contains:</b>	
	Zinc bisglycinate (Zinc)	15 mg
	Pyridoxine (Vitamin B <sub>6</sub> )	10 mg
	Folic acid (Vitamin B <sub>9</sub> )	0,4 mg
	Cyanocobalamin (Vitamin B <sub>12</sub> )	0,1 mg
28.	Excipients: Colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose	
29.	Sugar free.	
30.		
31.	<b>PHARMACOLOGICAL CLASSIFICATION:</b>	
32.	Category D: Complementary Medicine: Health Supplements.	
33.	<b>ViralGuard Vitamin C 1000 mg:</b> 34.11 Vitamins.	
34.	<b>ViralGuard D<sub>3</sub>:</b> 34.11 Vitamins.	
35.	<b>ViralGuard Zinc:</b> 34.12: Multiple Substance Formulation.	
36.	This unregistered medicine has not been evaluated by SAHPRA for its quality,	
37.	safety or intended use.	
38.		
39.	<b>PHARMACOLOGICAL ACTION:</b>	
40.		
41.	<b><u>ViralGuard Vitamin C 1000 mg:</u></b>	
42.	Vitamin C is a commonly used water-soluble vitamin. Vitamin C has a role in several	
43.	physiological functions. It is involved in tyrosine metabolism and is a cofactor in the	
44.	synthesis of carnitine, thyroxin, norepinephrine, dopamine, and tryptophan. Vitamin C is	
45.	also involved in a variety of metabolic processes including oxidation-reduction reactions	

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46.	and cellular respiration, carbohydrate metabolism, synthesis of lipids and proteins,
47.	catabolism of cholesterol to bile acids, conversion of folic acid to folinic acid, and iron
48.	metabolism. Vitamin C is probably best known for its effects as an antioxidant and its
49.	role in maintaining proper immune function.
50.	
51.	<b><u>ViralGuard D<sub>3</sub>:</u></b>
52.	The physiological role of vitamin D is to promote absorption and
53.	utilization of calcium and phosphate and for normal calcification of bones. The
54.	mechanism by which vitamin D acts to maintain normal concentrations of calcium and
55.	phosphate in plasma is to facilitate their absorption in the small intestine, to enhance
56.	their mobilization from bone and to decrease their excretion by the kidneys.
57.	
58.	<b><u>ViralGuard Zinc:</u></b>
59.	<i>Vitamin B<sub>6</sub></i> , a water-soluble vitamin, is involved mainly in amino acid metabolism, but is
60.	also involved in carbohydrate and fat metabolism. It is also required for the formation of
61.	haemoglobin.
62.	<i>Vitamin B<sub>12</sub></i> , a water-soluble vitamin, occurs in the body mainly as methylcobalamin
63.	(mecobalamin) and as adenosylcobalamin (cobamamide) and hydroxocobalamin.
64.	Mecobalamin and cobamamide act as coenzymes in nucleic acid synthesis.
65.	Mecobalamin is also closely involved with folic acid in several important metabolic
66.	pathways.
67.	<i>Folic acid</i> is a member of the vitamin B group. Folic acid is reduced in the body to
68.	tetrahydrofolate, which is a coenzyme for various metabolic processes including the
69.	synthesis of purine and pyrimidine nucleotides, and hence in the synthesis of DNA; it is
70.	also involved in some amino-acid conversions, and in the formation and utilisation of
71.	formate.

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72.	Zinc is an essential element of nutrition and traces are present in a wide range of foods.
73.	It is a constituent of many enzyme systems and is present in all tissues.
74.	
75.	<b>INDICATIONS:</b>
76.	<b><u>ViralGuard Vitamin C 1000 mg:</u></b>
77.	• Contributes to iron absorption from food
78.	• Helps to metabolise fats and proteins
79.	• Contributes to maintain the normal function of the immune system during and
80.	after intense physical stress.
81.	• Contributes to normal collagen formation for the normal function of blood
82.	vessels, bones, cartilage, gums, skin, teeth
83.	• Contributes to normal energy-yielding metabolism
84.	• Contributes to normal functioning of the nervous system
85.	• Contributes to normal psychological function
86.	• Contributes to the normal function of the immune system
87.	• Contributes to the protection of cells from oxidative stress
88.	• Contributes to the reduction of tiredness and fatigue
89.	• Contributes to the regeneration of the reduced form of Vitamin E
90.	• Helps in connective tissue formation
91.	• Contributes to wound healing
92.	• An antioxidant for the maintenance of good health
93.	• A factor in the maintenance of good health
94.	
95.	<b><u>ViralGuard D<sub>3</sub>:</u></b>
96.	• Helps in the absorption and use of calcium and phosphorous

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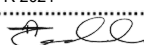
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**DOSAGE FORM AND STRENGTH:** Multicomponent

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97.	<ul style="list-style-type: none"><li>Contributes to normal cell division</li></ul>
98.	<ul style="list-style-type: none"><li>Contributes to normal blood calcium levels</li></ul>
99.	<ul style="list-style-type: none"><li>Contributes to the development and maintenance of strong bones and teeth</li></ul>
100.	<ul style="list-style-type: none"><li>Contributes to the maintenance of normal muscle function</li></ul>
101.	<ul style="list-style-type: none"><li>Contributes to the normal function of the immune system</li></ul>
102.	<ul style="list-style-type: none"><li>Calcium intake, when combined with sufficient vitamin D, a healthy diet and regular</li></ul>
103.	<ul style="list-style-type: none"><li>exercise, may reduce the risk of developing osteoporosis.</li></ul>
104.	<ul style="list-style-type: none"><li>A factor in the maintenance of good health</li></ul>
105.	<ul style="list-style-type: none"><li>Has a role in the process of cell division</li></ul>
106.	
107.	<b><u>ViralGuard Zinc:</u></b>
108.	<ul style="list-style-type: none"><li>Helps to metabolise carbohydrates, fats and proteins</li></ul>
109.	<ul style="list-style-type: none"><li>Contributes to tissue formation</li></ul>
110.	<ul style="list-style-type: none"><li>A factor in the maintenance of good health</li></ul>
111.	<ul style="list-style-type: none"><li>Multi-vitamin/mineral supplement</li></ul>
112.	<ul style="list-style-type: none"><li>Contributes to normal red blood cell formation</li></ul>
113.	<ul style="list-style-type: none"><li>Helps in connective tissue formation</li></ul>
114.	<ul style="list-style-type: none"><li>Helps to maintain healthy skin</li></ul>
115.	<ul style="list-style-type: none"><li>Helps to maintain immune function</li></ul>
116.	<ul style="list-style-type: none"><li>Contributes to normal functioning of the nervous system</li></ul>
117.	<ul style="list-style-type: none"><li>Contributes to the reduction of tiredness and fatigue</li></ul>
118.	
119.	<b>CONTRAINDICATIONS:</b>
120.	Hypersensitivity to any of the ingredients.
121.	

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122.	<b><u>ViralGuard D<sub>3</sub>:</u></b>
123.	Vitamin D should not be given to patients with hypercalcaemia.
124.	
125.	<b><u>ViralGuard Zinc:</u></b>
126.	Cyanocobalamin should not be used for Leber's disease or tobacco amblyopia since
127.	these optic neuropathies may degenerate further.
128.	
129.	<b>WARNINGS AND SPECIAL PRECAUTIONS:</b>
130.	
131.	<b><u>ViralGuard Vitamin C 1000 mg:</u></b>
132.	• Large doses of Vitamin C may result in hyperoxaluria and the formation of renal
133.	calcium oxalate calculi and ascorbic acid should therefore be given with care to
134.	patients with hyperoxaluria.
135.	• Tolerance may be induced with prolonged use of large doses, resulting in
136.	symptoms of deficiency when intake is reduced to normal.
137.	• Large doses of Vitamin C have resulted in haemolysis in patients with G6PD
138.	deficiency.
139.	• Contains sorbitol and may have a laxative effect.
140.	• Patients with rare hereditary condition of sorbitol should not take VIRALGUARD
141.	VITAMIN C 1000 mg.
142.	
143.	<b><u>ViralGuard D<sub>3</sub>:</u></b>
144.	• VIRALGUARD D <sub>3</sub> should be used with caution in patients with renal impairment or
145.	calculi, or heart disease, who might be at increased risk of organ damage if
146.	hypercalcaemia occurred.
147.	

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148.	<b>INTERACTIONS:</b>
149.	
150.	<b><u>ViralGuard Vitamin C 1000 mg:</u></b>
151.	Vitamin C has an effect on various medicines which include <i>hormonal contraceptives</i> ,
152.	<i>fluphenazine and warfarin</i> . <i>Omeprazole</i> may affect the bioavailability of dietary Vitamin
153.	C and Vitamin C may increase the absorption of <i>iron</i> in iron deficiency states.
154.	
155.	<b><u>ViralGuard D<sub>3</sub>:</u></b>
156.	• There is an increased risk of hypercalcaemia if vitamin D is given with <i>thiazide</i>
157.	<i>diuretics, calcium, or phosphate</i> .
158.	• Some antiepileptics may increase vitamin D requirements (e.g. <i>carbamazepine</i> ,
159.	<i>phenobarbital, phenytoin, and primidone</i> ).
160.	• <i>Rifampicin</i> and <i>isoniazid</i> may reduce the effectiveness of vitamin D.
161.	• <i>Corticosteroids</i> may counteract the effect of vitamin D.
162.	• <i>Ketoconazole</i> may inhibit the metabolism of paricalcitol and these drugs should be
163.	used with caution together; care should be taken when using paricalcitol with other
164.	potent inhibitors of the cytochrome P450 isoenzyme CYP3A4.
165.	
166.	<b><u>ViralGuard Zinc:</u></b>
167.	<i>Chloramphenicol</i> : Parenteral chloramphenicol may attenuate the effect of vitamin
168.	B <sub>12</sub> in anaemia.
169.	<i>Copper, Fluoroquinolones, Iron, Penicillamine, Tetracyclines</i> : Zinc reduces the
170.	absorption of these drugs.
171.	<i>Levodopa</i> : Vitamin B <sub>6</sub> reduces the effects of levodopa, but this does not occur if a
172.	dopa decarboxylase inhibitor is also given.
173.	<i>Phenobarbital</i> : Vitamin B <sub>6</sub> decreases serum concentrations of phenobarbital.

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174.	<i>Phenytoin:</i> Vitamin B <sub>6</sub> decreases serum concentrations of phenytoin.	
175.	<u>Nutrient Depletion:</u>	
176.	Vitamin B <sub>6</sub>	Hydralazine, isoniazid, penicillamine, and oral contraceptives.
	Vitamin B <sub>12</sub>	Neomycin, aminosalicylic acid, histamine H <sub>2</sub> -antagonists, omeprazole, colchicine, oral contraceptives.
	Folic acid	Anti-epileptics, oral contraceptives, anti-tuberculosis drugs, alcohol, glucarpidase, methotrexate, pyrimethamine, triamterene, trimethoprim, and sulfonamides.
	Zinc	Iron supplements, penicillamine, phosphorus-containing preparations, and tetracyclines.
177.		
178.	<b>PREGNANCY AND LACTATION:</b>	
179.	Safety during pregnancy and lactation has not been established. Please consult your	
180.	healthcare practitioner prior to use.	
181.		
182.	<b>DOSAGE AND DIRECTIONS FOR USE:</b>	
183.	Take one (1) capsule each of VIRALGUARD D <sub>3</sub> and VIRALGUARD ZINC daily.	
184.	Dissolve one (1) tablet of VIRALGUARD VITAMIN C 1000 mg separately in half a glass	
185.	of water, once daily.	
186.	Drink the mixture as soon as the effervescing has stopped.	
187.	All 3 products can be taken at the same time.	
188.	Do not exceed the recommended daily dosage.	
189.	Not recommended for use in children below 18 years of age.	
190.		
191.	<b>SIDE EFFECTS:</b>	
192.		



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193.	<b><u>ViralGuard Vitamin C 1000 mg:</u></b>
194.	Ascorbic acid is usually well tolerated. Large doses are reported to cause diarrhoea
195.	and other gastrointestinal disturbances.
196.	
197.	<b><u>ViralGuard D<sub>3</sub>:</u></b>
198.	Doses of vitamin D analogues that do not exceed the physiologic requirements are non-
199.	toxic.
200.	
201.	<b><u>ViralGuard Zinc:</u></b>
202.	No known side effects have been established.
203.	
204.	<b>KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS</b>
205.	<b>TREATMENT:</b>
206.	
207.	<b><u>ViralGuard Vitamin C 1000 mg:</u></b>
208.	Treatment is symptomatic and supportive.
209.	
210.	<b><u>ViralGuard Vitamin D<sub>3</sub>:</u></b>
211.	The acute or chronic administration of excessive amounts of vitamin D or enhanced
212.	responsiveness to normal amounts of the vitamin leads to a number of clinical
213.	syndromes that are the result of deranged calcium metabolism. Treatment should be
214.	symptomatic and supportive.
215.	
216.	<b><u>ViralGuard Zinc:</u></b>
217.	No known symptoms of overdose have been established. Treatment is symptomatic
218.	and supportive.

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219.	
220.	<b>IDENTIFICATION:</b>
221.	VIRALGUARD VITAMIN C 1000 mg are light orange, round, flat, bevelled edge
222.	effervescent tablets.
223.	VIRALGUARD D <sub>3</sub> are opaque white and green hard gelatin capsules.
224.	VIRALGUARD ZINC are opaque pink and white hard gelatin capsules.
225.	
226.	<b>PRESENTATION:</b>
227.	VIRALGUARD IMMUNE BOOSTER BOX is presented as an outer carton containing:
228.	• 10 VIRALGUARD VITAMIN C 1000 mg effervescent tablets in a plastic tube with a
229.	tamper-proof plastic closure
230.	• 10 VIRALGUARD D <sub>3</sub> capsules in a PVC/PVDC/Aluminium blister strip
231.	• 10 VIRALGUARD ZINC capsules in a PVC/PVDC/Aluminium blister strip
232.	
233.	<b>STORAGE INSTRUCTIONS:</b>
234.	Store in a cool, dry place at or below 25 °C.
235.	KEEP OUT OF REACH OF CHILDREN.
236.	Do not remove the effervescent tablet from its container until just before use.
237.	Protect from light and moisture.
238.	Store in carton until before use.
239.	
240.	<b>REGISTRATION NUMBER:</b>
241.	To be allocated.
242.	
243.	<b>NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF</b>
244.	<b>REGISTRATION:</b>

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Line No.	CLEAN PROPOSED PACKAGE INSERT
245.	Adcock Ingram Limited
246.	1 New Road,
247.	Erand Gardens,
248.	Midrand,
249.	1685
250.	<a href="http://www.adcock.com">www.adcock.com</a>
251.	Customer Care: 0860 ADCOCK/ 232625
252.	
253.	<b>DATE OF PUBLICATION OF THIS PACKAGE INSERT:</b>
254.	To be allocated.
255.	