

Product proprietary name: ViralGuard Fizzi Chews

Dosage form and strength: Probiotics blend consisting of *Lactobacillus rhamnosus* and *Bifidobacterium longum* 100 million CFU; Elderberry Extract 20 mg; Propolis Extract 5 mg; Beta Carotene 10% 4,1 mg; Vitamin A 140 µg; Thiamine(Vitamin B1) 0,9 mg; Riboflavin (Vitamin B2) 1 mg; Pyridoxine (Vitamin B6) 1 mg; Vitamin B12 0,2 µg; Vitamin D3 9 µg; Vitamin E 17 mg; Nicotinamide 10 mg; Folic Acid 200 µg; Biotin 40 µg; Calcium Pantothenate 10 mg; Vitamin C 65 mg; Zinc Oxide 5,4 mg; Magnesium Oxide 48,2 mg; Iron 2,3 mg; Selenium 29 µg, Calcium Carbonate 16 mg; Manganese Sulphate 0,58 mg per tablet

Applicant/PHCR: Adcock Ingram Limited

PART 1 C LABELLING

a) Package insert

The under-mentioned information with regard to this medicine shall appear on the package insert. The information shall be presented in the format stipulated, provided that the Council may authorize any deviation from such information or such format (refer to Regulation 9 of the Act).

1. Scheduling status
2. Proprietary name and dosage form
3. Composition
4. Pharmacological classification
5. Pharmacological action
(Pharmacokinetics, pharmacodynamics and summary of clinical studies, where applicable)
6. Indications
7. Contra-indications
8. Warnings
9. Interactions
10. Pregnancy and lactation
11. Dosage and directions for use
12. Side effects and special precautions
13. Known symptoms of overdosage and particulars of its treatment
14. Identification
15. Presentation
16. Storage instructions
17. Registration number
18. Name and business address of the holder of the certificate of registration
19. Date of publication of the package insert

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PROPOSED PACKAGED INSERT:

1. Scheduling status		
Not Scheduled		
2. Proprietary name and dosage form		
VIRALGUARD FIZZI CHEWS (Tablet)		
3. Composition		
VIRALGUARD FIZZI CHEWS contains:		
Ingredient	Per tablet	
Probiotic blend consisting of:		
<i>Lactobacillus rhamnosus</i>	100 million cfu*	
<i>Bifidobacterium longum</i>		
Elderberry Extract	20,0 mg	
Propolis Extract	5,0 mg	
Beta Carotene 10 %	4,1 mg	
Vitamin A	140 µg	
Thiamine (Vitamin B1)	0,9 mg	
Riboflavin (Vitamin B2)	1 mg	
Pyridoxine (Vitamin B6)	1 mg	
Vitamin B12	0,2 µg	
Vitamin D3	9,0 µg	
Vitamin E	17,0 mg	

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Nicotinamide	10 mg
Folic Acid	200,0 µg
Biotin	40,0 µg
Calcium Pantothenate	10,0 mg
Vitamin C	65,0 mg
Zinc Oxide	5,40 mg
Magnesium oxide	48,2 mg
Iron as Ferrous Fumerate	2,3 mg
Selenium A.A.C	29,0 µg
Calcium Carbonate	16,0 mg
Manganese Sulphate	0,58 mg

*cfu = colony forming unit

4. Pharmacological classification

A.34 Other

5. Pharmacological action

ViralGuard Fizzi Chews provide a combination of herbal extracts, vitamins and minerals that have well documented evidence which shows support for well-being. As growing children have demanding nutritional requirements, supplementation is often necessary to ensure that their vitamin and mineral needs are met.

A healthy immune system may protect you against colds and flu.

Elderberry extract: Assists to reduce cold and flu symptoms due to its anti-

References:

1 to 15

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<p>congestant properties.</p> <p>Propolis: An anti-oxidant with anti-viral and anti-bacterial properties which helps to support the immune system's effectiveness.</p> <p>Probiotics: Consumption of probiotics can increase the levels of beneficial bacteria in the gut, creating an environment that is favourable to the growth of good bacteria. Probiotics play a role in immune health.</p>	
<p>6. Indications</p> <p>ViralGuard Fizzi Chews is a nutritional supplement.</p> <p>Nutritional supplementation should not replace a balanced diet.</p>	
<p>7. Contra-indications</p> <p>ViralGuard Fizzi Chews is contraindicated in persons who are hypersensitive to any of the ingredients.</p>	
<p>8. Warnings</p> <p>Product contains propolis – people allergic to bee products must take care.</p> <p>If symptoms worsen, please consult your healthcare professional.</p> <p>This product is not intended to diagnose, treat, cure or prevent any disease.</p>	
<p>9. Interactions</p> <p>None known.</p>	
<p>10. Pregnancy and lactation</p> <p>Not suitable for pregnant and breastfeeding women.</p>	
<p>11. Dosage and directions for use</p> <p>Children 1 to 3 years: Chew 1 FizziChew tablet per day after a meal.</p>	

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<p>Children 4 to 10 years: Chew 2 FizziChew tablets per day after a meal.</p> <p><i>Do not swallow whole, this presents a choking hazard.</i></p> <p>This container has a child proof lid, for your child's safety.</p>	
<p>12. Side effects and special precautions</p> <p>Patients allergic to bees or bees' products may be more likely to experience allergic reactions to propolis.</p>	
<p>13. Known symptoms of overdosage and particulars of its treatment</p> <p>No known symptoms of overdosage recorded.</p>	
<p>14. Identification</p> <p>Light pink coloured chewable tablet with a distinctive strawberry flavour.</p>	
<p>15. Presentation</p> <p>White plastic containers containing 60 tablets.</p>	
<p>16. Storage instructions</p> <p>Store at or below 25 °C.</p> <p>KEEP OUT OF REACH OF CHILDREN.</p>	
<p>17. Registration number</p> <p>To be allocated.</p>	
<p>18. Name and business address of the holder of the certificate of registration</p> <p>Adcock Ingram Limited</p> <p>1 New Road</p> <p>Erاند Gardens</p> <p>Midrand</p>	

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<p>1685</p> <p>Gauteng</p> <p>South Africa</p> <p>Private Bag X69</p> <p>Bryanston, 2021</p> <p>www.adcock.com</p>	
<p>19. Date of publication of the package insert</p> <p>To be allocated.</p>	

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2.	Natural Medicines Comprehensive Database. Therapeutic Research Faculty (www.naturaldatabase.com). "Vitamin C (Ascorbic Acid)" (1995 – 2011) (Page 1, 4, and 9)
3.	Natural Standard Professional Monograph (www.naturalstandard.com) "Vitamin D" (2011) (Page 2)
4.	Natural Medicines Comprehensive Database. Therapeutic Research Faculty (www.naturaldatabase.com). "Zinc" (1995 – 2011) (Page 1 and 7)
5.	Natural Medicines Comprehensive Database. Therapeutic Research Faculty (www.naturaldatabase.com). "Selenium" (1995 – 2011) (Page 1 and 6)
6.	Natural Medicines Comprehensive Database. Therapeutic Research Faculty (www.naturaldatabase.com). "Propolis" (1995 – 2011) (Page 1)
7.	Natural Medicines Comprehensive Database. Therapeutic Research Faculty (www.naturaldatabase.com). "Beta Carotene" (1995 – 2011) (Page 1 and 5)
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15.	Natural Medicines Comprehensive Database. Therapeutic Research Faculty (www.naturaldatabase.com). "Biotin" (1995 – 2011) (Page 1 and 2)