

Product proprietary name: ViralGuard Tablets

Dosage form and strength: Probiotics: *Lactobacillus rhamnosus* & *Bifidobacterium longum* 1 billion C.F.U; Echinacea extract 80 mg; Elderberry Extract 20 mg; Garlic Extract 12,5 mg; Beta 1,3 glucans 5 mg; Vitamin C 150 mg; Vitamin A 1110 IU; Vitamin E 10 mg; Vitamin D 1,66 µg; Folic Acid 150 µg; Vitamin B12 2 µg; Vitamin B6 2 mg; Biotin 100 µg; Iron 2 mg; Zinc 3 mg; Selenium 20 µg 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

APPROVED / RECORDED BY MCC	
DATE	30/8/2016
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PROPOSED PACKAGED INSERT:

1. Scheduling status

Not Scheduled

2. Proprietary name and dosage form

VIRALGUARD TABLETS (TABLET)

3. Composition

Each tablet contains:

Probiotics:

Lactobacillus rhamnosus

1 Billion cfu*

Bifidobacterium longum

Echinacea Extract

80 mg

Elderberry Extract 4:1

20 mg

Garlic Extract 4:1

12,5 mg

Beta 1,3 Glucans

5 mg

Vitamin C

150 mg

Vitamin A

1110 IU

Vitamin E

10 mg

Vitamin D

1,66 µg

Folic acid

150 µg

Cyanocobalamin (Vitamin B12)

2 µg

Pyridoxine HCl (Vitamin B6)

2 mg

Biotin

100 µg

Iron as Ferrous Lactate

2 mg

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Zinc Oxide	3 mg
Selenium AAC	20 µg

Contains sugar: Lactose monohydrate 145,08 mg

*(cfu = colony forming units)

Other ingredients in the tablet are:

- Microcrystalline cellulose
- Sorbitol
- Mannitol
- Magnesium stearate
- Aerosil
- Opadry II Orange

4. Pharmacological classification

D.32. Other substances or agents

5. Pharmacological action

ViralGuard Tablets provide a combination of herbal extracts, vitamins and minerals that have well documented evidence which shows support of the immune system. The formulation also includes active probiotics that support the immune system's core defence.

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

Echinacea extract: Assists to maintain and support the immune system.

Vitamin C: A powerful antioxidant that also assists to maintain and protect the immune system.

References: 1
to 16

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<p>Vitamin D: Plays an important role in immune health.</p> <p>Zinc: Provides antioxidant support and helps maintain a healthy immune system.</p> <p>Selenium: Assists to support a healthy immune system.</p> <p>Probiotics: When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut.</p>	
<p>6. Indications</p> <p>ViralGuard Tablets is a nutritional supplement.</p> <p>Nutritional supplements should not replace a balanced diet.</p>	
<p>7. Contra-indications</p> <p>ViralGuard Tablets should not be taken by any person who is hypersensitive to any of the ingredients.</p>	
<p>8. Warnings</p> <p>If you are taking any medication or have a medical condition, please consult your healthcare professional before taking any dietary supplement.</p> <p>This medicine has not been evaluated by the Medicines Control Council. This medicine 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, as safety and efficacy has not been established during pregnancy or breastfeeding.</p>	

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<p>11. Dosage and directions for use</p> <p>Adults: 1 tablet 3 times a day as required or as directed by your healthcare professional.</p>	
<p>12. Side effects and special precautions</p> <p>None recorded.</p>	
<p>13. Known symptoms of overdosage and particulars of its treatment</p> <p>No known symptoms of overdosage recorded. In the event of overdose, medical assistance should be sought immediately.</p> <p>Treatment is symptomatic and supportive.</p>	
<p>14. Identification</p> <p>Orange film coated oval, biconvex shaped tablets.</p>	
<p>15. Presentation</p> <p>White plastic containers containing 30 tablets.</p> <p>White plastic containers containing 60 tablets.</p> <p>Not all pack sizes might be marketed simultaneously.</p>	
<p>16. Storage instructions</p> <p>Keep in a cool dry place 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>	

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<p>Erand Gardens</p> <p>Midrand</p> <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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3. Natural Standard Professional Monograph (www.naturalstandard.com) "Echinacea (Echinacea angustifolia DC, Echinacea pallid, Echinaceapurpurea" (2011) (Page 2, 5, 6, and 9)
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6. Natural Medicines Comprehensive Database. Therapeutic Research Faculty (www.naturaldatabase.com). "Zinc" (1995 – 2011) (Page 1 and 7)
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