

Product proprietary name: ViralGuard Junior Syrup

Dosage form and strength: Propolis 300 mg; Echinacea 150 mg; Elderberry Extract 2,5 mg; Vitamin A 180 µg RE; Thiamine (Vitamin B1) 0,7 mg; Riboflavin (Vitamin B2) 0,8 mg; Nicotinamide (Vitamin B3) 10 mg; Pantothenic Acid (Vitamin B5) 1,5 mg; Pyridoxine HCl (Vitamin B6) 0,75 mg; Cyanocobalamin (Vitamin B12) 1 µg; Vitamin C 30 mg; Vitamin D3 5 µg; Vitamin E 5 mg; L-Arginine 2,5 mg; Folic Acid 75 µg; Selenium 8,2 µg; Biotin 60 µg; Zinc 2 mg; Iron 1,92 mg per 5 ml of syrup

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 JUNIOR SYRUP (SYRUP)

3. Composition

VIRALGUARD JUNIOR SYRUP contains:

Ingredient	Per 5 ml
Propolis Concentrate	300 mg
Echinacea powder	150 mg
Elderberry Extract 4:1	2,5 mg
Vitamin A	180 µg
Thiamine (Vitamin B1)	0,7 mg
Riboflavin (Vitamin B2)	0,8 mg
Nicotinamide (Vitamin B3)	10 mg
Pantothenic Acid (Vitamin B5)	1,5 mg
Pyridoxine HCl (Vitamin B6)	0,75 mg
Cyanocobalamin (Vitamin B12)	1 µg
Vitamin C	30 mg
Vitamin D3	5 µg
Vitamin E	5 mg

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L-Arginine	2,5 mg
Folic Acid	75 µg
Selenium	8,2 µg
Biotin	60 µg
Zinc	2 mg
Iron	1,92 mg

Other ingredients in the syrup include:

- Methylparaben and propylparaben as preservatives
- Citric acid
- Sugar
- Keltrol
- Flavourants

4. Pharmacological classification

A.34 Other

5. Pharmacological action

ViralGuard Junior Syrup provides a combination of herbal extracts, vitamins and minerals that have well documented evidence which shows support of the immune system.

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

Propolis: An anti-oxidant with anti-viral and anti-bacterial properties which helps to support the immune system's effectiveness.

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

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Zinc: Provides antioxidant support and helps maintain a healthy immune system.

Selenium: Assists to support a healthy immune system.

6. Indications

ViralGuard Junior Syrup is a nutritional supplement.

7. Contra-indications

This product contains propolis – people allergic to bee products must take care.

ViralGuard Junior Syrup is contraindicated in persons who are hypersensitive to any of the ingredients.

8. Warnings

If symptoms worsen, please consult your healthcare professional. This medicine has not been evaluated by the Medicines Control Council. This product is not intended to diagnose, treat, cure or prevent any disease.

9. Interactions

None known.

10. Pregnancy and lactation

Not suitable for pregnant or breastfeeding women.

11. Dosage and directions for use

Shake bottle well before use, replace cap tightly after use.

Children: 1-3 years: ONE medicine measure (5ml) once a day with a meal.

Children: 4-10 years: ONE medicine measure (5ml) twice a day with meals.

Adults: TWO 5 ml medicine measures twice a day with meals as required or as directed by your healthcare professional.

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12. Side effects and special precautions

Patients allergic to bees or bees' products may be more likely to experience allergic reactions to propolis.

Possible gastrointestinal upsets including mild nausea and vomiting and abdominal pain. Possible allergic reactions in a form of a rash.

13. Known symptoms of overdose and particulars of its treatment

No known symptoms of over dosage recorded. In the event of overdose, medical assistance should be sought immediately.

Treatment is symptomatic and supportive.

14. Identification

Raspberry flavoured syrup

15. Presentation

200 ml, 250 ml, or 500 ml syrup in a white screw-cap bottle.

16. Storage instructions

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

17. Registration number

To be allocated.

18. Name and business address of the holder of the certificate of registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand

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South Africa

Private Bag X69

Bryanston, 2021

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19. Date of publication of the package insert

To be allocated.