

PROFESSIONAL INFORMATION

Category D: Complementary Medicine

Discipline Specific 33.7 Combination Product

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS:

S0

1. NAME OF THE MEDICINE:

VIRALGUARD JUNIOR SYRUP (syrup) Multicomponent

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml syrup contains:	
<i>Apis mellifera (propolis)</i>	4 mg
<i>Echinacea purpurea</i> (L.) Moench [dry pressed juice, 45:1]	50 mg
<i>Sambucus nigra</i> (elderberry) [flower, 4:1 extract providing 10 mg dried herb equivalent]	2,5 mg
Ascorbic acid (vitamin C)	30 mg
Ferrous gluconate providing iron (elemental)	16 mg 1,89 mg
Nicotinamide (vitamin B ₃)	5 mg
D-alpha-tocopherol acetate providing tocopherol (vitamin E)	10 mg 2,25 mg
Calcium d-pantothenate providing pantothenic acid (vitamin B ₅)	1,5 mg 1,38 mg
Zinc (elemental)	2 mg
Riboflavin phosphate sodium providing riboflavin (vitamin B ₂)	0,8 mg 0,58 mg
Thiamine hydrochloride providing thiamine (vitamin B ₁)	0,7 mg 0,55 mg
Pyridoxine (vitamin B ₆)	0,62 mg
Vitamin A acetate providing retinol (vitamin A)	1,33 mg 199,5 µg
Folic acid	75 µg
Biotin (vitamin H)	60 µg
Cholecalciferol (vitamin D ₃)	5 µg
Cyanocobalamin (vitamin B ₁₂)	1 µg

Excipient(s) with known effect:

Contains sugar: each 5 mL contains 2,875 g white sugar.

Contains preservatives: methylparaben 0,17 % *m/v* and propylparaben 0,09 % *m/v*.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Syrup.

Dark brown coloured syrup with a raspberry flavour.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications

VIRALGUARD JUNIOR SYRUP is a health supplement which contains vitamins, minerals, elderberry extract, echinacea extract and propolis extract which contribute to the maintenance of the immune function. VIRALGUARD JUNIOR SYRUP is a factor in the maintenance of good health.

4.2 Posology and method of administration

Shake the bottle before use. Replace cap immediately after use.

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

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

Adults: Two medicine measures (10 ml) twice a day with meals or as directed by your health care provider.

Method of administration

Orally

4.3 Contraindications

- Known hypersensitivity to the active substance or to any of the excipients listed under Section 6.1. For complementary medicines, hypersensitivity extended to other plants of the same family or to other parts of the same plant should be labelled as a contraindication, where applicable.

4.4 Special warnings and precautions for use

- Caution is advised if you are hypersensitive (allergic) to:
 - bees and bee products including honey
 - conifers and poplars
 - Balsam of Peru and salicylates (see section 4.5).
- Patients with rare glucose-galactose malabsorption or hereditary fructose intolerance (HFI) should not take VIRALGUARD JUNIOR SYRUP.

4.5 Interaction with other medicines and other forms of interaction

Caution is advised with the concomitant use of VIRALGUARD JUNIOR SYRUP and Balsam of Peru (see section 4.4).

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established. Not suitable for pregnant and breastfeeding women.

4.7 Effects on ability to drive and use machines

VIRALGUARD JUNIOR SYRUP is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders:

Frequency unknown: hypersensitivity / allergic reaction.

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions of VIRALGUARD JUNIOR SYRUP is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to the Adcock Ingram Pharmacovigilance department by e-mail to Adcock.Aereports@adcock.com, fax to +27 86 553 0128 or call 011 635 0134. Alternatively, it can be reported to the South African Health Products Regulatory Authority (SAHPRA) via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

See section 4.8, Undesirable effects.

In overdose, side effects can be precipitated and/or be of increased severity. In the event of overdosage, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic Properties

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Pharmacotherapeutic group: Multivitamins, other combinations.

ATC code: A11AB.

5.2 Pharmacokinetic Properties

VIRALGUARD JUNIOR SYRUP is a health supplement which contains vitamins, minerals, elderberry extract, echinacea and propolis extract which contributes to the maintenance of the immune function and is a factor in the maintenance of good health. A healthy immune system may protect you against colds and flu.

Propolis contains flavonoids which has antibacterial, anti-inflammatory, antioxidant. and antiviral properties which helps to support the immune system's effectiveness.

Echinacea has antibacterial, anti-inflammatory, antiviral and immunological effects. The oral bioavailability of *Echinacea purpurea* is variable based on the preparation used and has shown a half-life of about 1,3 hours.

Elderberry extract contains several flavonoids which assist to reduce cold and flu symptoms due to its anti-inflammatory, antioxidant, antiviral and immunological effects. Peak plasma concentration of the anthocyanidins from *Sambucus nigra* are reached within 3 to 4 hours and are eliminated through urine.

Vitamin A is a fat-soluble vitamin that is readily absorbed from the gastrointestinal tract and is excreted in the bile or urine.

Vitamin B₁ is a water-soluble B-vitamin and is absorbed by the proximal part of the small intestines. It occurs in the body as the metabolically active form thiamine diphosphate and is excreted in the urine.

Vitamin B₂ is readily absorbed from the gastrointestinal tract and is widely distributed in the body. It is excreted in the urine.

Vitamin B₃ is water-soluble and well absorbed and is excreted mainly via urine.

Vitamin B₅ is an essential B vitamin. It is required for intermediary metabolism of carbohydrates, proteins and lipids. Vitamin B₅ is excreted in the urine.

Vitamin B₆ is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.

Vitamin B₁₂ is an essential water-soluble vitamin. It is required for nucleoprotein and myelin synthesis, cell reproduction, normal growth, and normal erythropoiesis. It is absorbed in the terminal ileum. Vitamin B₁₂ has a half-life of about 25-30 hours.

Vitamin C is readily absorbed from the gastrointestinal tract and is widely distributed in the body. The main route of elimination is through urine.

Vitamin D is an essential fat-soluble vitamin. It is well absorbed and requires hydroxylation in the body to form the active metabolite, calcitriol.

Vitamin E is mostly absorbed in the small intestines by passive diffusion and is excreted mainly unchanged via the faeces.

Synthetic **folic acid** is almost 100 % bioavailable. After folic acid is absorbed, it is reduced to tetrahydrofolate and then enters a methylation cycle to be converted to L-methylfolate. Folic acid is excreted mainly in the urine; however, it is also found in the faeces.

Biotin is completely absorbed after oral administration and is bound to lysine residues of protein. It is excreted in the urine as unmetabolized biotin or as metabolites.

Zinc is a biologically essential trace element that is absorbed in the small intestines and is distributed in the body in skeletal muscle and bone. It is mainly excreted through the faeces.

Iron absorption is variable and is enhanced by the presence of ascorbic acid. Most of the iron absorbed is incorporated into haemoglobin and is mostly excreted in the faeces.

5.3 Preclinical safety data

No further information of relevance available.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients

- Caramel liquid colourant C821/S
- Citric acid anhydrous (30-100 mesh) [E330]
- Methylparaben (Nipagin M) (preservative) [E218]
- Propylparaben (Nipasol M) (preservative) [E216]
- Raspberry special flavour
- Sugar, white
- Water
- Xanthan gum (food grade 80 mesh) [E415]

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

Store at or below 25 °C.

6.4 Special precautions for storage

Store in airtight container, protected from light.
Protect from heat and moisture.

6.5 Nature and contents of container

200 ml syrup packed in an amber PVC bottle with a white PP screw-cap.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand
1685
Customer Care: 0860 ADCOCK/232625

8. REGISTRATION NUMBER(S)

To be allocated.

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

Not Applicable.

10. DATE OF REVISION OF THE TEXT

20 September 2023

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