

PROFESSIONAL INFORMATION

Category D: Complementary Medicine

Discipline Specific. 33.7 Combination product.

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

SCHEDULING STATUS:

S0

1. NAME OF THE MEDICINE:

VIRALGUARD FIZZI CHEWS Multicomponent tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:	
Probiotic blend consisting of:	100 million cfu*
<i>Lactobacillus rhamnosus</i>	
<i>Bifidobacterium longum</i> subsp. <i>Longum</i>	
<i>Apis mellifera</i> (propolis) concentrate	5 mg
<i>Sambucus nigra</i> (elderberry) [flower, 4:1 extract standardised to valerianic acid providing 20 mg dried herb equivalent]	5 mg
Calcium ascorbate	157,34 mg
providing ascorbic acid (vitamin C)	130 mg
providing calcium (elemental)	14,80 mg
Magnesium oxide	48,20 mg
providing magnesium (elemental)	29,07 mg
Tocopherol acetate	34 mg
providing d-alpha-tocopherol (vitamin E)	7,65 mg
Calcium carbonate	16,84 mg
providing calcium (elemental)	6,07mg
Calcium d-pantothenate	10 mg
providing pantothenic acid (vitamin B ₅)	9,2 mg

providing calcium (elemental)	0,8 mg
Nicotinamide (vitamin B ₃)	10 mg
Zinc oxide	5,40 mg
providing zinc (elemental)	4,34 mg
Beta-carotene 10 %	4,1 mg
providing vitamin A	219 µg
Ferrous fumarate	6,998 mg
providing iron (elemental)	2,3 mg
Pyridoxine hydrochloride	1,22 mg
providing pyridoxine (vitamin B ₆)	1 mg
Thiamine hydrochloride	1,14 mg
providing thiamine (vitamin B ₁)	0,9 mg
Riboflavin (vitamin B ₂)	1 mg
Folic acid	200 µg
Vitamin A acetate	161 µg
providing retinol (vitamin A)	24 µg
Biotin (vitamin H)	40 µg
Cholecalciferol (vitamin D ₃)	9 µg
Cyanocobalamin (vitamin B ₁₂)	0,2 µg
Total Retinal activity equivalents (RAE) from both Vitamin A and beta carotene = 58,56 µg RAE	

**CFU – Colony Forming Unit*

Excipient(s) with known effect:

Contains sugar: Each tablet contains 281,5 mg fructose, 265,45 mg dextrose monohydrate and 22 mg lactose.

Contains sweetener: Each tablet contains 16 mg sucralose.

Each tablet contains 52 mg xylitol, 114,7 mg sorbitol and 30 mg mannitol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Tablets.

Mottled pink to dark pink chewable tablet with a distinctive strawberry flavour and slight fizz action.

Capsule shape with score on one side only.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Children 1 to 13 years: Chew 1 VIRALGUARD FIZZI CHEWS tablet per day after a meal. Do not swallow whole as this presents a choking hazard.

4.3 Contraindications

- Known hypersensitivity to the active substance or to any of the excipients listed under Section 6.1.

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 FIZZI CHEWS.

Fructose may damage teeth.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Paediatric population

Not indicated for babies younger than 1 year old.

4.5 Interaction with other medicines and other forms of interaction

Caution is advised with the concomitant use of VIRALGUARD FIZZI CHEWS and salicylates and/or Balsam of Peru (see section 4.4).

No interaction studies have been performed.

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 FIZZI CHEWS 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 FIZZI CHEWS 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

In overdose, side effects can be precipitated and/or be of increased severity, see section 4.8.

In the event of overdosage, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES:

Category D: Discipline Specific. 33.7: Combination Product

Pharmacotherapeutic group: Multivitamins, other combinations.

ATC code: A11AB.

5.1 Pharmacodynamic properties

VIRALGUARD FIZZI CHEWS is a health supplement which contains vitamins, minerals, probiotics, elderberry extract and propolis extract, which contribute 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.

Probiotics play a role in immune health and can increase the levels of beneficial bacteria in the gut, creating an environment that is favourable to the growth of beneficial bacteria.

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.

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

Beta-carotene belongs to a class of red, orange and yellow pigments called carotenoids. Beta-carotene is a precursor of vitamin A which also has activity independent of its conversion to vitamin A. Beta-carotene supports the immune system by its anti-inflammatory and antioxidant effects. Some ingested beta-carotene is converted to vitamin A in the intestinal mucosa and/or liver. Carotenoids are mainly carried in the blood by low-density lipoproteins. Beta-carotene is excreted in the faeces.

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 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 absorbed in the terminal ileum and is mainly stored in the liver. Vitamin B₁₂ is excreted via urine, faeces and bile.

Vitamin D is a fat-soluble vitamin. It is well absorbed and requires hydroxylation in the body to form the active metabolite, calcitriol. Excretion occurs mainly through the bile and faeces, with small amounts appearing in urine.

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

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

Folic acid is rapidly absorbed from the gastrointestinal tract, mainly the jejunum, and enters portal circulation where it is converted to the metabolically active form 5-methyltetrahydrofolate in the plasma and liver. It is excreted mainly in the urine.

Biotin is completely absorbed after oral administration and is bound to plasma proteins. It is excreted in the urine as unmetabolised biotin or as metabolites.

Vitamin B₅ is an essential B vitamin. It is absorbed from the small intestines and widely distributed through the body. About 70 % is excreted unchanged in the urine, and 30 % in the faeces.

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

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.

Magnesium requires both parathyroid hormone and vitamin D for absorption. Magnesium is absorbed throughout the gastrointestinal tract, is distributed in the skeleton and soft tissue, and excreted primarily via the kidneys.

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.

Calcium absorption is affected by several factors like age, race, environmental and dietary conditions. Dietary calcium absorption is inversely correlated with total dietary calcium, dietary fibre, alcohol intake and physical activity. Calcium is distributed in the bones and teeth and excreted via the urine and faeces.

5.3 Preclinical safety data

No further information of relevance available.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients

- Berries and Cream FD 10263-2
- Dextrose monohydrate
- Citric acid anhydrous 30-100 mesh [E330]
- Fructose
- Lactose (Tabletose 80)
- Magnesium stearate [E572 EP]
- Mannitol [E421 USP/EP]
- Microcrystalline cellulose (MCC-102) [E460]
- Ponceau 4R Lake C411/L/S
- Pregelatinised starch
- Silica (Aerosil® 200 pharma) [E551]
- Sodium bicarbonate
- Sorbitol LTS Powder 50 M (NEOSORB P 60 W) [E420]
- Strawberry flavour J1183
- Sucralose [E955]
- Xylitol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

Store in a dry, cool place.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

60 tablets are packed in a white HDPE container with a white PP child resistant 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: 08600 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

25 August 2023

PI 0AI-PIL028 10/2023

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