

SCHEDULING STAUS

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PROPRIETARY NAME AND DOSAGE FORM

Vivamed 4-in-1 Immune Booster Effervescent Tablet

COMPOSITION

Ingredients	Quantity per tablet
Ascorbic acid (Vitamin C)	1 000 mg
Cholecalciferol (Vitamin D3) 100 IU/mg	400 IU
Zinc Lactate	116,3 mg
Providing Zinc Elemental	25 mg
Selenium Amino Acid Chelate	25 mg
Providing Selenium Elemental	50 µg

Excipients: citric acid, sodium bicarbonate, orange flavour J1431, PEG 6000, Colourant (Sunset yellow)

Contains Sweetener: 393 mg of sorbitol, 15 mg sucralose

CATEGORY AND CLASS

Category D. Health Supplement: 34.12 Multiple Substance Formulation

PHARMACOLOGICAL ACTION

Pharmacological Action

The combination of ingredients found in VIVAMED 4-IN-1 IMMUNE BBOOSTER work together to maintain immune function and good health.

Pharmacokinetic Properties

Ascorbic Acid (Vitamin C)

Ascorbic acid is widely distributed in the body tissues after it is readily absorbed from the gastro-intestinal tract. Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine.

Cholecalciferol (Vitamin D₃)

Cholecalciferol is absorbed into the circulation via the gastro-intestinal tract. It is hydroxylated to 25-hydroxycholecalciferol, in the liver and is subject to entero-hepatic circulation and is further hydroxylated to 1,25-dihydroxycholecalciferol in the renal tubule cells. Vitamin D metabolites are bound to specific plasma proteins.

Selenium Amino Acid Chelate (Selenium)

It has been established that selenium is essential to human life, however, very little information is available on its function and metabolism.

Zinc Lactate (Zinc)

Zinc is poorly absorbed from the gastro-intestinal tract. It is widely distributed throughout the body. It is excreted in the faeces with traces appearing in the urine.

INDICATIONS

- Helps to maintain immune function.
- A factor in the maintenance of good health.
- Multi-vitamin/multi-mineral supplement.
- Helps in connective tissue formation.
- Helps to maintain healthy skin.
- Helps the body metabolise carbohydrate, fats and proteins.

WARNINGS AND SPECIAL PRECAUTIONS

Not permitted in children under the age of 18 years.

If you have a history of non-melanoma skin cancer, consult a health care practitioner prior to use.

Zinc supplementation can cause a copper deficiency. you are unsure whether you are taking enough copper, consult a health care practitioner prior to use.

In general, health supplements should not be intended for supply to any children under the age of seven (7) months old unless where supplementation is medically warranted.

INTERACTIONS

None known.

HUMAN REPRODUCTION

Consult a relevant and registered healthcare provider before use if you are pregnant or breastfeeding.

DOSAGE AND DIRECTIONS FOR USE

Adults: Dissolve 1 (one) tablet in a glass of water once daily. Take with food.

Take a few hours before or after taking other medications or natural health products.

SIDE EFFECTS

Adverse reactions are listed below by system organ class and by frequency. Frequencies are defined as: Very common ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1,000$, $< 1/100$), rare ($\geq 1/10,000$, $< 1/1,000$), very rare ($< 1/10,000$), according to the MedDRA frequency convention and system organ classification.

Immune system disorders

Frequency unknown

Hypersensitivity reaction

General disorders

Frequency unknown

Copper deficiency

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

CONTRAINDICATIONS

Children under the age of 18 years.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENT

See section Warnings and Special Precautions and Side Effects.

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

Treatment should be symptomatic and supportive.

IDENTIFICATION

Pale orange, round effervescent tablet, 25mm in diameter.

PRESENTATION

PP cylindrical tube containing 20 effervescent tablets.

STORAGE INSTRUCTIONS

Store in a dark, dry place in an airtight container at or below 25°C.

REGISTRATION NUMBER

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

NAME AND BUSINESS ADDRESS OF THE APPLICANT

MC Pharma (Pty) Ltd

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