zyora zyvit+™
Healthcare for women

PROFESSIONAL INFORMATION FOR zyvit+™

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
S0

1. NAME OF MEDICINE
zyvit+™ effervescent tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each effervescent tablet contains:

Ascorbic acid (Vitamin C)	500 mg
Calcium carbonate	555 mg
providing Calcium (elemental)	200 mg
Potassium chloride	143 mg
providing Potassium (elemental)	75 mg
Magnesium oxide	85 mg
providing Magnesium (elemental)	50 mg
Niacinamide (Vitamin B3)	20 mg
Zinc oxide	14 mg
providing Zinc (elemental)	11 mg
Calcium D-pantothenate	11 mg
providing Pantothenic acid (Vitamin B5)	10 mg
Alpha-tocopherol acetate	20 mg
providing Alpha-tocopherol (Vitamin E)	10 mg
Iron amino acid chelate (AAC)	50 mg
providing Iron (elemental)	5 mg
Pyridoxine HCl	3,2 mg
providing Pyridoxine (Vitamin B6)	2,6 mg
Manganese sulphate monohydrate	7,2 mg
providing Manganese (elemental)	2,3 mg
Thiamine HCl	2,3 mg
providing Thiamine (Vitamin B1)	2 mg
Riboflavin 5-phosphate sodium	2,4 mg
providing Riboflavin (Vitamin B2)	1,8 mg
Vitamin A acetate	10 000 µg
providing Vitamin A	1 000 µg
Folic acid	400 µg
Copper sulphate anhydrous	761 µg
providing Copper (elemental)	300 µg
Biotin (Vitamin H)	60 µg
Selenium amino acid chelate (AAC)	27 500 µg
providing Selenium (elemental)	55 µg
Potassium iodide	66 µg
providing Iodine (elemental)	50 µg
MecobalActive® as methylcobalamin (Vitamin B12)	50 µg
Chromium picolinate	284 µg
providing Chromium (elemental)	35 µg
Cholecalciferol (Vitamin D3)	1 000 IU

Excipients with known effect:
Contains sweetener: 12 mg sucralose per tablet.
Contains sugar alcohol: 600 mg sorbitol per tablet.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Effervescent tablets.
Light yellow, orange flavoured, round flat effervescent tablet, with a bevelled edge.

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
zyvit+™ is a multi-vitamin/mineral health supplement that may assist with:
- The normal functioning of the immune system.
- The reduction of tiredness & fatigue.
- Normal mental performance.
- Cellular protection from free radical damage.
- The maintenance of good health.

4.2. Posology and method of administration
Adults: Take 1 (one) effervescent tablet daily dissolved in half to a full glass of water.
Children:
Not suitable for children under the age of 18 years.
4.3. Contraindications
Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 6.1.
4.4. Special warnings and precautions for use
- zyvit+™ may cause excessive bleeding and interfere with blood glucose control during and after surgical procedures. Patients should be advised to discontinue zyvit+™ at least 2 weeks prior to any surgical procedures.
- Patients with a kidney disorder or a history of kidney stones should consult a health care provider prior to use.
- zyvit+™ may interfere with blood glucose levels in patients with diabetes mellitus. Dose adjustment of antidiabetic medicine might be necessary (see section 4.5). Use with caution.
- Patients on any medication or suffering from any medical condition, should be advised to seek medical advice before starting any new medicine, supplement or remedy.
- zyvit+™ contains sugar alcohol (600 mg sorbitol per tablet). The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in zyvit+™ may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) should not take zyvit+™.
- The recommended daily dosage should not be exceeded without consulting a health care provider.

Paediatric population
The safety and efficacy of zyvit+™ have not been established in children under the age of 18 years.
4.5. Interaction with other medicines and other forms of interaction
Medicines
- Concomitant use of zyvit+™ with anticoagulant/antiplatelet medicines or herbal supplements with blood thinning effects, may increase the risk of bruising and bleeding.
- Concomitant use of zyvit+™ with antidiabetic medicines or herbal supplements may interfere with blood glucose control. Use with caution.
- Concomitant use of zyvit+™ with antibiotics may reduce absorption. Doses should be separated by at least 2 hours prior, or 4 to 6 hours after taking zyvit+™.
- Concomitant use of zyvit+™ with levothyroxine may reduce absorption. Patients should be advised to take levothyroxine and zyvit+™ at least 4 hours apart.

Laboratory tests
Absorption of vitamin B12 from the gastrointestinal tract may be reduced by concomitant use of neomycin, aminosalicylic acid, histamine H2-antagonists, omeprazole, and colchicine and serum concentrations of vitamin B12 may be decreased by use of oral contraceptives. Many of these interactions should be considered when performing assays for blood concentrations.
Food
Concomitant use with alcohol should be avoided as it may inhibit absorption.
4.6. Fertility, pregnancy and lactation
Safety in pregnancy and breastfeeding has not been established. There is no data available on the possible effects on male and female fertility.
4.7. Effects on ability to drive and use machines
zyvit+™ may cause side effects, such as dizziness and drowsiness, and may have an influence on driving performance or the ability to use machines.
4.8. Undesirable effects
zyvit+™ is generally well tolerated.
Immune system disorders:
Frequency unknown: hypersensitivity and/or allergic reactions.
Metabolism and nutrition disorders:
Frequency unknown: loss of appetite.
Psychiatric disorders:
Frequency unknown: insomnia.
Nervous system disorders:
Frequency unknown: headache, dizziness, drowsiness.
Vascular disorders:
Frequency unknown: flushing.
Gastrointestinal disorders:
Frequency unknown: nausea, vomiting, heartburn, abdominal pain or cramps, gastrointestinal irritation, diarrhoea, belching, flatulence, constipation.
Skin and subcutaneous tissue disorders:
Less frequent: skin rash or itching.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of zyvit+™ is important. It allows continued monitoring of the benefit/risk balance of zyvit+™. Health care providers are asked to report any suspected adverse reactions 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).
Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1. Pharmacodynamic properties
Category and class:
D 34.12 Multiple substance formulation.
zyvit+™ is a multi-vitamin/mineral health supplement that may assist with the normal functioning of the immune system, the reduction of tiredness & fatigue, normal mental performance, cellular protection from free radical damage and the maintenance of good health.
5.2 Pharmacokinetic properties
Ascorbic acid (Vitamin C) is readily absorbed from the gastrointestinal tract and is widely distributed in the body. The main route of elimination is through the urine.
Calcium absorption is affected by several factors like age, race, environmental and dietary conditions. Calcium is distributed in the bones and teeth and excreted via the urine and faeces.
Potassium in the body is regulated by the kidneys. Approximately 80 % of dietary potassium is excreted via urine.
Magnesium is absorbed throughout the gastrointestinal tract, is distributed in the skeleton and soft tissue, and excreted primary via the kidneys.
Niacinamide (Vitamin B3) is rapidly absorbed from the gastrointestinal tract and is excreted mainly via urine.
Zinc is absorbed in the small intestines, distributed in the body in skeletal muscle and bone and mainly excreted through the faeces.
Pantothenic acid (Vitamin B5) is the precursor of coenzyme A (CoA) and is excreted in the urine.
Alpha-tocopherol (Vitamin E) is mostly absorbed in the small intestines by passive diffusion and is excreted mainly unchanged via the faeces.
Iron's 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.
Pyridoxine (Vitamin B6) is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.
Manganese is not well absorbed and is cleared hepatically.
Thiamine (Vitamin B1) is absorbed at 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.
Oral supplementation with Riboflavin (Vitamin B2) results in the production of 7-hydroxymethylriboflavin in blood plasma and is excreted in the urine.
Vitamin A is readily absorbed from the gastrointestinal tract and is excreted primarily in the urine.
After absorption, folic acid is reduced to tetrahydrofolate and then converted to L-methylfolate. It is excreted mainly in the urine.
Copper is absorbed primarily from the small intestines, mainly distributed to the skeleton and muscles and excreted in the urine.
Biotin (Vitamin H) is completely absorbed after oral administration. Biotin metabolites are formed by beta-oxidation, sulfur oxidation, or both, and is excreted in the urine.
The kidney accumulates the highest level of selenium and is the major source of plasma glutathione peroxidase. It is excreted mainly in the urine.
Iodine is absorbed through the stomach and duodenum and is converted to iodide. Iodine is excreted mainly in the urine, with small amounts excreted in faeces, sweat and saliva.
Methylcobalamin (Vitamin B12) is absorbed in the terminal ileum and has a half-life of about 25 – 30 hours. Absorption also occurs by passive diffusion. Vitamin B12 is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling. Part of a dose is excreted in the urine.
The small percentage of chromium that is absorbed, approximately 0,5 % to 2 %, is rapidly excreted in the urine and unabsorbed chromium in the faeces.
Cholecalciferol (Vitamin D3) is well absorbed and requires hydroxylation in the body to form the active metabolite, calcitriol.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Citric acid anhydrous
Orange flavour
Polyethylene glycol
Sodium bicarbonate
Sorbitol
Sucralose
Sunset yellow (colourant).
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 a cool, dry place, protected from light.
6.5 Nature and contents of container
15 tablets are packed in a PP tube with a closure containing a desiccant. 2 tubes are packed inside a carton.
6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Technikon Laboratories (Pty) Ltd
1073 Anvil Road
Robertville
Florida
1710

8. REGISTRATION NUMBER
Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION
Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT
This leaflet was last revised in June 2021.

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