PROFESSIONAL INFORMATION
TURBOVITE® VITALITY syrup

- Complementary Medicine
- Discipline: D34.13 Health Supplements - Other
- Health Supplements are intended only to complement health or supplement the diet. 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
TURBOVITE® VITALITY (syrup)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
The product contains:

Active ingredients	Per single dosage (10 ml)	Per daily dose (20 ml)	%NRV# per max daily dosage (20 ml)
Vitamin B1 (Thiamine hydrochloride)	1,2 mg	2,4 mg	200 %
Vitamin B2 (Riboflavin)	2 mg	4 mg	308 %
Vitamin B3 (Nicotinamide)	9 mg	18 mg	113 %
Vitamin B5 (Calcium D-Pantothenate)	3 mg	6 mg	120 %
Vitamin B6 (Pyridoxine hydrochloride)	2,5 mg	5 mg	294 %
Vitamin B9 (Folic acid)	250 µg	500 µg	125 %
Vitamin B12 (Cyanocobalamin)	8 µg	16 µg	667 %
Biotin (D-biotin)	50 µg	100 µg	333 %
Ascorbic acid (vitamin C)	60 mg	120 mg	120 %

Nutrient Reference Values for adults and children older than 4 years.
*NRV not established.
Inactive ingredients: RO water, glycerine, passion fruit flavouring and xanthan gum.
Turbovite® Vitality syrup is sugar free. Contains the artificial sweeteners sucralose (4,16 mg/10 ml and stevia (8,32 mg/10 ml).
Contains the preservative potassium sorbate (0,20 % m/v).
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Syrup
Turbovite® Vitality syrup is a clear, yellow liquid.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Turbovite® Vitality syrup is a health supplement high in B Complex Vitamins and Vitamin C to help fuel your mental and physical performance.

4.2 Posology and method of administration
The recommended daily dosage is
Adults 18 years and older:
1-2 medicine measures (5-10 ml) in the morning and early afternoon, after meals.

4.3 Contraindications
- Hypersensitivity to any of the ingredients of Turbovite® Vitality syrup (see section 6.1 List of excipients).
- Turbovite® Vitality syrup contains nicotinamide, which is contraindicated in patients with liver disease or in patients with active peptic ulcer disease.
- Turbovite® Vitality syrup contains vitamin B12, which is contraindicated in patients with cobalamin or cobalt hypersensitivity.

4.4 Special warnings and precautions for use
- Must not be given to patients with known hypersensitivity or allergy towards any of the ingredients. Patients should be advised to consult their medical practitioner if in doubt.
- Patients with a history of oxalate kidney stones should avoid high doses of vitamin C due to increased risk of kidney stone formation.

Porphyria
Safety has not been established.

4.5 Interaction with other medicinal products and other forms of interaction

Active ingredient	Medicine	Description
Vitamin B6	Levodopa	Pyridoxine enhances the metabolism of levodopa, reducing its antiparkinsonism effects. However, this interaction does not occur when carbidopa is used in combination with levodopa.
Vitamin B12	Chloramphenicol	Chloramphenicol may delay or interrupt the reticulocyte response to vitamin B12. Therefore, blood counts need to be closely monitored if this combination can't be avoided.
Vitamin B9	Vitamin B12 deficiency	Patients should use Turbovite® Vitality syrup with caution if they have a vitamin B12 deficiency, as vitamin B9 (Folic acid) could mask the deficiency.
Vitamin B9	Methotrexate	Folic acid supplementation may reduce the effectiveness of methotrexate in the treatment of acute lymphoblastic leukemia and theoretically, the efficacy in the treatment of other cancers.

4.6 Fertility, pregnancy and lactation
Pregnancy
There are no known effects for use of Turbovite® Vitality syrup in pregnant woman
Breastfeeding
There are no known effects of Turbovite® Vitality syrup in breastfeeding women.
Fertility
There are no known effects of Turbovite® Vitality syrup on fertility.

4.7 Effects on the ability to drive and use machines.
Based on the side effect profile, Turbovite® Vitality syrup should not affect your ability to drive or operate machinery.

4.8 Undesirable effects
Patients experiencing any side effects or sensitivity to any of the ingredients, should discontinue use.

Adverse events table		
System organ clas	**Frequency**	**Adverse Events**
Immune system disorders	frequency unknown	Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria, itching
Gastrointestinal Disorders	Frequency unknown	Abdominal discomfort, diarrhoea, difficulty swallowing, heartburn, nausea, vomiting
Skin and subcutaneous tissue disorders	frequency unknown	Hypersensitivity reaction (dermatitis, erythema or urticaria)

If symptoms persist, or if any adverse reactions occur, advise the patient to consult a healthcare provider.
Reporting of suspected adverse reactions
Reporting of suspected adverse reactions after authorization of the medicinal product 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

4.9 Overdose
Symptoms
See **4.8 Undesirable effects**
In overdose, side effects can be precipitated and/or be of increased severity.
Treatment
There is no evidence that this product can lead to an overdose when used as recommended.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Vitamin B1
Thiamine is a water-soluble B vitamin that is essential for carbohydrate metabolism in its diphosphate form.
Vitamin B2
Riboflavin is an essential for the utilisation of energy from food. Additionally, the active phosphorylated forms (flavine mononucleotide and flavine adenine dinucleotide) are involved as coenzymes in oxidation-reduction metabolic reactions.
Vitamin B3
Nicotinamide is a water-soluble B vitamin, which is converted in the body to nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). Both NAD and NADP are essential components of oxidation-reduction reactions, ATP synthesis and ADP-ribose transfer reactions.
Vitamin B5
It is a component of coenzyme A, which is essential in the metabolism of carbohydrate, fat, and protein.
Vitamin B6
Pyridoxine is essential for amino acid metabolism and to a lesser extent involved in carbohydrate and fat metabolism.
Vitamin B9
Folic acid is reduced in the body to tetrahydrofolate, which is a coenzyme for various metabolic processes including the synthesis of purine and pyrimidine nucleotides, and hence in the synthesis of DNA; it is also involved in some amino acid conversions, and in the formation and utilisation of formate.
Vitamin B12
Vitamin B12, in the form cyanocobalamin, can be converted to coenzyme B12, which is an essential component for the conversion of methylmalonate to succinate and for the synthesis of methionine from homocysteine. Additionally, vitamin B12 is a requirement for nucleoprotein and myelin synthesis, cell reproduction, normal growth, normal erythropoiesis and is also involved in maintaining sulfhydryl groups in the reduced form that is required by enzymes involved in both fat and carbohydrate metabolism as well as protein synthesis.
Biotin
It is an essential coenzyme in fat metabolism and in other carboxylation reactions.
Vitamin C
The beneficial effects of vitamin C are primarily associated with its use as an antioxidant and ability to scavenge free radicals.

5.2 Pharmacokinetic properties
Vitamins and minerals
The combination of vitamins and minerals is typical of the normal diet. Therefore, the pharmacological metabolism and fate of Turbovite® Vitality syrup is anticipated to be similar.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Water
Glycerine
Passion fruit flavour
Xanthan gum

Turbovite® Vitality syrup contains sweetener: sucralose (4,16 mg per 10 ml) and stevia (8,32 mg per 10 ml).
Turbovite® Vitality syrup contains preservatives: potassium sorbate (0,20% m/v).
Turbovite® Vitality syrup is sugar free.

6.2 Incompatibilities
None known

6.3 Shelf life
24 months

6.4 Special precautions for storage
- Store in a cool, dry place at or below 25 °C.
- Protect from light and moisture.
- Keep in original packaging until required for use.

6.5 Nature and contents of container
Turbovite® Vitality syrup is a yellow liquid with a passion fruit flavour.
Turbovite® Vitality syrup is available in 10 ml sachets, packed in a 48's pack in a printed unit carton.

6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
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8. REGISTRATION NUMBER(S)
To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
To be allocated

10. DATE OF REVISION OF THE TEXT
March 2021

PPIL285/01