PROFESSIONAL INFORMATION
GO!® VITALITY BOOST EFFERVESCENT TABLETS

- Complementary Medicine.
- Discipline: D.34.12 Health Supplements – Multiple substance formulation
- 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
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1. NAME OF THE MEDICINE
GO!® VITALITY BOOST (effervescent tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients	Per effervescent tablet (maximum daily dosage)	% NRV# per maximum daily dosage
Calcium carbonate Providing Calcium (elemental)	335 mg 133 mg	10 %
Magnesium oxide Providing Magnesium (elemental)	110 mg 66 mg	16 %
Ascorbic acid (Vitamin C)	80 mg	80 %
Nicotinamide (Vitamin B3)	16 mg	100 %
Calcium D-Pantothenate (Vitamin B5)	6 mg	120 %
Riboflavin (Vitamin B2)	1,4 mg	108 %
Pyridoxine hydrochloride (Vitamin B6)	1,4 mg	82 %
Thiamine hydrochloride (Vitamin B1)	1,1 mg	92 %
Folic acid (Vitamin B9)	200 µg	50 %
D-biotin (Biotin)	50 µg	167 %
Cholecalciferol (Vitamin D3)	5 µg (200 IU)	33 %
Cyanocobalamin (Vitamin B12)	2,5 µg	104 %

Nutrient reference values for adults and children older than 4 years.
Go!® Vitality Boost effervescent tablets are sugar free.
Contains sweeteners (aspartame 15 mg/tablet, acesulfame potassium 10 mg/tablet and sorbitol 450 mg/tablet).
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Effervescent tablet.
Go!® Vitality Boost effervescent tablets are round, disc shaped, light yellow and orange flavoured.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Go!® Vitality Boost is a multivitamin and mineral health supplement indicated for the maintenance of healthy energy levels and immune function.
Go!® Vitality Boost contains;

- B complex vitamins, biotin and magnesium which assist the body's healthy energy yielding metabolism,
- B vitamins and biotin that contribute to normal nervous system and psychological function,
- B vitamins and magnesium help in the reduction of tiredness and fatigue,
- Vitamin C functions as an antioxidant to help protect cells from oxidative stress and together with vitamin D to maintain normal immune function.

4.2 Posology and method of administration
The recommended daily dosage is
Adults and children 12 years and older:
One (1) effervescent tablet daily, dissolved in a glass of water, after a meal.

Advise patients not to exceed the daily dose.
Advise the patient to not take dosage at the same time as other medications (see **4.5**).
4.3 Contraindications

- Hypersensitivity to any of the ingredients of Go!® Vitality Boost effervescent tablets (see section 6.1 List of excipients).
- Go!® Vitality Boost effervescent tablets contains nicotinamide, which is contraindicated in patients with liver disease or in patients with active peptic ulcer disease.
- Go!® Vitality Boost effervescent tablets contains vitamin B12, which is contraindicated in patients with cobalamin or cobalt hypersensitivity.
- Must not be given to patients with a known history of kidney stones as Go!® Vitality Boost contains a high dose of vitamin C and vitamin D.

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.
- Acute and chronic overdose increases the risk of side effects. Individuals receiving other vitamin or multivitamin preparations, any other medication, placed on a restricted diet, or those with conditions such as diabetes, glaucoma or detrusor instability should consult a healthcare professional before use of the product.
- Use with caution in patients with iron deficiencies as Go!® Vitality Boost contains a high dose of vitamin C which can increase iron absorption.
- Use with caution if the patient has hypercalcemia or hypercalciuria as Go!® Vitality Boost contains vitamin D which can worsen the conditions.
- Use with caution if the patient has hyperphosphatemia as Go!® Vitality Boost contains vitamin D which can worsen the condition.

Porphyria
Safety has not been established.
4.5 Interaction with other medicinal products and other forms of interactions
No interaction studies have been performed on Go!® Vitality Boost effervescent tablets, see below interactions with individual ingredients.

Active ingredient	Medicine	Description
Vitamin B2, vitamin E and minerals (magnesium and calcium)	Antibiotics	The absorption of antibiotics may be decreased. Oral antibiotics should be taken at least two (2) hours before, or four (4) hours after Go!® Vitality Boost effervescent tablets or similar supplements.
Vitamin D	Calcium supplements	Vitamin D has the potential to increase the absorption of calcium when used concomitantly with calcium supplements.

4.6 Fertility, pregnancy and lactation
Pregnancy
If you are pregnant please consult your doctor, pharmacist or other healthcare professional for advice on taking this medicine.
Breastfeeding
If you are breastfeeding please consult your doctor, pharmacist or other healthcare professional for advice on taking this medicine.
Fertility
There are no known effects of Go!® Vitality Boost effervescent tablets on fertility.
4.7 Effects on the ability to drive and use machines
Based on the side effect profile, Go!® Vitality Boost effervescent tablets should not affect the ability to drive or operate machinery.
4.8 Undesirable effects
Go!® Vitality Boost effervescent tablets are generally well tolerated with the occurrence of adverse events unknown. Patients experiencing any side effects or sensitivity to any of the ingredients, should discontinue use.
Adverse reactions reported in the literature are listed below, by system organ class and frequency. Frequencies are defined as:

- very common (≥1/10)
- common (≥1/100 to <1/10)
- uncommon (≥1/1,000 to <1/100)
- rare (≥1/10,000 to 1</1,000)
- very rare (<1/10,000)
- not known (cannot be estimated from the available data)

Adverse events tableg		
System Organ Class	**Frequency**	**Adverse Event**
Immune system disorders	Not known	Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria, itching.
Gastrointestinal Disorders	Not known	Abdominal discomfort, diarrhoea, dry mouth, dyspepsia, constipation, heartburn, loss of appetite, nausea, vomiting.
Skin and subcutaneous tissue disorders	Not known	Hypersensitivity reaction (dermatitis, erythema and 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 authorisation of the medicinal product 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 SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form,**" found online under SAHPRA's publications: https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf
4.9 Overdose
Symptoms
In overdose, side effects can be precipitated and/or be of increased severity.
See **4.8 Undesirable effects**
There is no evidence that this product can lead to an overdose when used as recommended.
Vitamin D intoxication can occur when vitamin D supplements are taken orally in excessive doses.
Treatment
If an accidental overdose occurs, treatment is symptomatic and supportive.
5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Category and class: D.34.12 Health Supplements – Multiple substance formulation
Pharmacotherapeutic classification: Vitamin B-Complex, other combinations
ATC code: A11EX
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
Ascorbic acid can scavenge free radicals and, therefore, protect normal tissues against oxidative damage caused by reactive oxygen species. Additionally, it can increase collagen production and improve collagen organisation.
Vitamin D
Vitamin D is a fat-soluble vitamin and appears to have immunological activity. It is also an essential vitamin for the proper regulation of calcium and phosphate homeostasis and bone mineralisation.
Calcium
Calcium is essential for multiple functions including, muscle contraction, vascular contraction, vasodilation, glandular secretion, enzyme reactions, nerve transmission, respiration, renal function, and blood coagulation. It also plays a key role in neurotransmitter and hormone release and storage.
Magnesium
Extracellular magnesium is essential for maintaining nerve and muscle electrical potentials as well as for transmitting nerve impulses across neuromuscular junctions. Additionally, magnesium appears to have neuroprotective effects.
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 Go!® Vitality Boost effervescent tablets is anticipated to be similar.
6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Acesulfame potassium
Aspartame
Citric acid
Croscarmellose sodium
Maltodextrin
Orange flavour
Polyethylene glycol 6000
Polysorbate 60
Sodium bicarbonate
Sorbitol
Sunset Yellow (E110).
6.2 Incompatibilities
None known
6.3 Shelf life
24 months
6.4 Special precautions for storage

- Store in a 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
Go!® Vitality Boost effervescent tablets are round, disc shaped, light yellow and orange flavoured.
Go!® Vitality Boost effervescent tablets are available in:
One (1) plastic tube container capped with 10 effervescent tablets, in a unit carton that includes a patient information leaflet.
Three (3) plastic tube containers capped with 10 effervescent tablets each (30 effervescent tablets in total), in a unit carton that includes a patient information leaflet.
6.6 Special precautions for disposal and other handling
No special requirements.
7. HOLDER OF CERTIFICATE OF REGISTRATION
Nativa (Pty) Ltd
260 Cradock Avenue, Lyttelton, Centurion, 0157, Gauteng, South Africa
Tel: +27 (0) 12 664 7110
Customer care line: 0860 628 482
Email: health@nativa.co.za
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 2022