

## PROFESSIONAL INFORMATION

### TURBOVITE® VITALITY EFFERVESCENT TABLETS

#### SCHEDULING STATUS

[S0]

#### PROPRIETARY NAME AND DOSAGE FORM

##### TURBOVITE® VITALITY EFFERVESCENT TABLETS (effervescent tablet)

#### COMPOSITION

| Active Ingredients                    | per effervescent tablet (maximum daily dosage) | % NRV # per maximum daily dosage |
|---------------------------------------|--|----------------------------------|
| Vitamin B1 (Thiamine hydrochloride)   | 18 mg  | 1500                             |
| Vitamin B2 (Riboflavin)               | 10 mg  | 769                              |
| Vitamin B3 (Nicotinamide)             | 18 mg  | 113                              |
| Vitamin B5 (Calcium D-Pantothenate)   | 25 mg  | 500                              |
| Vitamin B6 (Pyridoxine hydrochloride) | 10 mg  | 588                              |
| Vitamin B9 (Folic acid)               | 500 µg   | 125                              |
| Vitamin B12 (Cyanocobalamin)          | 20 µg  | 833                              |
| Biotin (D-biotin)                     | 100 µg   | 333                              |
| Vitamin C (Ascorbic acid)             | 500 mg   | 500                              |
| Magnesium (Magnesium sulfate)         | 84 mg  | 20                               |
| Zinc (Zinc gluconate)                 | 11 mg  | 100                              |

# Nutrient Reference Values for adults and children older than 4 years.

Excipients: citric acid, maltodextrin, mannitol, orange flavour, polyethylene glycol 6000, polysorbate 60 sodium bicarbonate, sodium carbonate, sodium cyclamate, saccharin sodium.

Contains sweeteners (sodium cyclamate 30 mg/tablet, and saccharin sodium 20 mg/tablet)

TURBOVITE® VITALITY EFFERVESCENT TABLETS are sugar free.

#### CATEGORY AND CLASS

D.34.13 Complementary Medicines: Health Supplements – Other.

#### PHARMACOLOGICAL ACTION

##### Pharmacodynamic properties

TURBOVITE® VITALITY EFFERVESCENT TABLETS contains a combination of vitamins and minerals. A sufficient intake of vitamins and minerals is necessary to maintain normal energy metabolism, and physical and physiological function. Unbalanced diet and insufficient dietary intake of vitamins and minerals can result in subnormal health.

##### Pharmacokinetic properties

TURBOVITE® VITALITY EFFERVESCENT TABLETS contains a combination of vitamins and minerals typical of the normal diet. Therefore, the pharmacological metabolism and fate of TURBOVITE® VITALITY EFFERVESCENT TABLETS is anticipated to be similar.

#### INDICATIONS

TURBOVITE® VITALITY EFFERVESCENT TABLETS is a multi-vitamin and mineral health supplement indicated for the maintenance of healthy energy levels.

TURBOVITE® VITALITY EFFERVESCENT TABLETS contain:

B complex vitamins, biotin, magnesium and zinc 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 and zinc function as antioxidants to help protect cells from oxidative stress and maintain normal immune function.

#### CONTRAINDICATIONS

Hypersensitivity to any of the ingredients of TURBOVITE® VITALITY EFFERVESCENT TABLETS (see **COMPOSITION**). TURBOVITE® VITALITY EFFERVESCENT TABLETS contains nicotinamide, which is contraindicated in patients with liver disease or in patients with active peptic ulcer disease. Contains vitamin B12, which is contraindicated in patients with cobalamin or cobalt hypersensitivity.

#### WARNINGS AND SPECIAL PRECAUTIONS

##### Warnings

Do not use if known hypersensitivity or allergy exists to any of the ingredients. If in doubt, consult your medical practitioner. The ingredients in TURBOVITE® VITALITY EFFERVESCENT TABLETS may interact with other medications (see **INTERACTIONS**).

##### Special precautions

**Porphyria:** Safety has not been established.

##### Effects on ability to drive vehicles and use machines

There is insufficient information available on the effects of TURBOVITE® VITALITY EFFERVESCENT TABLETS on the ability to drive or operate machinery.

#### INTERACTIONS

Take TURBOVITE® VITALITY EFFERVESCENT TABLETS a few hours before or after taking other medications (see **DOSAGE AND DIRECTIONS FOR USE**). TURBOVITE® VITALITY EFFERVESCENT TABLETS contains magnesium and zinc which may interact with tetracycline antibiotics and reduce their absorption. It is recommended that all oral antibiotics are taken at least two (2) hours before, or four (4) to six (6) hours after TURBOVITE® VITALITY EFFERVESCENT TABLETS or similar supplements. Zinc supplementation can cause a copper deficiency. Folic acid can mask a vitamin B12 deficiency. If in doubt, consult your medical practitioner.

#### HUMAN REPRODUCTION

##### Pregnancy

TURBOVITE® VITALITY EFFERVESCENT TABLETS are considered safe for use during pregnancy, however always consult with a medical practitioner before using any supplements at this time.

##### Women of Childbearing Potential

There are no known restrictions for use of TURBOVITE® VITALITY EFFERVESCENT TABLETS in women of childbearing age.

##### Lactation

TURBOVITE® VITALITY EFFERVESCENT TABLETS are considered safe for use while lactating, however always consult with a medical practitioner before using any supplements at this time.

##### Fertility

There are no known effects of TURBOVITE® VITALITY EFFERVESCENT TABLETS on fertility.

#### DOSAGE AND DIRECTIONS FOR USE

##### Dosage

Do not exceed the recommended daily dosage.

*Adults and children 14 years and older:*

Take one (1) effervescent tablet daily.

##### Directions for use

Dissolve one (1) effervescent tablet in a glass of water daily, after a meal. Take a few hours before or after taking other medications (see **INTERACTIONS**).

#### SIDE EFFECTS

If you experience any side effects or sensitivity towards any of the ingredients, discontinue use.

If symptoms persist, or if any adverse reactions occur, consult a medical practitioner.

Side effects may include, but are not limited to:

##### Gastrointestinal disorders

*Frequency unknown:* dyspepsia (including upper abdominal (epigastric) discomfort and nausea), vomiting, dysphagia, heartburn and diarrhoea

##### Skin and subcutaneous tissue disorders:

*Frequency unknown:* hypersensitivity reaction (dermatitis, erythema and urticaria)

##### Product issues

No product issues are available on TURBOVITE® VITALITY EFFERVESCENT TABLETS.

##### Post-marketing data

No side effects of TURBOVITE® VITALITY EFFERVESCENT TABLETS have been reported post-marketing.

#### KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

##### Symptoms of Overdosage

See **SIDE EFFECTS**.

Do not exceed the recommended daily dosage.

TURBOVITE® VITALITY EFFERVESCENT TABLETS contains zinc, which may cause copper deficiency. If you are unsure whether you are taking enough copper, consult a medical practitioner prior to use.

Other possible symptoms of TURBOVITE® VITALITY EFFERVESCENT TABLETS overdose may include but are not limited to, headache, insomnia, flushing of the skin, polyuria, and chromaturia, dizziness and drowsiness. Patients with a history of oxalate kidney stones should avoid high doses of vitamin C due to increased risk of kidney stone formation.

##### Treatment of Overdosage

If an accidental overdose occurs, consult a medical practitioner.

Treatment is symptomatic and supportive.

#### IDENTIFICATION

Light yellow, round, orange flavoured effervescent tablets.

#### PRESENTATION

One (1) printed, white, polypropylene effervescent tube with white effervescent spiral cap, containing 10 effervescent tablets, and a package insert in a unit carton.

Two (2) effervescent tubes with above description, containing 10 effervescent tablets each (20 effervescent tablets in total), and a package insert in a unit carton.

Three (3) effervescent tubes with above description, containing 10 effervescent tablets each (30 effervescent tablets in total), and a package insert in a unit carton.

#### STORAGE INSTRUCTIONS

Store at or below 25 °C.

Replace cap firmly after use.

Protect from light and moisture.

Keep in original packaging until required for use.

Do not use after the expiry date printed on the carton and tube.

KEEP OUT OF REACH OF CHILDREN.

#### REGISTRATION NUMBER

To be allocated

#### NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE 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

Website: www.nativa.co.za

#### DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

To be allocated

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To be allocated

#### COMPLEMENTARY MEDICINE

Health Supplement

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.

PPIL208/01