

PROFESSIONAL INFORMATION

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

SCHEDULING STATUS:

Unscheduled: Complementary Medicine

PROPRIETARY NAME AND DOSAGE FORM:

CAL-C-VITA® COMBO EFFERVESCENT TABLETS

COMPOSITION:

Active Ingredients

Name of ingredient	Content	% NRV
Vitamin B ₁	15.00 mg	1250
Vitamin B ₂	15.00 mg	1154
Nicotinamide	25.00 mg	156
Pantothenic Acid	23.00 mg	460
Vitamin B ₆	10.00 mg	590
Folic acid	0.40 mg	100
Vitamin B ₁₂	0.01 mg	417
Biotin	0.15 mg	500
Vitamin C	300.00 mg	300
Calcium	100.00 mg	8
Magnesium	100.0 mg	24
Zinc	10 mg	91
<i>NRV: Nutrient Reference Value</i>		

Inactive Ingredients:

Acesulfame potassium, aspartame, beet root juice, beta carotene, citric acid anhydrous, crillet 3, mannitol powder, orange flavour permaseal, sodium bicarbonate, sodium carbonate anhydrous, sodium chloride and polysorbate 60.

Contains sugar: Mannitol 362.85 mg/tablet

Contains sweetener: Aspartame 25 mg/tablet and acesulfame potassium 20 mg/tablet

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CATEGORY AND CLASS:

Combination Complementary Medicine

INDICATIONS:

For the stimulation of immune functions and the restoration of resistance to infection (illness) in situation of inadequate micronutrient supply.

CONTRA-INDICATIONS:

- Known hypersensitivity to any ingredient in the product.
- Hypercalcaemia
- Hypermagnesaemia
- Severe hypercalciuria
- Impaired renal function
- Hyperoxaluria

WARNINGS:

- The recommended daily dose of one tablet per day must not be exceeded unless under the supervision of a Doctor or Pharmacist.
- Folic acid, vitamin B12 and iron may mask certain forms of anaemia.
- Cal-C-Vita® Combo Effervescent Tablets must not be taken by patients with phenylketonuria since the product contains a source of phenylalanine (aspartame).
- Cal-C-Vita® Combo Effervescent Tablets contain 341 mg of sodium per tablet. To be taken into consideration by patients on a controlled sodium diet.
- High doses of vitamin C might interfere with diagnostic measures. Inform your physician when taking this product and diagnostic measures are planned on being done.

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INTERACTIONS:

When used as recommended no specific interactions are expected. Potential interactions are reported in the literature for the single ingredients, thus patients receiving any other medication or those under medical care should consult a Doctor or Pharmacist before taking Cal-C-Vita® Combo Effervescent Tablets.

HUMAN REPRODUCTION:

This product is not intended for use in pregnant or lactating women.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years: One (1) effervescent tablet a day dissolved in a glass of water or as recommended by a doctor or health professional.

The recommended daily dose of one tablet per day must not be exceeded unless under supervision of a Doctor or Pharmacist.

This medicinal product is not recommended for children below 12 years.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

In general, this product is well-tolerated. However, in rare cases gastrointestinal symptoms (e.g. abdominal discomfort, stomach discomfort, constipation, vomiting, diarrhoea, and nausea) might occur.

In very rare cases this product may cause allergic reaction. Symptoms may include facial swelling, skin reddening, and rash. If an allergic reaction occurs, treatment must be stopped and a healthcare professional consulted. A slight yellow discolouration of urine may be noticed. This effect is harmless and is due to the vitamin B2 contained in the preparation.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:

There is no evidence that this product can lead to an overdose when used as recommended.

Most, if not all reports concerning overdoses are associated with concomitant intake of high dosed single and/or multivitamin preparations.

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Uncharacteristic initial symptoms, such as confusion, and gastrointestinal disturbances such as constipation, diarrhoea, nausea, and vomiting might be indicative for an acute overdose.

If such symptoms occur, treatment must be stopped and a healthcare professional consulted.

IDENTIFICATION:

A speckled pale orange, cylindrical biplanar tablet.

When dissolved in water it makes an orange solution.

PRESENTATION:

Cal-C-Vita® Combo Effervescent Tablets are packed in polypropylene tube with MS/SiO₂ desiccant with polyethylene cap. The tubes are packed into a carton in pack sizes of 10's, 20's and 30's Tablets.

STORAGE INSTRUCTIONS:

Keep the tube tightly closed. Store in a cool dry place at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

Not applicable

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Bayer (Pty) Limited,

27 Wrench Road, Isando, 1600, South Africa

Co. Reg. no. 1968/011192/07

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

Not applicable

Manufactured and packed by Aviz Laboratories, Midrand, for Bayer (Pty) Ltd.