

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:

BEROCCA® BOOST EFFERVESCENT TABLETS

COMPOSITION:

Active Ingredients:

Name of ingredient	Declaration	% NRV
Vitamin B ₁ -in form of thiamine monophosphoric acid ester chloride dihydrate	1.4 mg	116
Vitamin B ₂ - in form of riboflavin sodium phosphate	1.6 mg	123
Nicotinamide	18.0 mg	112
Pantothenic Acid -in form of calcium pantothenate	6.0 mg	120
Vitamin B ₆ - in form pyridoxine hydrochloride	2.0 mg	118
Vitamin B ₁₂ -in form of vitamin B ₁₂ 0.1 % WS	0.001 mg	42
Biotin	0.150 mg	500
Vitamin C - in form of ascorbic acid	50.0 mg	50
Calcium -in form of calcium carbonate	100.0 mg	8
Magnesium -in form of magnesium carbonate (40 mg magnesium) -in form of magnesium sulphate dehydrate (60 mg magnesium)	100.0 mg	27
Zinc -in form of zinc citrate trihydrate	9.5 mg	95
Guarana extracts -in form of guarana seeds dry extract 18 % caffeine content	40.00 mg	*
NRV: Nutrient Reference Value *:NRV Not Determined		

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Inactive Ingredients:

Acerola flavour, acesulfame potassium, aspartame, beet red juice powder, citric acid anhydrous, dextrose, hydroxypropyl methylcellulose, mannitol, polysorbate 60, simethicone 30 % powder, sodium carbonate anhydrous, sodium hydrogen carbonate and sorbitol.

Contains sugar: Sorbitol 7, 5 mg/tablet and mannitol 2.0 mg/tablet

Contains sweetener: Aspartame 150 µg/tablet and acesulfame potassium 100 mg/tablet

CATEGORY AND CLASS:

Combination Complementary Medicine

INDICATIONS:

The combination of vitamin B-complex, vitamin C, minerals and guarana works in synergy to increase physical energy while decreasing tiredness.

Background information

Since most of the water-soluble vitamins of the B-complex and vitamin C are not stored by the body to any appreciable extent, their supply might be insufficient for instance in demanding periods such as during extensive physical exercise.

CONTRAINDICATIONS:

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

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WARNINGS AND SPECIAL PRECAUTIONS:

- 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.
- Berocca® Boost effervescent tablets must not be taken by patients with phenylketonuria since the product contains a source of phenylalanine (aspartame).
- Berocca® Boost 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.
- Patients with rare hereditary conditions of sorbitol intolerance should not take Berocca® Boost effervescent tablets.

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 this product.

HUMAN REPRODUCTION:

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

DOSAGE AND DIRECTIONS FOR USE:

Adults and adolescents: 1 effervescent tablet daily dissolved in a glass of water.

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.

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SIDE EFFECTS:

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.

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 pale pink, cylindrical biplane tablet.

When dissolved in water it makes a pale pink solution.

PRESENTATION:

Tubes: Berocca® Boost Effervescent Tablets are packed in a Polypropylene Tube with MS/SiO₂ desiccant 1.9 LDPE Stopper. The tubes containing 10 tablets are packed into a carton in pack sizes of 10's, 20's and 30's Tablets.

Sachet: Berocca® Boost Effervescent Tablet Singles (1) one tablet is packed in a 12mic Pet/9mic Foil/40mic LDPE sachet. Thirty (30) sachets are packed into a cardboard dispenser.

STORAGE INSTRUCTIONS:

Store in the original container at or below 25 °C. Keep the container tightly closed.

KEEP OUT OF REACH OF CHILDREN.

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REGISTRATION NUMBER:

Not applicable

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

Bayer (Pty) Ltd,

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.