

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® PERFORMANCE ORANGE EFFERVESCENT TABLETS

COMPOSITION:

Active Ingredients

Name of ingredient	Content	% NRV
Vitamin B ₁ -in form of thiamine monophosphoric acid ester chloride dihydrate	15.00 mg	1250
Vitamin B ₂ - in form of riboflavin sodium phosphate	15.00 mg	1154
Nicotinamide	25.00 mg	156
Pantothenic Acid -in form of calcium pantothenate	23.00 mg	460
Vitamin B ₆ - in form of pyridoxine hydrochloride	10.00 mg	588
Folic acid	0.40 mg	100
Vitamin B ₁₂ -in form of vitamin B ₁₂ 0.1 % WS	0.01 mg	417
Biotin	0.15 mg	500
Vitamin C - in form of ascorbic acid	300.00 mg	300
Calcium -in form of calcium carbonate -in form of calcium pantothenate	100.00 mg	8
Magnesium -in form of magnesium carbonate -in form of magnesium sulphate dihydrate	100.0 mg	27
Zinc -in form of zinc citrate trihydrate	10 mg	100
NRV: Nutrient Reference Value		

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:

The combination of vitamin B-complex, vitamin C and minerals works in synergy to provide you with the essential micro-nutrients for sustained mental performance and physical well-being.

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

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® Performance Orange effervescent tablets must not be taken by patients with phenylketonuria since the product contains a source of phenylalanine (aspartame).
- Berocca® Performance Orange 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 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.

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.

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IDENTIFICATION:

A speckled pale orange, cylindrical biplane tablet.

When dissolved in water it makes an orange solution.

PRESENTATION:

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

STORAGE INSTRUCTIONS:

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

KEEP OUT OF REACH OF CHILDREN.

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.