

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 50 + EFFERVESCENT TABLETS

COMPOSITION:

Active Ingredients

Name of ingredient	Label Claim	% NRV
Vitamin C	300.00 mg	300
Niacinamide	16.00 mg	100
d-Biotin	0.15 mg	500
Folic acid	0.40 mg	100
Pyridoxine hydrochloride	10.00 mg	588
Thiamine hydrochloride	15.00 mg	1250
Riboflavin	15.00 mg	1154
Vitamin B12	0.025 mg	1042
Calcium d-pantothenate	23.00 mg	460
Calcium	100.00 mg	8
Magnesium	100.00 mg	27
Zinc	10.00 mg	100
Panax Ginseng	50.00 mg	*
NRV: Nutrient Reference Value		
*:NRV Not Determined		

Inactive Ingredients:

Acesulfame potassium, aspartame, beet root juice, beta carotene, citric acid anhydrous, mannitol powder, polysorbate 60, povidone, sodium bicarbonate, sodium carbonate anhydrous, sodium chloride and tangerine.

Contains sugar: Mannitol 240.9 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, minerals and ginseng works in synergy to improve concentration, clarity and stamina.

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 50 + effervescent tablets must not be taken by patients with phenylketonuria since the product contains a source of phenylalanine (aspartame).
- Berocca® Performance 50 + 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 before diagnostic measures are planned on being done.
- A slight yellow discolouration of urine may be noticed. This effect is harmless and is due to the vitamin B₂ contained in the preparation.
- Berocca® Performance 50 + effervescent tablets contain ginseng caution is advised during pregnancy and lactation due to a lack of controlled human clinical studies.

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INTERACTIONS:

Berocca® Performance 50 + effervescent tablets may interact with warfarin when taken concurrently. Precaution should be taken to avoid concomitant use of Berocca® Performance 50 + effervescent tablets with Aspirin. These 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 Berocca® Performance 50 + effervescent tablets.

HUMAN REPRODUCTION:

Berocca® Performance 50 + effervescent tablets contain ginseng, caution is advised during pregnancy and lactation due to a lack of controlled human clinical studies.

DOSAGE AND DIRECTIONS FOR USE:

ADULTS: 1 effervescent tablet dissolved in a glass of water. Take daily or as directed by your health professional.

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:

Ten (10) Berocca® Performance 50 + effervescent tablets are packed in a polypropylene tube with MS/SiO₂ desiccant 1.9 polyethylene cap. The tubes are packed into a carton in pack sizes of 20 and 30 tablets.

STORAGE INSTRUCTIONS:

Keep 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) 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.