

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 + FILM COATED 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:

Croscarmellose sodium, lactose, magnesium stearate, mannitol, povidone and talc.

Contains sugar: Lactose 56,72 mg/tablet and mannitol 27,25mg/tablet

CATEGORY AND CLASS:

Combination Complementary Medicine

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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 of Berocca® Performance 50 + Film Coated Tablet
- 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.
- 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 + Film Coated Tablets contain ginseng caution is advised during pregnancy and lactation due to a lack of controlled human clinical studies.
- Contains lactose/fructose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take Berocca® Performance 50 + Film Coated Tablets.

INTERACTIONS:

Berocca® Performance 50 + Film Coated Tablets may interact with warfarin when taken concurrently.

Precaution should be taken to avoid concomitant use of Berocca® Performance 50 + Film Coated

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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 + Film Coated Tablets.

HUMAN REPRODUCTION:

Berocca® Performance 50 + Film Coated 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 tablet taken daily with water or as directed by your health professional.

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

Berocca® Performance 50 + Film Coated is not recommended for children under 12 years of age.

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 Berocca® Performance 50 + Film Coated Tablets 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.

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

IDENTIFICATION:

Modified capsule-shaped light green film coated tablet with a break line.

PRESENTATION:

Berocca® Performance 50 + Film Coated Tablets are packed in a high density polyethylene (HDPE) white plastic bottle with 50x20 mm sponge and twist polypropylene white cap. The bottle is packed into a carton.

STORAGE INSTRUCTIONS:

Store in a cool dry place 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 Hersol Manufacturing Laboratories (Pty) Ltd, Johannesburg, for Bayer (Pty) Ltd.