

## **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 FILM COATED TABLETS

### **COMPOSITION:**

#### **Active Ingredients**

<b>Name of ingredient</b>	<b>Label Claim</b>	<b>% NRV</b>
Vitamin B1	15.00 mg	1250
Vitamin B2	15.00 mg	1154
Nicotinamide	25.00 mg	156
Pantothenic Acid	23.00 mg	460
Vitamin B6	10.00 mg	588
Folic acid	0.40 mg	100
Vitamin B12	0.01 mg	417
Biotin	0.15 mg	500
Vitamin C	300.00 mg	300
Calcium	100.00 mg	8
Magnesium	100.0 mg	27
Zinc	10 mg	100
<b><i>NRV: Nutrient Reference Value</i></b>		

#### **Inactive Ingredients:**

Castor oil, croscarmellose sodium, flexicoat peach, magnesium stearate, microcrystalline cellulose, povidone, silicone dioxide and talc.

### **CATEGORY AND CLASS:**

Combination Complementary Medicine

## **PROFESSIONAL INFORMATION**

### **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.
- 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.
- A slight yellow discolouration of urine may be noticed. This effect is harmless and is due to the vitamin B2 contained in the preparation.

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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:**

Berocca® Performance Film Coated tablets is not intended for use in pregnant or lactating women.

### **DOSAGE AND DIRECTIONS FOR USE:**

From age of 12 to adult: 1 tablet daily.

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

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

### **SIDE EFFECTS:**

In general, Berocca® Performance Film Coated 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 Berocca® Performance Film Coated 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 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.

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

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### **IDENTIFICATION:**

Modified capsule shaped peach coloured coated tablets with a break line.

### **PRESENTATION:**

Berocca® Performance 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 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 Hersol Manufacturing Laboratories (Pty) Ltd, Johannesburg, for Bayer (Pty) Ltd.