

#### PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

#### **Berocca® Sport Powder**

#### Sugar free

Contains sweeteners: xylitol 415 mg, sucralose 2,88 mg and acesulfame potassium 0,90 mg per sachet.

D: Complementary Medicine HEALTH SUPPLEMENT: Multiple substance formulation

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

#### Read all of this leaflet carefully because it contains important information for you.

Berocca® Sport Powder is available without a doctor's prescription, for you to maintain your health.

Nevertheless, you still need to use Berocca® Sport Powder carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Berocca® Sport Powder with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

#### What is in this leaflet

- 1. What Berocca® Sport Powder is and what it is used for
- 2. What you need to know before you take Berocca® Sport Powder
- 3. How to take Berocca® Sport Powder
- 4. Possible side effects
- 5. How to store Berocca® Sport Powder
- 6. Contents of the pack and other information



#### 1. What Berocca® Sport Powder is and what it is used for.

Berocca® Sport Powder is a health supplement and a multiple substance formulation. **Berocca® Sport**Powder is used for:

- Reducing tiredness and fatigue: Contains vitamins B<sub>6</sub> and B<sub>12</sub>, plus vitamin C, which can help reduce tiredness & fatigue,
- Supporting electrolyte balance: Electrolytes play an important role in your body, such as supporting nerve & muscle function – electrolytes are lost in sweat, so it is important to replenish them. Berocca® Sport Powder contains magnesium to support electrolyte balance,
- **Helping you feel energised**: Contains vitamins B<sub>1</sub> and B<sub>2</sub> that contribute to normal energy metabolism,
- Supporting your muscles: Contains magnesium, which contributes to your muscle function,
- Helps to improve your focus: Contains caffeine, which temporarily promotes alertness and wakefulness - providing you with a mental boost,
- Temporarily assist to increase mental activity,
- Contribute to normal psychological function.

Berocca® Sport Powder works by enhancing mental and physical performance through the action of caffeine, vitamins and minerals on the basic metabolic processes.

## 2. What you need to know before you take Berocca® Sport Powder

#### Do not take Berocca® Sport Powder

- If you are hypersensitive (allergic) to the active ingredients or any of the other ingredients of Berocca® Sport Powder (listed in section 6).
- If you are taking it in combination with ephedrine, ephedra or other stimulants.
- If you have been told that you have an intolerance to some sugars, you should not take
   Berocca® Sport Powder.



- If you are under 18 years of age.
- If you are pregnant or breastfeeding.

#### Warnings and precautions

Take special care with Berocca® Sport Powder

- Contains 75 mg of caffeine per sachet. Instant coffee contains approximately 80 mg of caffeine.
- Consult a registered healthcare professional if you-
  - are taking any other medicine (such as lithium) including chronic, complementary or traditional medicines; or
  - have high blood pressure, glaucoma, and/or detrusor instability (overactive bladder syndrome).
- Consumption with other medicines (e.g. bitter orange extract, synephrine, octopamine, ephedra, ephedrine) which increase blood pressure is not recommended.
- Use of caffeine may result in sleep deprivation.
- Consumption with other caffeine-containing products or foods (e.g. medications, coffee, tea, colas, cocoa, guarana, maté) is not recommended.
- Discontinue use two weeks prior to surgery.
- If you are of childbearing age, pregnant or breastfeeding and have concerns that your daily intake of caffeine from all sources may exceed 200 mg per day, please consult a relevant health care provider prior to use.
- Excessive consumption may cause laxative effects.
- Contains mannitol, sorbitol, xylitol and may have laxative effect.

#### Children

Not suitable for children under the age of 18 years.



## Other medicines and Berocca® Sport Powder

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicine).

Do not consume with medicines that increase blood pressure.

Active ingredient	Medicine	Description
Vitamin C	Desferrioxamine (medicine used	Vitamin C may enhance tissue iron toxicity,
	to remove excess iron or	especially in the heart, causing cardiac
	aluminum from the body.)	decompensation.
	Cyclosporine (immunosuppressive medicine)	Antioxidant supplementation including
		vitamin C may reduce cyclosporine blood
		level.
	Disulfiram (a drug used to	Chronic or high doses of vitamin C may
	support the treatment of alcohol	interfere with the effectiveness of the
	use disorder)	disulfiram.
	Warfarin (blood thinning	High dose vitamin C may interfere with the
	medicine)	effectiveness of warfarin.
Vitamin B <sub>6</sub>	Levodopa	Pyridoxine enhances the metabolism of
		levodopa, reducing its anti-parkinsonism
		effects. However, this interaction does not
		occur when carbidopa is in combination with
		levodopa.
Vitamin B <sub>12</sub>	Chloramphenicol (an antibiotic)	Chloramphenicol may delay or interrupt the
		reticulocyte response to vitamin B <sub>12</sub> .
		Therefore, blood counts need to be closely
		monitored if this combination can't be
		avoided.



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		Folic acid supplementation may reduce the
Folic Acid	Methotrexate (immune system suppressant)	effectiveness of methotrexate in the
		treatment of acute lymphoblastic leukaemia,
		and theoretically, the efficacy in the treatment
		of other cancers.
		Thiazide diuretics reduce the urinary
Calcium	Thiazide Diuretics (water tablets)	excretion of calcium. Due to an increased risk
		of hypercalcemia, serum calcium should be
		regularly monitored during concomitant use
		of thiazide diuretics.
		Potassium-sparing diuretics also have
Magnesium, Zinc	Potassium-Sparing Diuretics	magnesium-sparing and/or zinc-sparing
		properties. Increased magnesium and/or zinc
		levels could result with concomitant use of
		potassium-sparing diuretics and
		supplementation.
	Tetracycline antibiotics	Polyvalent cations, such as calcium,
	Quinolone antibiotics	magnesium, and/or zinc, form complexes
	Penicillamine	with certain substances resulting in
Calcium,	Biphosphonates	decreased absorption of both substances.
Magnesium, Zinc	Levothyroxine	Separate intake of the product either 2 hours
	Methyldopa	before or 4 hours after other medication,
	Mycophenolate mofetil	unless otherwise specified, will minimize risk
	Eltrombopag	for this interaction.

Berocca® Sport Powder with food, drink and alcohol



- Vitamin C may increase iron absorption. Patients with iron overload should avoid intake of vitamin C greater than 500 mg per day.
- Do not consume more than 300 mg of caffeine per day from all sources.
- Do not consume with other caffeine containing products (e.g. medications, coffee, tea, colas, cocoa, guarana).
- Do not take Berocca® Sport Powder with alcohol.

## Pregnancy, breastfeeding and fertility

Do not take Berocca® Sport Powder if you are pregnant or breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking Berocca® Sport Powder.

#### **Driving and using machines**

No effects on ability to drive and use machines have been observed.

#### 3. How to take Berocca® Sport Powder

Always take Berocca® Sport Powder exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take Berocca® Sport Powder orally directly onto the tongue before exercising.

#### The usual dose is:

#### Adults:

Take 1 sachet daily before exercising- simply pour the powder directly on to the tongue.



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Do not exceed the recommended dosage of one sachet per day.

Not suitable for children under 18 years of age, pregnant or breastfeeding women.

Individuals are advised not to consume more than 300 mg of caffeine per day from all sources.

What to do if you take more Berocca® Sport Powder than you should

There is no evidence that this product can lead to an overdose when used as recommended. General manifestation of overdose may include confusion and gastrointestinal disturbances such as constipation, diarrhoea, nausea, and vomiting.

If such symptoms occur, the product should be stopped, and a consult your doctor, pharmacist or other healthcare professional. If neither available, seek help at the nearest hospital or poison control centre.

#### 4. Possible side effects

Berocca® Sport Powder can have side effects.

Not all side effects reported for Berocca® Sport Powder are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Berocca® Sport Powder, please consult your doctor, pharmacist or other healthcare professional for advice.

Berocca® Sport Powder may cause some allergic reactions and symptoms may include difficulty breathing or swallowing, itchy throat, skin reddening and rash.

Rare gastrointestinal symptoms such as constipation, nausea, abdominal discomfort, diarrhoea and vomiting may occur.

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A slight orange-yellow discolouration of urine may be noticed, however this is harmless and is due to the Vitamin B<sub>2</sub> in Berocca® Sport Powder.

#### Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <a href="https://www.sahpra.org.za/Publications/Index/8">https://www.sahpra.org.za/Publications/Index/8</a> or you can report the side effects directly to Bayer Pharmacovigilance Department by sending and email to <a href="mailto:zapv@bayer.com">zapv@bayer.com</a> or via the Bayer website (<a href="www.bayer.co.za">www.bayer.co.za</a>). By reporting side effects, you can help provide more information on the safety of Berocca® Sport Powder.

#### 5. How to store Berocca® Sport Powder

Store at or below 25 °C

Keep out of reach of children

Do not used after the expiry date stated on the label and carton.

Do not dispose unused medicines in drains or sewerage (e.g. toilets)

## 6. Contents of the pack and other information

#### What Berocca® Sport Powder contains:

The active substances of Berocca® Sport Powder are vitamin B<sub>1</sub> (thiamine hydrochloride) 1,4 mg, vitamin B<sub>2</sub> (riboflavin-5-phosphate) 1,6 mg, vitamin B<sub>3</sub> (niacin) 18 mg, vitamin B<sub>5</sub> (pantothenic acid) 6,0 mg, vitamin B<sub>6</sub> (pyridoxine hydrochloride) 2,0 mg, folic acid 0,2 mg, vitamin B<sub>12</sub> (cyanocobalamin) 0,001 mg, biotin 0,1 mg, vitamin C 60 mg, calcium (calcium-D-pantothenate) 100 mg, magnesium (magnesium oxide heavy) 100 mg, zinc 9,5 mg (zinc citrate trihydrate) and caffeine 75 mg contained in each sachet.



**The other ingredients** are xylitol, sorbitol, mannitol, citric acid anhydrous, sodium hydrogen carbonate, masking flavour bitterness, cola flavour, sucralose, apricot flavour and acesulfame potassium.

## What Berocca® Sport Powder looks like and contents of the pack

Berocca® Sport Powder is packed in aluminium foil sachets. The sachets are packed in cartons containing 14 units.

## **Holder of Certificate of Registration**

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#### This leaflet was last revised in

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## Berocca® Sport Powder PIL-English

## Registration number

[to be updated upon approval]

## **Access to the corresponding Professional Information**

The corresponding professional information may be obtained electronically on the following web address:

https://www.bayer.co.za