SELECT THE REQUIRED INFORMATION

PROFESSIONAL INFORMATION

PATIENT INFORMATION LEAFLET

COMPLEMENTARY MEDICINE: HEALTH SUMPLEMENT
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

BEROCCA® EXPERT Mg 125 mg, Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains the following active ingredients:

Ingredient Name	Quantity
Total Magnesium (elemental) From the following sources (magnesium oxide 75,0 mg; magnesium citrate 32,5 mg; magnesium bisglycinate 12,5 mg; magnesium gluconate 2,5 mg; and magnesium glycerophosphate 2,5 mg)	125 mg

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard gel capsules

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Berocca® expert Mg, Capsules is a mineral health supplement that:

- Contributes to a reduction of tiredness and fatigue,
- Contributes to the maintenance of normal muscle function and
- Contributes to normal functioning of the nervous system.

4.2. Posology and method of administration

Posology

For oral use.
The recommended intake for adults over the age of 18 years is two capsules per day.

4.3. Contraindications

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Impaired renal function

4.4. Special warnings and precautions for use

Do not exceed the stated recommended daily dose. Acute and chronic overdose increases the risk of adverse effects. Allowance should be made for intake of minerals from all other sources including fortified foods, dietary supplements, and concomitant medications (see section 4.9).
Health supplements should not be used as a substitute for a varied diet.
Separate intake of the product from other medications by four (4) hours unless otherwise specified (see section 4.5).

4.5. Interaction with other medicines and other forms of interaction

Manifold potential interactions are reported in the literature for the single ingredients, thus individuals receiving any other medication, dietary/health supplements, or those under medical care should consult a physician or health care professional before use of the product. When used as recommended no specific interactions are expected.

Drug interactions

Active Ingredient	Drug	Description
Magnesium	Tetracycline antibiotics	Magnesium is a polyvalent cation and may form complexes with certain substances resulting in decreased absorption of both substances. Separate intake of the product and these medications by 4 hours, unless otherwise specified, will minimize risk for this interaction.
	Quinolone antibiotics	
	Biphosphonates	
	Levothyroxine	
	Methyldopa	
	Mycophenolate mofetil	
	Gastric acid suppressive medications	

4.6. Fertility, pregnancy and lactation

Fertility

There is no evidence suggestive that normal endogenous levels of the vitamins and minerals in the product cause adverse reproductive effects in humans.

Pregnancy & Breastfeeding

BEROCCA® Expert Mg Capsules is not recommended in case of pregnancy or lactation.

4.7. Effects on ability to drive and use machines

The product has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

The listed adverse reactions have been identified during post-approval use of the product. Because these reactions are reported voluntarily, it is not possible to estimate their frequency.

Gastrointestinal disorders

Gastrointestinal and abdominal pain, constipation, diarrhoea, nausea and vomiting may occur.

Immune system disorders
in isolated cases this product may cause allergic or anaphylactic reaction. Symptoms may include hives, facial swelling, wheezing, skin reddening, rash, blisters, and shock. If an allergic reaction occurs, treatment must be stopped, and a health care professional consulted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Alternatively, you can report to Bayer SafeTrack site (https://www.safetrack-public.bayer.com) or via the Bayer website (www.bayer.co.za). By reporting side effects, you can help provide more information on the safety of BEROCCA® Expert Mg Capsules.

4.9. Overdose

There is no evidence that this product can lead to an overdose when used as recommended.
Most, if not all reports concerning overdoses of vitamins and minerals are associated with concomitant intake of high dosed single and/or multivitamin preparations.
Uncharacteristic initial symptoms such as gastrointestinal disturbances (such as constipation, diarrhea) nausea, and vomiting might be indicative for an acute overdose.
If such symptoms occur, treatment must be stopped and a health care professional consulted.
Specific clinical manifestations may include the following:
If overdose with the product is suspected, intake should be stopped, and a health care professional consulted for treatment of clinical manifestations.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacological classification: category D 34.12 (Multiple substance formulation).
Multivitamins, other combinations constitute a distinct pharmacotherapeutic group under the ATC code A12CC.

Minerals (including trace elements) are inorganic substances and must be taken up through food, whereas vitamins can be synthesized by many species. Humans, however, have lost this ability and cannot synthesize most vitamins in sufficient amounts, and are therefore dependent on a continuous exogenous supply.
Magnesium is an intracellular mineral that is essential for the optimal function of a diversity of life-sustaining processes. It serves as a cofactor for more than 300 enzymatic reactions in which food is catabolized and new chemical products are formed; it is required for both aerobic and anaerobic energy production, and for glycolysis as part of the Mg-ATP complex, synthesis of fatty acids and proteins. Magnesium also serves as a regulator of many physiologic functions, including neuromuscular, cardiovascular, immune and hormonal functions, as well as the maintenance of cellular membrane stability.

5.2. Pharmacokinetic properties

Absorption:

Absorption of magnesium as a function of intake appears curvilinear. The curved portion is compatible with a saturable process (facilitated diffusion or active absorption) and the linear function reflects passive diffusion. Passive diffusion has been estimated to contribute around 7-10 %. Intestinal perfusion techniques in human subjects indicate magnesium to be absorbed by both jejunum and ileum with absorption being fully saturable in the ileum but not the jejunum.

Distribution:

More than half the total body magnesium is found in bone (60-65 %) with almost all the rest in soft tissue: muscle 27 %, other cells 6-7 %, extracellular < 1 %. The greater proportion of intracellular magnesium exists in bound form, e.g. in muscle mainly bound to adenosine triphosphate (ATP), phosphocreatine and myosin. Average plasma magnesium concentration is about 0,85 mM (range 0,65 to 1,0 mM) and is maintained remarkably constant in healthy individuals by poorly understood homeostatic controls, which do not appear to be regulated by hormonal mechanism.

Metabolism:

There a number of biochemical and physiological processes require or are modulated by magnesium. As the Mg-ATP2- complex, magnesium is important for all biosynthetic processes, for glycolysis, formation of cyclic-AMP (adenosine monophosphate), energy-dependent membrane transport, and transmission of the genetic code. More than 300 enzymes are known to be activated by magnesium.

Excretion:

Magnesium is retained either for tissue growth (including bone) or as turnover replacement; the remainder is excreted in the urine. Plasma magnesium levels are believed to be regulated primarily by the kidney. Approximately 70 % of plasma protein is not bound to protein and is therefore filterable.
About 30 % of filtered magnesium is reabsorbed in the proximal tubule and another 65 % is reabsorbed in the loop of Henle, the site at which major adjustments in response to plasma concentrations appear to take place.

5.3. Preclinical safety data

There is no specific study with this product but the preclinical safety of the individual components has been extensively documented.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Magnesium stearate,
Pregelatinized Maize starch, and
Hydroxypropyl methylcellulose (for the hard gel capsule shells)

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at or below 25°C.

6.5. Nature and contents of container

Hard gel capsule
The plastic bottles are labelled or printed on the external side, and then packed in a non-functional secondary packaging (folding carton), possibly with a leaflet enclosed.

6.6. Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Bayer (Pty) Ltd
Collaboration Hub
1st Floor, Waterfall Circle
9 Country Estate Drive
Waterfall City
Midrand, 2090
South Africa
Co Reg. no.: 1968/011192/07
Tel: +27 11 921 5000

8. REGISTRATION NUMBER(S)

To be confirmed upon registration.

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

To be confirmed upon registration.

10. DATE OF REVISION OF TEXT

11. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

To be confirmed upon registration.

Manufacturer:
PiLeJe Industrie S.A.S.,Naturopôle Nutrition Santé, Les Tiolans, F-03800 Saint-Bonnet de Rochefort, France.