PROFESSIONAL INFORMATION

D: 34.12: Multiple substance formulation
Complementary Medicine: Health Supplement
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

BEROCCA ELECTRO effervescent powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Berocca Electro is a health supplement with magnesium, potassium and vitamins, in the form of effervescent granules.
Each 4 g sachet contains following active ingredients:

Active ingredient name	Quantity
Vitamin B1 (Thiamine hydrochloride)	2,1 mg
Vitamin B6 (Pyridoxine hydrochloride)	3,0 mg
Vitamin B12 (Cyanocobalamin)	9,0 µg
Vitamin C (Ascorbic acid)	250,0 mg
Folic acid (Pteroylmonoglutamic acid)	200,0 µg
Magnesium (Magnesium oxide)	225,0 mg
Potassium (Potassium bicarbonate)	300,0 mg

Contains sugar (sorbitol 159 mg).
Contains sweetener (acesulfame 45 mg).

For full list of excipients, see section 6.1.

3. PHARMACETUICAL FORM

Effervescent powder.
Pink granules with a sweet orange flavour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Berocca Electro is a multi-mineral and vitamin supplement which contributes to normal electrolyte balance.

4.2. Posology and method of administration

Posology

For oral use.

The recommended intake for adults (above 18 years of age) is one (1) sachet per day.

Method of administration

Dissolve the sachet in a glass (i.e. approximately 200 ml) of water.

4.3. Contraindications

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Younger than 18 years old.
- Concomitant use with other potassium-containing supplements or with potassium-containing salt-substitutes.
- This product is not intended for use during pregnancy and lactation.

4.4. Special warnings and precautions for use

Allowance should be made for intake of the vitamins and minerals from all other sources including fortified foods, dietary supplements, and concomitant medications.

Berocca Electro contains 159 mg sorbitol in each sachet. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.

Berocca Electro contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

4.5. Interaction with other medicines and other forms of interaction

No interaction studies have been performed on Berocca Electro.

Concomitant use with potassium-containing supplements or with potassium containing salt substitutes may results in hyperkalaemia.

4.6. Pregnancy and lactation

Pregnancy

This product is not intended for use during pregnancy and lactation. Considering that Berocca Electro does not fulfil the wide spectrum of the specific nutrient requirements or quantitative composition for use during pregnancy, it is not recommended for use without first consulting with a healthcare professional.

Breastfeeding

The vitamins and minerals in the product are excreted into breast milk. This should be taken into consideration.

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 ingredients contained in Berocca Electro are within the limits as recommended by SAHPRA and serious adverse reactions are not expected.

Expected adverse reactions include:
Gastrointestinal disorders: Diarrhoea

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).

4.9. Overdose

General manifestations of overdose may include diarrhoea. If such symptoms occur, the product should be stopped and a health care professional consulted.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Multivitamins with minerals (incl. combinations with trace elements) constitute a distinct pharmacotherapeutic group under the ATC code **A11AA**.
Class: 34.12: Multiple substance formulation

Berocca Electro effervescent powder is a multivitamin and -mineral preparation. It is especially developed for use in adults and consists of the vitamins B1, B6, folic acid, vitamin B12, vitamin C, as well as of the two minerals magnesium and potassium.

5.2. Pharmacokinetic properties

There is no specific study with this product but the pharmacokinetic properties of the individual components have been extensively documented.
Human health and well-being are naturally dependent on the continuous uptake and management of vitamins and trace elements and their absorption, distribution, metabolism and elimination are maintained by specific physiological mechanisms.

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

Citric acid anhydrous

Sorbitol (E420)
Orange flavour
Acesulfame (E950)
Beetroot red (E162)
Riboflavin sodium phosphate (E101)

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 months

6.4. Special precautions for storage

Do not store above 25°C.

6.5. Nature and contents of container

4 g effervescent powder is packed in a multi-layer polyethylene/aluminium sachet.
Sachets are packed in secondary packaging (folding carton) with a leaflet.
Pack size: 14

6.6. Special precautions for disposal

special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Bayer (Pty) Ltd.
Collaboration Hub, 1st Floor
Waterfall Circle, 9 Country Estate Drive
Waterfall City
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.