PROFESSIONAL INFORMATION

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® Junior Beans Soft chewable tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Berocca Junior Beans contains the following active ingredients:

Ingredient	Quantity		
	1 soft chewable tablet	3 soft chewable tablets	4 soft chewable tablets
Vitamin A (retinyl palmitate)	66,80 µg	200,40 µg	267,20 µg
Vitamin B3 (nicotinamide)	2,70 mg	8,10 mg	10,80 mg
Vitamin B6 (pyridoxine hydrochloride)	0,23 mg	0,69 mg	0,92 mg
Biotin (D-biotin)	8,30 µg	24,90 µg	33,20 µg
Vitamin B12 (cyanocobalamin)	0,42 µg	1,26 µg	1,68 µg
Vitamin C (ascorbic acid)	16,00 mg	48,00 mg	64,00 mg
Vitamin D3 (cholecalciferol)	0,83 µg	2,49 µg	3,32 µg
Vitamin E (D-alpha-tocopherol)	2,50 mg	7,50 mg	10,00 mg
Vitamin K1 (phytomenadione)	13,00 µg	39,00 µg	52,00 µg
Iodine (potassium iodide)	15,00 µg	45,00 µg	60,00 µg
Zinc (zinc sulphate)	0,50 mg	1,50 mg	2,00 mg

Contains sugar. Each soft chewable tablet contains 1 009,8 mg sucrose. Orange and lemon flavoured soft chewable tablet contain 525,6 mg glucose. Strawberry flavoured soft chewable tablet contain 527,4 mg glucose.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Soft chewable tablets.

Berocca Junior Beans contains a mixture of orange jelly bean shaped soft chewable tablets with an orange flavour; red jelly bean shaped soft chewable tablets with a strawberry flavour; and yellow jelly bean shaped soft chewable tablets with a lemon flavour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Berocca Junior Beans is a health supplement with vitamins and minerals, in the form of soft chewable tablet, with sugar.
Berocca Junior Beans helps support children's normal growth; contributes to normal cognitive function; contributes to normal function of the immune system; contributes to normal collagen formation and the normal function of cartilage, teeth, and bones; and contributes to the maintenance of normal vision.

4.2. Posology and method of administration

Posology

Children 3 to 10 years old: 3 soft chewable tablets per day.
Children 11 years and older: 4 soft chewable tablets per day.

Method of administration

For oral use. To be chewed slowly and swallowed once dissolved in the mouth.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Do not exceed the recommended dose.

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take Berocca Junior Beans.

Berocca Junior Beans contains less than 1 mmol (23 mg) sodium.

4.5. Interaction with other medicines and other forms of interaction

When used as recommended no specific interactions are expected. However, potential interactions for single ingredients are reported in the literature, thus patients receiving any other medication or those under medical care should consult a physician or healthcare professional before taking Berocca Junior Beans.

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

Many vitamins and minerals can cross the placenta. A women’s nutritional status should be evaluated before determining the safe use of Berocca Junior Beans during pregnancy.

Lactation

Vitamins and minerals can be excreted in breastmilk. A women's nutritional status should be evaluated before determining the safe use of Berocca Junior Beans while lactating.

4.7. Effects on ability to drive and use machines

Berocca Junior Beans has no effect on the ability to drive and use machines.

4.8. Undesirable effects

Berocca Junior Beans is safe when taken in the recommended doses. Adverse effects are more likely to occur with higher doses. Adverse events commonly associated to the individual vitamins and minerals contained in Berocca Junior Beans are listed below.

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)

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 are associated with concomitant intake of high dosed single and/or multivitamin preparations.
Overdoses and chronic overdoses are reported in the medical literature for the single ingredients. Laboratory and clinical manifestations of toxicity are highly diverse and dependent on the patient's susceptibility and surrounding circumstances.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacological classification: category D 34.12 (Multiple substance formulation).
Pharmacotherapeutic group: Multivitamins and other minerals, including combinations
ATC code: A11AA03

Berocca Junior Beans is a multivitamin/multimineral formula containing vitamins in combination with minerals especially designed to contribute to the healthy growth and development of children and adolescents.

5.2. Pharmacokinetic properties

Human health and well-being is naturally dependent on the continuous uptake and management of vitamins and minerals and their absorption, distribution, metabolism and elimination are maintained by specific physiological mechanisms.
The active ingredients of this preparation are essential micronutrients, which are widely distributed in the human body. The discrimination between the physiological nutrient concentration in the plasma and its changes after additional intake of corresponding pharmaceutical preparations is, on the one hand, difficult to assess and conveys, on the other hand, little or no information on the biological activity of the individual nutrient in the target tissue. The plasma and tissue levels of micronutrients are homeostatically regulated and affected by various factors such as diurnal fluctuations, nutritional status, growth, and pregnancy and lactation No pharmacokinetic data are available on the active ingredients of this preparation, but the pharmacokinetic properties of the individual components have been extensively documented.

Absorption
The absorption of Vitamin C is through the oropharynx, stomach and the entire length of the small intestine. The absorption of Vitamins A, B3 and B6 are primarily through upper small intestine. The absorption of Vitamins D, E, biotin and zinc are through the entire length of the small intestine. The absorption of and iodine is through the entire length of the small intestine and the colon. Vitamin K1 is rapidly absorbed via bile-dependent intestinal mechanisms.

Distribution
Primarily all vitamins and minerals are required for cellular functions and are distributed throughout the body. Water soluble vitamins are stored only to a minor extent, while fat soluble can be stored in liver and adipose tissue.

Metabolism/Biotransformation
Vitamin A is metabolised by the intestinal cells. Liver is the primary organ for metabolism/biotransformation of Vitamins A, B6, B12, C, D, E and K1. Vitamin D is further metabolised by the kidney.

Excretion/Elimination
Vitamin A enters enterohepatic circulation, and is eliminated by the faeces and kidneys. All the other vitamins and minerals are eliminated through kidneys. In addition, Vitamins D, E, K1, B12 and zinc can be eliminated though faeces.

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

Sugar (sucrose)
Glucose syrup
Modified potato starch
Citric acid, anhydrous
Trisodium citrate
Maltodextrin
Vegetable oil (palm)
Limonene
Carnauba wax
Colouring agents: orange/red/yellow
Flavours: orange/strawberry/lemon

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at or below 25 °C.
The container should always be tightly closed.

6.5. Nature and contents of container

Coloured transparent PET bottle with a child-resistant closure. Bottles are sealed with a tamper-evident seal.
Pack sizes: 60, 90 and 120 soft chewable tablets. Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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

July 2026

Manufacturer:
F Hunziker & Co AG Switzerland.