

PATIENT INFORMATION LEAFLET

Complementary Medicine	Health Supplement
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.	

SCHEDULING STATUS: S0**BEROCCA® COMPLETE film-coated tablets**
Sugar free**Read all of this leaflet carefully because it contains important information for you**

Berocca® Complete film-coated tablets is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Berocca® Complete film-coated tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Berocca® Complete film-coated tablets 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® Complete film-coated tablets is and what it is used for
2. What you need to know before you take Berocca® Complete film-coated tablets
3. How to take Berocca® Complete film-coated tablets
4. Possible side effects
5. How to store Berocca® Complete film-coated tablets
6. Contents of the pack and other information

1 What Berocca® Complete film-coated tablets is and what it is used for

Berocca Complete film-coated tablets consist of thirteen vitamins, nine minerals and trace elements together with CoQ10.

Berocca Complete film-coated tablets Complete A to Z vitamins and minerals for overall health, mental performance, and physical energy.

Berocca® Complete film-coated tablets provides a comprehensive range of A-to-Z vitamins and minerals for overall health, mental performance, and physical energy.

2 What you need to know before you take Berocca® Complete film-coated tablets**Do not take Berocca® Complete film-coated tablets:**

- If you are hypersensitive (allergic) to any of the other ingredients of Berocca® Complete film-coated tablets (listed in section 6).
- If you have too much iron in your blood (hemochromatosis) or kidney problems. This includes people on dialysis.
- If you have problems with how your body handles iron or copper, you should avoid this product.
- If you already have too much vitamin A or D in your body, you shouldn't use this product.

- If you already have too much calcium in your blood (hypercalcaemia), a history of kidney stones (nephrolithiasis), or too much oxalate in their urine (hyperoxaluria) you should avoid this product.
- If your kidneys don't work as well as they should (renal insufficiency), this product isn't suitable for you.
- If you're already taking vitamin A, retinoids, beta-carotene, or similar substances like isotretinoin and etretinate, you shouldn't use this product.

Warnings and precautions

Don't exceed the recommended dose. Overdosing can lead to harmful effects. Special care should be taken with Berocca® Complete film-coated tablets:

- If you're already taking other vitamins, medications, or if you're under medical care, you should talk to a healthcare professional before using this product.
- If you're taking medicines similar to vitamin D, you should avoid this product to prevent having too much vitamin D or calcium in your body. If you must take them together, you need to regularly check your blood and urine for calcium levels.
- Patients on vitamin K antagonists or other anticoagulation treatments should consult a healthcare professional before using Berocca® Complete film-coated tablets.
- Avoid using this product with other products containing Vitamin A, isotretinoin, etretinate, or beta-carotene, as it may lead to an excess of vitamin A (hypervitaminosis A).
- If you suffer from kidney stones or urinary stones you should be cautious when using vitamin supplements, such as calcium, ascorbic acid, and vitamin D may affect stone formation.
- When taking this product, make sure to take it at least four hours apart from other medications unless otherwise specified.

Other medicines

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Active Ingredient	Drug	Description
Vitamin C	Desferrioxamine (medicine used to remove excess iron or aluminium from the body)	Vitamin C may enhance tissue iron toxicity, especially in the heart, causing cardiac decompensation.
	Cyclosporine (immunosuppressive medication)	Antioxidant supplementation including vitamin C may reduce cyclosporine blood level.
	Disulfiram (used to treat chronic alcoholic misuse)	Chronic or high doses of vitamin C may interfere with the effectiveness of the disulfiram.
	Warfarin (blood thinning medicine)	High dose vitamin C may interfere with the effectiveness of warfarin.
Vitamin B₆	Levodopa (prescription medicine used in the treatment of Parkinson's disease)	Pyridoxine enhances the metabolism of levodopa, reducing its anti-parkinsonism effects. However, this interaction does not occur when carbidopa is in combination with levodopa (i.e. Sinemet®).
Folic Acid	Methotrexate (medicine used to treat rheumatoid arthritis and severe forms of a skin disease called psoriasis)	Folic acid supplementation may reduce the effectiveness of methotrexate in the treatment of acute lymphoblastic leukaemia, and theoretically, the efficacy in the treatment of other cancers.

Active Ingredient	Drug	Description
Vitamin A	Retinoids* (a class of medicines derived from vitamin A)	Vitamin A supplementation must be avoided during treatment with vitamin A, retinoids, beta-carotene, and/or the synthetic isomers due to increased risk of vitamin A toxicity. Synthetic isomers include isotretinoin, etretinate, acitretin, and bexarotene.
Vitamin D3	Vitamin D analogues (vitamin supplements used for treating disorders caused by vitamin D deficiency)	Concomitant treatment with vitamin D analogues should be avoided due to increased risk of hypervitaminosis D and/or hypercalcemia. Vitamin D analogues include ergocalciferol and calcitriol. If deemed essential, serum and urine calcium levels should be monitored.
Vitamin A and vitamin D	Cholestyramine (cholesterol lowering medication)	Gastro-intestinal absorption of vitamin A and vitamin D is decreased with simultaneous administration. Separate intake of the product and these medications by four hours, unless otherwise specified, will minimize risk for any interaction.
Vitamin A, Vitamin D, and Vitamin E	Orlistat (a certain type of weight-loss medication)	Gastro-intestinal absorption of vitamin A, vitamin D, and vitamin E is decreased with simultaneous administration. Separate intake of the product and these medications by four hours, unless otherwise specified, will minimize risk for any interaction.
Copper, Iron, Selenium, and Zinc	Mineral Oil	Polyvalent cations, such as copper, iron, selenium, and/or zinc, 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.
	Tetracycline antibiotics	
	Quinolone antibiotics	
	Penicillamine	
	Bisphosphonates	
	Levothyroxine	
	Methyldopa	
	Mycophenolate mofetil	
	Gastric acid suppressive medications	
	Antiviral agents	
	Thiazide diuretics	
	Eltrombopag	
*Major		

Berocca® Complete film-coated tablets with food

Allowance should be made for intake of the vitamins and minerals from all other sources including fortified foods.

Oxalic acid (in spinach and rhubarb) and phytic acid (in fiber-rich whole grains) can interfere with your body's ability to absorb calcium. If you're taking Berocca® Complete film-coated tablets avoid eating foods high in these substances within two hours of taking it to ensure better calcium absorption.

Pregnancy and breastfeeding

Berocca® Complete film-coated tablets is not intended for use during pregnancy and lactation. The product should only be used in pregnancy or lactation if deemed essential and as directed by the physician.

Driving and using machines

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

3 How to take Berocca® Complete film-coated tablets

Do not share medicines prescribed for you with any other person.

Always take Berocca® Complete film-coated tablets 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.

The usual dose for adults is one film-coated tablet a day taken by mouth with sufficient water (i.e. approximately 200 ml).

If you take more Berocca® Complete film-coated tablets than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you take too much of this product, you might suddenly get a headache, feel confused, or have stomach problems like constipation, diarrhoea, feeling sick, or throwing up. If you notice any of these things, stop using the product right away and get in touch with a doctor or nurse.

Taking too much of this product over a short or long period of time can lead to an overload of vitamins A and D in your body. It can also cause harmful effects due to excess of other ingredients in the product, such as vitamin C, zinc, selenium, iron, and copper.

The specific signs that you've taken too much can vary a lot. They depend on things such as how your body reacts and your given circumstances. So, it's important to pay attention to how you're feeling and get medical help if you think you've taken too much.

If you forget to take more Berocca® Complete film-coated tablets

Do not take double dose to make up for forgotten individual doses.

If you stop taking Berocca® Complete film-coated tablets

Berocca® Complete film-coated tablets have no withdrawal symptoms or effects should you stop, or interrupt, or end treatment early.

4 Possible side effects

Berocca® Complete film-coated tablets can have side effects.

Not all side effects reported for Berocca® Complete film-coated tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Berocca® Complete film-coated tablets, please consult your health care provider for advice.

If any of the following happens, stop taking Berocca® Complete film-coated tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Berocca® Complete film-coated tablets. You may need urgent medical attention or hospitalisation. Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Blood in the urine or pain with urination,
- Needing to go urgently or frequently, or
- bedwetting.

These are all serious side effects. You may have hypercalciuria and may need urgent medical attention. Tell your doctor if you notice any of the following:

- Nausea,
- Slight yellow discoloration of urine (chromaturia)
- Abdominal discomfort,
- Diarrhoea,
- and vomiting.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via 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>). By reporting side effects, you can help provide more information on the safety of Berocca® Complete film-coated tablets.

5 How to store Berocca® Complete film-coated tablets

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the container tightly closed and protect from moisture.

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

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

6 Contents of the pack and other information

What Berocca® Complete film-coated tablets contains:

- The active substances are: vitamin A (retinyl palmitate) 2666 IU; vitamin D3 (cholecalciferol) 200 IU; vitamin E (dl- α -tocopheryl acetate) 12 mg; vitamin K (phytomenadione) 25 μ g; vitamin B₁ (thiamine mononitrate) 1,1 mg; vitamin B₂ (riboflavin) 1,4 mg; vitamin B₃ (nicotinamide) 16 mg; vitamin B₅ (calcium-D-pantothenate) 6,0 mg; vitamin B₆ (pyridoxine hydrochloride) 1,4 mg; folic acid (pteroylmonoglutamic acid) 200 μ g; vitamin B₁₂ (cyanocobalamin) 2,5 μ g; biotin (D-biotin) 50 μ g; vitamin C (ascorbic acid) 80 mg; calcium (dibasic calcium phosphate, calcium-D-pantothenate and calcium silicate) 120 mg; magnesium (magnesium oxide) 80,0 mg; iron (ferrous fumarate) 14 mg; copper (cupric sulphate pentahydrate) 1,0 mg; iodine (potassium iodide) 150 μ g; zinc (zinc citrate) 10 mg; manganese (manganese sulphate) 2,0 mg; selenium (sodium selenate) 50 μ g; molybdenum (sodium molybdate anhydrous) 50 μ g; and coenzyme Q10 4,50 mg.

- The other ingredient are microcrystalline cellulose, sodium croscarmellose, magnesium stearate, silicon dioxide anhydrous, polyvinylpyrrolidone, silicon dioxide, calcium silicate, hydroxypropylmethylcellulose, polydextrose, talc, calcium carbonate, and maltodextrin.

What Berocca® Complete film-coated tablets looks like and contents of the pack

Film-coated tablets packed in a plastic bottle (HDPE) with a screwing neck. Plastic screwing closure with desiccant arranged in it and with a tamper evidence ring, possibly with a child resistant system, seals the bottles. Each bottle may contain 30, 60, 90 or 120 tablets.

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.

Holder of Certificate of Registration

Bayer (Pty) Ltd.

9 Country Estate Drive

Waterfall City

Johannesburg

2090

South Africa

Co Reg. no.: 1968/011192/07

Tel: +27 11 921 5000

Registration number(s)

To be confirmed upon registration.

Access to the corresponding Professional Information

The corresponding professional information may be obtained electronically on the following web address: <https://www.bayer.co.za>.