Multivitamins and Minerals

Berocca ® Performance

Effervescent Tablet

1. Name of the Product
Multivitamins and Minerals (Berocca Performance) Effervescent Tablet.

2. Description of the Product
This product is a multivitamin preparation with high dosed B-complex vitamins and vitamin C as well as calcium, magnesium and zinc.

3. What is in the medicine?
COMPOSITION

Each effervescent tablet contains:

Ascorbic acid (Vit. C)	500 mg
Calcium (as calcium carbonate and calcium pantothenate)	100 mg
Magnesium (as magnesium carbonate and magnesium sulfate dihydrate)	100 mg
Nicotinamide (Vit. B3)	50 mg
Pantothenic acid (Vit. B5) (as calcium pantothenate)	23 mg
Thiamine hydrochloride (Vit. B1)	15 mg
Riboflavin (Vit. B2) (as riboflavin sodium phosphate)	15 mg
Pyridoxine hydrochloride (Vit. B6)	10 mg
Zinc (as zinc citrate trihydrate)	10 mg
Folic acid	400 mcg
Biotin (Vit. H)	150 mcg
Cyanocobalamin (Vit. B12)	10 mcg

4. Strength of the Medicine
This product is a multivitamin and mineral preparation, containing 9 vitamins and 3 minerals. Refer to composition listed in number 3.

5. What is this Medicine used for?
For deficiency and increased requirement of Vitamin C, Vitamin B, and Zinc. Most water-soluble vitamins of B-complex and Vitamin C are not stored by the body adequately: these are needed during extensive physical exercise or during emotional and physiological stress, and in cases of chronic alcohol abuse.

6. How much and how often should you use this Medicine?
Adults and Adolescents: 1 effervescent tablet daily.
The recommended daily dose should not be exceeded.
This product is not recommended for children below 12 years old, as no efficacy and safety data are available in this age group.
For oral use.
Effervescent tablets have to be dissolved in a glass of water (200 mL).

7. When should you not take this Medicine?
- Hypersensitivity to any of the active substances or to any of the excipients,
- Severe renal insufficiency (GFR <30ml/min) including individuals on dialysis.
- Nephrolithiasis or history of nephrolithiasis
- Hyperoxaluria
- Hypercalcemia
- Severe hypercalciuria.

8. Care that should be taken when taking this Medicine?
Do not exceed labelled dose. Acute and chronic overdose increases risk of adverse effects. Allowance should be made for intake of the vitamins and minerals from all other sources including fortified foods, dietary supplements, and concomitant medications.

Individuals receiving other single vitamins or multivitamin preparations, any other medication, placed on a restricted diet, or those on medical care should first consult a health care professional before use of the product.
Intake of the product should be separated from other medications by 4 hours unless otherwise specified.
The product may interfere with laboratory tests resulting in false reading. Inform your physician or health care professional when taking this product and laboratory tests are planned.
Vitamin C may interfere with testing kits and meters that measure glucose levels resulting in false readings. Refer to the package insert of the testing kit or the meter for guidance.

Vitamin C increases iron absorption. Individuals with hemochromatosis should use precaution with use of the product and avoid intake of vitamin C >500mg/ day.
Overdose of vitamin C in individuals with glucose-6-phosphate dehydrogenase deficiency (>3g in children and > 15g in adults) has been associated with hemolytic anemia.
The product is not formulated for treatment of Vitamin B12 deficiency due to atrophic gastritis, disorder of the ileum or pancreas and gastro-intestinal malabsorption of vitamin B12 or intrinsic factor deficiency.
Precautions related to excipients:
For formulation that contain lactose:
Individuals with rare hereditary disorders of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take the product.

For formulations that contain phenylalanine (aspartame):
Individuals with phenylketonuria should avoid products that contain aspartame as it is a source of phenylalanine.

For effervescent formulations: For effervescent tablet dosage form contains sodium. This should be taken into consideration by individuals on a controlled sodium diet.

PREGNANCY AND LACTATION
The product is generally considered safe during pregnancy or lactation within labelled dose but should only be used when recommended by the physician. The labelled dose should not be exceeded as it may be harmful to the fetus or neonate. The vitamins and minerals in the product are excreted into breast milk.

9. Undesirable Effects of this Medicine
The following adverse reactions were identified during post-approval use of the product and it is not possible to estimate their frequency.

Gastrointestinal Disorders
Diarrhea, nausea, vomiting, gastrointestinal and abdominal pains, constipation

Immune System Disorders
Allergic reaction, anaphylactic reaction, anaphylactic shock, Hypersensitivity reactions that cause asthma syndrome, mild to moderate reactions affecting either skin, and/or respiratory tract, gastrointestinal tract, and/or cardiovascular system.

Nervous System Disorders
Headache, dizziness, insomnia, nervousness may occur.

Renal and Urinary Disorders
Chromaturia: A slightly yellow discoloration of urine may be noticed. This effect is harmless and is due to Vitamin B2 present.

10. What other medicine or food should be avoided while taking this Medicine?

Drug-Interactions per Active Ingredient in the Product:

Active Ingredient	Drug	Description
Vitamin C	Desferrioxamine	Vitamin C may enhance tissue iron toxicity, especially in the heart, causing cardiac decompensation.
	Cyclosporine	Antioxidant supplementation including vitamin C may reduce cyclosporine blood level.
	Disulfiram	Chronic or high doses of vitamin C may interfere with the effectiveness of the disulfiram.
	Warfarin	High dose vitamin C may interfere with the effectiveness of warfarin.
Vitamin B6	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 (i.e. Sinemet®).
Vitamin B12	Chloramphenicol	Chloramphenicol may delay or interrupt the reticulocyte response to vitamin B12. Therefore, blood counts need to be closely monitored if this combination can't be avoided.
Folic Acid	Methotrexate	Folic acid supplementation may reduce the effectiveness of methotrexate in the treatment of acute lymphoblastic leukemia, and theoretically, the efficacy in the treatment of other cancers.
Calcium	Thiazide Diuretics	Thiazide diuretics reduce the urinary excretion of calcium. Due to an increased risk of hypercalcemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.
Magnesium, Zinc	Potassium-Sparing Diuretics	Potassium-sparing diuretics also have magnesium-sparing and/or zinc-sparing properties. Increased magnesium and/or zinc levels could result with concomitant use of potassium sparing diuretics and supplementation.
Calcium, Magnesium, Zinc	Tetracycline antibiotics	Polyvalent cations, such as calcium, magnesium, and/or zinc, form complexes with certain substances resulting in decreased absorption of both substances. Separate intake of the product either 2 hours before or 4 hours after other medication, unless otherwise specified, will minimize risk for this interaction.
	Quinolone antibiotics	
	Penicillamine	
	Biphosphonates	
	Levothyroxine	
	Methyldopa	
	Mycophenolate mofetil	
	Eltrombopag	

Food Interaction

Vitamin C
Iron: Vitamin C may enhance iron absorption, especially in individuals with iron deficiency. Small incremental increases of iron could be important in subjects with conditions such as hereditary hemochromatosis or in subjects heterozygous to this condition, as it may exacerbate iron overload.

Calcium, Magnesium, and Zinc
Since oxalic acid (found in spinach and rhubarb) and phytic acid (found in whole cereals) may inhibit calcium, magnesium, and zinc absorption, it is not recommended to take this product within two hours of eating foods containing high oxalic acid and phytic acid concentrations.

Lab Interactions

Vitamin C

Because vitamin C is a strong reducing agent (i.e. electron donor), it can cause chemical interference in laboratory tests that involve oxidation-reduction reactions, such as the analyses of glucose, creatinine, carbamazepine, uric acid, and inorganic phosphates in urine, serum and of occult blood in feces. Using specific tests that are not dependent on reducing properties or discontinuing extra dietary vitamin C will avoid any undesirable interference. Refer to the manufacturer's information to determine if vitamin C interferes with the test.

Vitamin C may interfere with tests that measure urinary and blood glucose resulting in false readings, although it has no effect on blood glucose levels. Refer to the package insert of the meter or testing kit to determine if vitamin C (ascorbic acid) interferes and guidance for accuracy in readings.

Vitamin B1 and Vitamin B6
Urobilinogen: Thiamine and/or pyridoxine can cause a false positive result in the spot test with Ehrlich's reagent.

11. What should you do if you miss a dose?
No available information.

12. Signs and Symptoms of Overdose
There is no evidence that this product can lead to an overdose when used as labeled.

Allowance should be made for intake of the vitamins and minerals from all other sources. General manifestation of overdose may include confusion and gastrointestinal disturbances such as constipation, diarrhea, nausea, and vomiting.

If such symptoms occur, the product should be stopped and a health care professional consulted.

Acute or chronic overdose of the product (i.e. with intake up to 10 times the labelled dose) may cause specific toxicity associated with vitamin C, vitamin B6, or zinc.

Specific clinical signs and symptoms, laboratory findings, and consequences of overdose are highly diverse, dependent on an individual's susceptibility, and surrounding circumstances.

Specific clinical manifestations (i.e. with intake of the product up to 10 times the daily dose) may include the following:

Vitamin C:
Acute or chronic overdose of vitamin C (> 2 g / day in adults) may significantly elevate serum and urinary oxalate levels. In some instances, this result in hyperoxaluria, calcium oxalate crystalluria, calcium oxalate deposition, kidney stone formation, tubulointerstitial nephropathy, and acute renal failure.

Chronic consumption of high doses of ascorbic acid (> 500 mg / day in adults) may exacerbate iron overload and result in tissue damage in patients with hemochromatosis.

Overdose of vitamin C in individuals with glucose-6-phosphate dehydrogenase deficiency (>3 g / day in children and > 15 g / day in adults) may result in oxidative hemolysis or disseminated intravascular coagulation.

Vitamin B6:
Intake above UL (> 60 mg in adolescents 12 of age and 100 mg/day in adults) increases risk of sensory axonal neuropathy. Central effects have also been described. Neuropathy has been most commonly reported after chronic ingestion of 200 to 6000 mg/day for months or years. The neuropathy gradually improved in all cases, following removal of pyridoxine. Irreversible destruction of sensory ganglion cells (neuronopathy) may also occur after a single extremely large parenteral dose, but the exact toxic amount is not well documented in humans.

Zinc:
Zinc overdose (> 40 mg / day in adults) can cause diarrhea, irritation, and corrosion of the gastrointestinal (GI) tract, acute renal tubular necrosis, interstitial nephritis, copper deficiency, sideroblastic anemia and myeloneuropathies.

Calcium, Magnesium, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B7, Vitamin B9, Vitamin B12:
No discernible effects other than increase in general gastro-intestinal distress are expected with intake of product of up to 10 times the daily dose due to calcium, magnesium, and vitamins B1, B2, B3, B5, B7, B9, and B12.
If overdose is suspected, the product should be stopped and a health care professional consulted for treatment of clinical manifestations.

13. What to do when you have taken more than the recommended dosage?
There is no specific antidote however patients should still consult their physician.

14. How should you keep this Medicine?
STORAGE CONDITION:
DR-XY43475 / DR-XY45715 / DR-XY46749: Store at temperatures not exceeding 30ºC.
DR-XY43453: Store at temperatures not exceeding 25ºC.
Keep out of reach of children.
Keep the container tightly closed.

15. When should you consult your doctor?
If symptoms of overdosage occur, the product should be stopped and a health care professional consulted.

16. Name and Address of Marketing Authorization Holder
Bayer Philippines, Inc.
8th Floor Science Hub Tower 1,
Campus Avenue Corner Turin St.,
McKinley Hill Cyberpark, Pinagsama, Taguig City

17. Name and Address of Manufacturer
PT Bayer Indonesia
Jalan Raya Jakarta Bogor KM 32
Cisalak, Kec. Sukmajaya, Kota Depok,
Jawa Barat, Indonesia

18. ADR Reporting Statement
If you want to report a product complaint or side effect, please contact your health care professional or the Philippine FDA at adr@fda.gov.ph
Inquiries can also be directed to:
Bayer Philippines, Inc.
Taguig City, Philippines
E-mail: MedInfoCH-PH@bayer.com
drugsafety.philippines@bayer.com

19. Registration Number
DR-XY43475 (orange): Tube x 10's, 15's, (Box of 10's, 15s, 20s and 30s)
DR-XY43453 (mixed berries): Tube x 15's (Box of 15s)
DR-XY45715 (orange): Polycellonium Strip Pack x 2's (Box of 24's)
DR-XY46749 (mango orange): Tube x 15's (Box of 15s)

20. Date of First Authorization/ Renewal of the Authorization
DR-XY43475 (orange): 09 June 2014
DR-XY43453 (mixed berries): 30 May 2014
DR-XY45715 (orange): 16 December 2016
DR-XY46749 (mango orange): 25 October 2019

21. Date of Revision of Patient Information Leaflet

Date of Revision: November 2022 (Based on CCDS version 4 dated 10-July-2015)

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